9/12/2018 VidiStar(TM) PACS & DICOM Viewer SW system Cl II

Company:Hitachi Healthcare Americas Corp Informatics Division.
Date of Enforcement Report 9/12/2018
Class II:<p>
PRODUCT
VidiStar(TM) PACS & DICOM Viewer Software system.
Recall Number: Z-2992-2018<p>
REASON
The secure filesystem client software used in the interface between the Vidistar PACS and an EHR system may cause intermixed images from multiple patients showing in a single study.<p>
RECALLING FIRM/MANUFACTURER
Hitachi Healthcare Americas Corp Informatics Division, Greenville, NC on 8/28/2018 Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
12<p>
DISTRIBUTION
DSC, CO, IL, AZ, MT, OH, IN, TX, GA, MA<p>

9/12/2018 McKesson Cardiology Hemo, Cl II

Company:McKesson Israel Ltd..
Date of Enforcement Report 9/12/2018
Class II:<p>
PRODUCT
McKesson Cardiology Hemo, Release SW version 13.0. Used for physiological monitoring, image and data processing. McKesson Cardiology Hemo is intended for complete physiological/hemodynamic monitoring, clinical data acquisition, medical image and data processing, and analytical assessment. McKesson Cardiology Hemo is also intended for patient/procedural data management, such as documentation, logging, reporting, trending, storing, reviewing, carrying out clinical calculations and exporting various representations of the acquired data
Recall Number: Z-2968-2018<p>
REASON
Change Healthcare has identified an issue where, under certain circumstances, the Real Time Monitor (RTM) may not display physiological signals.<p>
RECALLING FIRM/MANUFACTURER
McKesson Israel Ltd., Tel Aviv, Israel on 3/12/2018 Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
31<p>
DISTRIBUTION
US Distribution to states of: CA, CO, CT, FL, GA, KS, IN, LA, NJ, NY, OK, OH, SC, and TX; and internationally to: UK. <p>

9/12/2018 Canon DRAD-3000E (Radrex-i) TFP-4336W Cl II

Company:Canon Medical System, USA, INC.
Date of Enforcement Report 9/12/2018
Class II:<p>
PRODUCT
Vertebral Motion Analyzer (VMA) Version 2.3.252. VMA software is a quantitative imaging software application intended to be used to process digital image files.
Recall Number: Z-2964-2018<p>
REASON
It was found when an operator performs a radiography using the wireless flat panel detector (FPD), a

message window was displayed on the monitor stating image transmission was not completed and there was no image. It also showed the OK button to reacquire image data form the FPD, and the Cancel button to cancel the reacquisition. When the operator selects the OK button, the same message window appears. The operator then repeated the same operation several times and finally selected the Cancel button to quit the reacquisition mode.<p>
RECALLING FIRM/MANUFACTURER
Canon Medical System, USA, INC. Tustin, CA on 4/18/2018 Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
43<p>
DISTRIBUTION
Domestic: AR, FL, GA, PA, IL, LA, MI, NC, NJ, NY, OH, TN, TX, UT, VT, WI, and WV Foreign: Australia, Canada, The Netherlands, South Korea, and Malaysia <p>

8/29/2018 Ortho Kinematics Vertebral Motion Analyzer
Cl II
Company:Ortho Kinematics, Inc
Date of Enforcement Report 8/29/2018
Class II:<p>
PRODUCT
Vertebral Motion Analyzer (VMA) Version 2.3.252. VMA software is a quantitative imaging software application intended to be used to process digital image files.
Recall Number: Z-2882-2018<p>
REASON
Ortho Kinematics Inc. sent a Notice of Correction to Released Testing Results, Radiological Read Report for the Vertebral Motion Analyzer (VMA) test because it contained an error. The error occurred due to a software bug that has been corrected.<p>
RECALLING FIRM/MANUFACTURER
Ortho Kinematics, Inc, West Lake Hills, TX on 1/11/2017 Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
1<p>
DISTRIBUTION
Nationwide <p>

8/29/2018 Liebel-Flarsheim Digital Imaging System Cl II
Company:LIEBEL-FLARSHEIM COMPANY LLC
Date of Enforcement Report 8/29/2018
Class II:<p>
PRODUCT
Liebel-Flarsheim Direct Digital Imaging System (DDIS) Liebel-Flarsheim urology systems facilitate radiologic and/or fluoroscopic procedures requiring a beam of diagnostic quality radiation, primarily for urological applications such as functional x-ray diagnostics, endourology and minimal invasive urology/ surgery.uch as functional x-ray diagnostics, endourology and minimal invasive urology/ surgery.
Recall Number: Z-2834-2018<p>
REASON
Software issue. The difference between the display and dosimeter readings In the Child/Pediatric automatic exposure mode is in the range of 52-65%. The display in all other modes deviated by less than 35% from the dosimeter readings.<p>
RECALLING FIRM/MANUFACTURER
LIEBEL-FLARSHEIM COMPANY LLC, St Louis, MO on 2/27/2017. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
28<p>

DISTRIBUTION
Nationwide <p>

8/29/2018 Liebel-Flarsheim Hydra Vision Urology X-Ray
Cl II
Company:LIEBEL-FLARSHEIM COMPANY LLC
Date of Enforcement Report 8/29/2018
Class II:<p>
PRODUCT
Liebel-Flarsheim Hydra Vision Urology X-Ray System (DR) Liebel-Flarsheim urology systems facilitate radiologic and/or fluoroscopic procedures requiring a beam of diagnostic quality radiation, primarily for urological applications such as functional x-ray diagnostics, endourology and minimal invasive urology/ surgery.
Recall Number: Z-2833-2018<p>
REASON
Software issue. The difference between the display and dosimeter readings In the Child/Pediatric automatic exposure mode is in the range of 52-65%. The display in all other modes deviated by less than 35% from the dosimeter readings.<p>
RECALLING FIRM/MANUFACTURER
LIEBEL-FLARSHEIM COMPANY LLC, St Louis, MO on 2/27/2017. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
313<p>
DISTRIBUTION
Nationwide <p>

8/22/2018 Arkon Anesthesia Delivery System Cl II
Company:Spacelabs Healthcare, Ltd.
Date of Enforcement Report 8/22/2018
Class II:<p>
PRODUCT
Arkon Anesthesia Delivery System with Arkon Software Version 2.70, Display Unit Assembly 650-1769-00 installed, and Model #: 99999. This system includes a ventilator. The Spacelabs Arkon Anesthesia Workstation is intended for use in the hospital environment and operating room.
Recall Number: Z-2589-2018<p>
REASON
Arkon Anesthesia Delivery System may go into a failed state (mechanical ventilation ceases) while the machine is in use or while idle.<p>
RECALLING FIRM/MANUFACTURER
Spacelabs Healthcare, Ltd., Hertford United Kingdom. on 7/11/2018. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
328<p>
DISTRIBUTION
Nationwide and Internationally <p>

8/22/2018 G8 Automated HPLC Analyzer, Cl II
Company:Tosoh Bioscience Inc
Date of Enforcement Report 8/22/2018
Class II:<p>
PRODUCT
NG8 Automated HPLC Analyzer: HLC-723G8-ST, 021560; and HLC-723G8-LA, 021674 Product Usage: The Tosoh Automated Glycohemoglobin Analyzer HLC-723G8 is intended for in vitro diagnostic

use for the quantitative measurement of % hemoglobin A1c (HbA1c) (DCCT/NGSP) and mmol/mol hemoglobin A1c (IFCC) in whole blood specimens. This test is to be used as an aid in diagnosis of diabetes and as an aid in identifying patients who may be at risk for developing diabetes.
Recall Number: Z-2745-2018<p>
REASON
HbAE is known to interfere with the HbA1c assay on the current version of software, Ver. 5.23. Customers should exercise caution when reviewing chromatograms and ensure that Flag 43 is enabled on their device to avoid reporting invalid test results in the presence of HbAE..<p>
RECALLING FIRM/MANUFACTURER
Tosoh Bioscience Inc, Grove City, OH on 6/6/2018. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
665<p>
DISTRIBUTION
Nationwide and Internationally <p>

8/10/2018 Arkon Anesthesia Delivery System Class I
Company:Spacelabs Healthcare, Ltd
Date of Enforcement Report 8/10/2018
Class I:<p>
PRODUCT
The Arkon Anesthesia Delivery System is intended for use in hospitals and operating rooms. It may be used to deliver oxygen, air, and nitrous oxide in a controlled manner to various patient breathing circuits (accessory sets that include tubing and breathing bags) with or without the use of a mechanical ventilator, and may be used for the delivery of anesthetic vapor (anesthesia that can be inhaled) with a dismountable vaporizer.
Recall Number: Z-<p>
REASON
Spacelabs Healthcare recalled the Arkon Anesthesia Delivery System due to the system going into a "failed state," during which the mechanical ventilation function stops working, while the machine is in use, or while idle. The firm has not identified the reason for the failed state. When the machine goes into a failed state, a buzzer sounds, and the following image is shown on the large display monitor: Warning image, which consists of a yellow triangle with black exclamation point, and images of hands using manual ventilation, and a hand selecting emergency oxygen. Caption: Failed state warning image, which alerts users of the error, and indicates that manual ventilation and emergency oxygen are available alternatives.
During the failed state, the anesthesiologist cannot access mechanical ventilation or monitor ventilation, which could increase the risk of patient injury. Emergency oxygen, vaporized agent delivery, and manual ventilation are still available. The firm has not received any reports of malfunctions, injuries, or deaths.
Continued use of this product may cause serious adverse health consequences, including death..<p>
RECALLING FIRM/MANUFACTURER
Spacelabs Healthcare, Ltd/. Snoqualmie, WA 98065 on 7/11/2018. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
253 units in the U.S,<p>
DISTRIBUTION
U.S.<p>

8/8/2018 NS Therapy Programming System, Cl II
Company:LivaNova USA Inc
Date of Enforcement Report 8/8/2018
Class II:<p>
PRODUCT

NS Therapy Programming System, Rx Only, Model 3000, v1.0.2.2
Recall Number: Z-2572-2018<p>
REASON
Unintended warning message displayed on generators programmed with a Model 3000 v.1.0.2.2 programmer.<p>
RECALLING FIRM/MANUFACTURER
LivaNova USA Inc., Houston, TX on 7/25/2018. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
243 devices total<p>
DISTRIBUTION
Nationwide <p>

8/8/2018 ENVOY 500 ISE CALIBRATOR Kit, Cl II
Company:ELITech Clinical Systems SAS
Date of Enforcement Report 8/8/2018
Class II:<p>
PRODUCT
ENVOY 500 ISE CALIBRATOR KIT, reference 55117 (contained 6 x 20 mL Calibrator High level and 6 x 20 mL Calibrator Low level). Model/Catalog Number: 55117
Recall Number: Z-2591-2018<p>
REASON
ELITech Clinical Systems SAS initiated this recall because some users of ENVOY 500 ISE CALIBRATOR Kit (Part number: 55117), for Envoy 500 systems are observing trouble while calibrating with some vials. Users contacted the firm when they received the messages "ISE OUT OF REPRODUCIBILITY" or "ISE SLOPE OUT OF RANGE" (i.e., failed calibration). This has resulted in delay in obtaining patient results until the calibrator lot is replaced<p>
RECALLING FIRM/MANUFACTURER
ELITech Clinical Systems SAS, Sees, France on 4/18/2018. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
<p>
DISTRIBUTION
Nationwide <p>

8/8/2018 Siemens SOMATOM Spirit, Cl II
Company:Siemens Medical Solutions USA, Inc
Date of Enforcement Report 8/8/2018
Class II:<p>
PRODUCT
SOMATOM Spirit(Model 10045692)
Recall Number: Z-2478-2018<p>
REASON
A potential risk of unnecessary radiation exposure due to a software issue.<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Malvern, PA on 2/1/2018. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
<p>
DISTRIBUTION
Nationwide <p>

8/8/2018 Siemens SOMATOM Scope Power, Cl II
Company:Siemens Medical Solutions USA, Inc
Date of Enforcement Report 8/8/2018
Class II:<p>
PRODUCT
SOMATOM Scope Power (Model 10967888)
Recall Number: Z-2477-2018<p>
REASON
A potential risk of unnecessary radiation exposure due to a software issue.<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Malvern, PA on 2/1/2018. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
<p>
DISTRIBUTION
Nationwide <p>

8/8/2018 Siemens SOMATOM Scope, Cl II
Company:Siemens Medical Solutions USA, Inc
Date of Enforcement Report 8/8/2018
Class II:<p>
PRODUCT
SOMATOM Scope (Model 10967666)
Recall Number: Z-2476-2018<p>
REASON
A potential risk of unnecessary radiation exposure due to a software issue.<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Malvern, PA on 2/1/2018. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
<p>
DISTRIBUTION
Nationwide <p>

8/8/2018 Siemens SOMATOM Perspective 16 Cl II
Company:Siemens Medical Solutions USA, Inc
Date of Enforcement Report 8/8/2018
Class II:<p>
PRODUCT
SOMATOM Perspective 16 (Model 10891666)
Recall Number: Z-2475-2018<p>
REASON
A potential risk of unnecessary radiation exposure due to a software issue.<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Malvern, PA on 2/1/2018. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
<p>
DISTRIBUTION
Nationwide <p>

8/8/2018 Siemens SOMATOM Perspective (10495568) Cl II

Company:Siemens Medical Solutions USA, Inc
Date of Enforcement Report 8/8/2018
Class II:<p>
PRODUCT
SOMATOM Perspective (Model 10495568)
Recall Number: Z-2474-2018<p>
REASON
A potential risk of unnecessary radiation exposure due to a software issue.<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Malvern, PA on 2/1/2018. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
<p>
DISTRIBUTION
Nationwide <p>

8/8/2018 Siemens SOMATOM Emotion 16 (10165977) Cl II

Company:Siemens Medical Solutions USA, Inc
Date of Enforcement Report 8/8/2018
Class II:<p>
PRODUCT
SOMATOM Emotion 16 (10165977)
Recall Number: Z-2473-2018<p>
REASON
A potential risk of unnecessary radiation exposure due to a software issue.<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Malvern, PA on 2/1/2018. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
<p>
DISTRIBUTION
Nationwide <p>

8/8/2018 Siemens SOMATOM Emotion 6 Model 10165888 Cl II

Company:Siemens Medical Solutions USA, Inc
Date of Enforcement Report 8/8/2018
Class II:<p>
PRODUCT
SOMATOM Emotion 6 (Model 10165888)
Recall Number: Z-2472-2018<p>
REASON
A potential risk of unnecessary radiation exposure due to a software issue.<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Malvern, PA on 2/1/2018. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
<p>
DISTRIBUTION
Nationwide <p>

8/1/2018 RayStation Treatment Planning System; Cl II
Company:RAYSEARCH LABORATORIES AB
Date of Enforcement Report 7/25/2018
Class II:<p>
PRODUCT
RayStation Radiation Therapy Treatment Planning System, Model nos. 2.5, 3.5, 4.0, 4.3, 4.5, 4.7, 4.9, 5.0, 6.0, 6.1, 6.2, 7.0 Product Usage RayStation is a software system designed for treatment planning and analysis of radiation therapy.
Recall Number: Z-2554-2018<p>
REASON
The firm has learned that some RayStation/RayPlan users have commissioned machines with erroneous Beam profile correction parameters. These parameters affect the dose calculated in corners of large or off-axis fields. This effect cannot be seen in the Beam Commissioning module and dose in large or off-axis fields needs to be validated using the Beam 3D Modeling module in RayPhysics/RayPlan Physics. The user must be aware to avoid incorrect dose calculations during treatment planning. <p>
RECALLING FIRM/MANUFACTURER
RAYSEARCH LABORATORIES AB, Stockholm, Sweden on 6/6/2018. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
718<p>
DISTRIBUTION
Nationwide<p>

8/1/2018 Forte Automation Patient Positioning System
Cl II
Company: Forte Automation Systems Inc.
Date of Enforcement Report 8/1/2018
Class II:<p>
PRODUCT
Patient Positioning System with KRC2 controller using software versions 2.3.1 2.3.10 Product Usage: The patient positioning system is a SCARA designed robotic arm designed to position a patient for medical procedures prescribed by oncologists and others that require a high degree of accuracy and repeatability.
Recall Number: Z-2537-2018<p>
REASON
Communications between the Patient Positioning System and the accuracy filter can periodically fail with no clear indication to the operator.<p>
RECALLING FIRM/MANUFACTURER
Forte Automation Systems Inc., Machesney Park, IL on 9/5/2017. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
13<p>
DISTRIBUTION
California<p>

8/1/2018 Vivo 65, Continuous Ventilator, Cl III
Company:Human Design Medical Llc
Date of Enforcement Report 8/1/2018
Class III:<p>
PRODUCT
Vivo 65, Continuous Ventilator, Home Use, Cat. No. 204000 Product Usage: To provide continuous or

intermittent ventilatory support for the care of individuals who require mechanical ventilation
Recall Number: Z-2530-2018<p>
REASON
Some Vivo 65 devices have an unreleased version of the Firmware upgrade tool.<p>
RECALLING FIRM/MANUFACTURER
Human Design Medical Llc, Boston, MA on 5/8/2018. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
45<p>
DISTRIBUTION
CA, FL, GA, MI, SC, and TX.<p>

8/1/2018 CardioMEMS HF, Cl II
Company: Abbott Laboratories, Inc.
Date of Enforcement Report 8/1/2018
Class II:<p>
PRODUCT
CardioMEMS HF System Hospital and Patient Electronics Units: (a) Patient Electronics System, Model CM1100 (b) Hospital Electronics System, Model CM3000
Recall Number: Z-2522-2018<p>
REASON
Abbott is advising customers that a small number of CardioMEMS(R) Hospital Electronics Systems (Model CM3000) and Patient Electronics Systems (Model CM1100) may deliver a system error, known as Error 5. While this error message is intended to present if the electronics system exceeds a certain temperature, these units may deliver a false Error 5 message due to an incorrectly configured component within the device electronics.<p>
RECALLING FIRM/MANUFACTURER
Abbott Laboratories, Inc, Atlanta, GA on 6/14/2018. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
2521 units<p>
DISTRIBUTION
Nationwide and Internationally<p>

7/25/2018 RayStation stand-alone sw treatment planning Cl II
Company:RAYSEARCH LABORATORIES AB
Date of Enforcement Report 7/25/2018
Class II:<p>
PRODUCT
RayStation stand-alone software treatment planning system, RayStation 4.5, RayStation 4.7, RayStation 4.9 (RayPlan 1), RayStation 5, RayStation 6 (RayPlan 2), RayStation 7 (RayPlan 7) and RayStation 8A (RayPlan 8A)Product Usage:RayStation is a software system designed for treatment planning and analysis of radiation therapy.
Recall Number: Z-2497-2018<p>
REASON
If the beam model has a highly asymmetric primary source, it is not correctly taken into account in the calculation of DMLC fields when the collimator is rotated. This could lead to potentially significant overdosage at delivery. The user must be aware of the issue to avoid incorrect dose calculations during treatment planning.<p>
RECALLING FIRM/MANUFACTURER
RAYSEARCH LABORATORIES AB, Stockholm, Sweden on 6/29/2018. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
746<p>

DISTRIBUTION
Nationwide<p>

7/25/2018 Disinfection unit for Celldiscoverer 7, Cl II
Company:Zeiss, Carl Inc.
Date of Enforcement Report 7/25/2018
Class II:<p>
PRODUCT
Disinfection unit UV (432332-9020-000) for the Celldiscoverer 7 microscope
Recall Number: Z-2441-2018<p>
REASON
Under certain circumstances, the firmware makes it possible for the Disinfection unit UV (432332-9020-000) to activate outside of the Celldiscoverer 7 housing. This may result in exposure of the users to harmful UV radiation..<p>
RECALLING FIRM/MANUFACTURER
Zeiss, Carl Inc., Thornwood, NYon 5/29/2018. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
8<p>
DISTRIBUTION
Nationwide<p>

7/25/2018 Health Harmony Mobile application software, Cl II
Company:Intel-GE Care Innovations LLC
Date of Enforcement Report 7/25/2018
Class II:<p>
PRODUCT
Health Harmony Mobile application software Product Usage: Care Innovations Health Harmony Mobile is intended as a communication tool to display medical device data from third party devices for patients to view, and to collect assessment (question & answers) from patients in the home.
Recall Number: Z-2442-2018<p>
REASON
It was discovered that in certain situations, including partial sessions and when taking adhoc measurements, the patient data was not synchronizing in a timely manner with the backend database, resulting in the patient's clinician not getting patient data tor one or two days.<p>
RECALLING FIRM/MANUFACTURER
Intel-GE Care Innovations LLC., Roseville, CA on 12/6/2017. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
1302<p>
DISTRIBUTION
US Nationwide Distribution in the states of CO, ID, PA, and LA<p>

7/25/2018 T2100 Micro flex Drive Treadmill, Cl II
Company:GE Medical Systems Ultrasound & Primary Care Diagnostics, LL
Date of Enforcement Report 7/25/2018
Class II:<p>
PRODUCT
T2100 Micro flex Drive Treadmill, powered Product Usage: Powered exercise equipment consist of powered devices intended for medical purposes, such as to redevelop muscles or restore motion to joints or for use as an adjunct treatment for obesity. Specifically the T210 Treadmill is intended for use in Exercise Testing, facilitating accurate blood pressure measurements and exercise testing within speed range of 0-13.5 miles per hour.

Recall Number: Z-2467-2018<p>
REASON
A performance issue with customer owned spare parts, T2100 Microflex drive (2026182-002 or 2026182-004), was not addressed with a previous safety correction. If these parts were installed from customer owned stock on the T2100 Treadmill, uncontrolled walking belt motion during a stress exercise test could occur.<p>
RECALLING FIRM/MANUFACTURER
GE Medical Systems Ultrasound & Primary Care Diagnostics, LL, Milwaukee, WI on 4/2/2018. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
3,721 devices total<p>
DISTRIBUTION
Nationwide and Internationally <p>

7/25/2018 Tandem Diabetes Care t:slim G4 Insulin Pump, Cl II

Company:Tandem Diabetes Care Inc.
Date of Enforcement Report 7/25/2018
Class II:<p>
PRODUCT
t:slim G4 Insulin Pump with Dexcom G4 Platinum CGM Software version: 4.3.4.3, Firmware version: 004722, Firmware, Fuel Gauge, Binary Rev B.
Recall Number: Z-2471-2018<p>
REASON
The fuel gauge, the component that reads and reports the battery parameters to the pump, could provide inaccurate readings, which present to the user in one of two ways: A) by triggering a Malfunction 4 Alarm, or B) by triggering a succession of notifications prior to the pump shutting off, including Alert 2 (Battery Low), Alert 3 (Battery Very Low) and Alarm 12 (Battery Very Low). The alarms in both scenarios notify the user that the pump has stopped delivering insulin.<p>
RECALLING FIRM/MANUFACTURER
Tandem Diabetes Care Inc., San Diego, CA on 4/23/2018. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
55<p>
DISTRIBUTION
U.S. Consignees: IN, AZ, UT, TX, NY, NJ, MD, MN, IL, CO, AL, WI, CA, PA, OH, OR, MS, FL, NM, ID, NV, KY, VA,<p>

7/18/2018 Proteus 235, Cl II

Company:Ion Beam Applications S.A.
Date of Enforcement Report 7/18/2018
Class II:<p>
PRODUCT
Proteus 235, Version PTS-11.0.1.2 and PTS-11.0.2 Product Usage: A device designed to produce and deliver a proton beam for the treatment of patients with localized tumors and other conditions susceptible to treatment by radiation.
Recall Number: Z-2424-2018<p>
REASON
Correction vector confirmation message is lost if access point is changed after sending the correction vector. As a result, the patient will be treated in the setup position or treatment position instead of the corrected position.<p>
RECALLING FIRM/MANUFACTURER
Ion Beam Applications S.A, Louvain La Neuve . on 5/16/2018. Voluntary: Firm Initiated recall is

ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
3 units<p>
DISTRIBUTION
US Nationwide in the states of FL and the countries of Sweden, The Netherlands<p>

7/18/2018 Reliance 1227 Cart & Utensil Washer/Disinfec
Cl II

Company:Steris Corporation
Date of Enforcement Report 7/18/2018
Class II:<p>
PRODUCT
Reliance 1227 Cart and Utensil Washer/Disinfector, FW03101, FW03102, FW03S003 Product Usage: The Reliance 1227 Cart and Utensil Washer/Disinfector is intended for use in the cleaning and low-level disinfection of bedpans and urinals, basins, carts, beds, theatre shoes and other miscellaneous reusable items used in the care of patients.
Recall Number: Z-2392-2018<p>
REASON
The firm has become aware that the Reliance 1227 Cart and Utensil Washer/Disinfector s Chemical Low Level alarm, intended to prevent the user from initiating a cycle when a low chemical level situation occurs, does not operate as intended. Currently, if a low chemical level situation occurs, the alarm will only be generated at the unit s next power-up or when accessing service mode. The failure of the Reliance 1227 to identify that the chemicals used for cleaning are low or empty could result in bedpans and urinals, basins, case carts, beds, theater shoes and other miscellaneous reusable patient care items not being properly cleaned before disinfection or reuse.<p>
RECALLING FIRM/MANUFACTURER
Steris Corporation, Mentor, OH on 5/23/2018. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
118<p>
DISTRIBUTION
Nationwide and Canada<p>

7/11/2018 Medtronic MiniMed Paradigm Vea Insulin
Pump, Cl II

Company:Medtronic Inc.
Date of Enforcement Report 7/11/2018
Class II:<p>
PRODUCT
Medtronic MiniMed Paradigm Vea Insulin Pump Product Catalog Number: MMT-554, MMT-754
Recall Number: Z-2377-2018<p>
REASON
Medtronic notified customers/users of MiniMed" Paradigm" Veo" insulin pump that the pump has an error that impacts the Arabic language translation.This translation error occurs in the Predictive Alerts setting screen, which allows user to program alerts that will sound if users are predicted to reach their pre-set low or high sensor glucose values..<p>
RECALLING FIRM/MANUFACTURER
Medtronic Inc., Northridge, CA on 4/24/2018. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
239,859<p>
DISTRIBUTION
Internationally (no US)<p>

7/11/2018 GE Healthcare CARESCAPE Monitor B650, Cl
II
Company:GE Healthcare Finland Oy
Date of Enforcement Report 7/11/2018
Class II:<p>
PRODUCT
GE Healthcare CARESCAPE Monitor B650
Recall Number: Z-2340-2018<p>
REASON
When multiple CARESCAPE Monitor B650 units are connected to the same network and a network overload occurs for a prolonged time, the monitors may simultaneously restart as designed. The monitor restart will not be completed until the network issue has been corrected.<p>
RECALLING FIRM/MANUFACTURER
GE Healthcare Finland Oy, Helsinki, Finland on 5/25/2018. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
69231 units<p>
DISTRIBUTION
Worldwide<p>

7/4/2018 Siemens Artis zeego, Material no. 10280959; Cl
II
Company:Siemens Medical Solutions USA, Inc
Date of Enforcement Report 7/4/2018
Class II:<p>
PRODUCT
Artis zeego, Material no. 10280959
Recall Number: Z-2314-2018<p>
REASON
After the Large Display returns from power save mode, it may not show an image, and stay black without showing an error message although X-ray is still possible. The problem does not occur during an ongoing procedure. If the problem occurs, the system cannot be operated normally. It may be necessary to cancel or restart the treatment or transfer the patient to an alternate or another system..<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Malvern, PA on 5/1/2018. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
56<p>
DISTRIBUTION
Nationwide and Internationally <p>

7/4/2018 Siemens Artis zee MP; Cl II
Company:Siemens Medical Solutions USA, Inc
Date of Enforcement Report 7/4/2018
Class II:<p>
PRODUCT
Artis zee MP, Material no. 10094139,, for angiography and whole body radiographic/fluoroscopic procedures.
Recall Number: Z-2313-2018<p>
REASON
After the Large Display returns from power save mode, it may not show an image, and stay black without showing an error message although X-ray is still possible. The problem does not occur during

an ongoing procedure. If the problem occurs, the system cannot be operated normally. It may be necessary to cancel or restart the treatment or transfer the patient to an alternate or another system..<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Malvern, PA on 5/1/2018. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
1<p>
DISTRIBUTION
Nationwide and Internationally <p>

7/4/2018 Siemens Artis zee floor MN; Cl II

Company:Siemens Medical Solutions USA, Inc
Date of Enforcement Report 7/4/2018
Class II:<p>
PRODUCT
Artis zee floor MN, Material no. 10094142, for angiography and whole body radiographic/fluoroscopic procedures.
Recall Number: Z-2312-2018<p>
REASON
After the Large Display returns from power save mode, it may not show an image, and stay black without showing an error message although X-ray is still possible. The problem does not occur during an ongoing procedure. If the problem occurs, the system cannot be operated normally. It may be necessary to cancel or restart the treatment or transfer the patient to an alternate or another system..<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Malvern, PA on 5/1/2018. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
1<p>
DISTRIBUTION
Nationwide and Internationally <p>

7/4/2018 Siemens Artis zee floor; Cl II

Company:Siemens Medical Solutions USA, Inc
Date of Enforcement Report 7/4/2018
Class II:<p>
PRODUCT
Artis zee floor, Material no. 10094135, for angiography and whole body radiographic/fluoroscopic procedures.
Recall Number: Z-2311-2018<p>
REASON
After the Large Display returns from power save mode, it may not show an image, and stay black without showing an error message although X-ray is still possible. The problem does not occur during an ongoing procedure. If the problem occurs, the system cannot be operated normally. It may be necessary to cancel or restart the treatment or transfer the patient to an alternate or another system..<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Malvern, PA on 5/1/2018. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
14<p>
DISTRIBUTION

Nationwide and Internationally <p>

7/4/2018 Siemens Artis zee ceiling; Cl II
Company:Siemens Medical Solutions USA, Inc
Date of Enforcement Report 7/4/2018
Class II:<p>
PRODUCT
Artis zee ceiling, Material no. 10094137, for angiography and whole body radiographic/fluoroscopic procedures.
Recall Number: Z-2310-2018<p>
REASON
After the Large Display returns from power save mode, it may not show an image, and stay black without showing an error message although X-ray is still possible. The problem does not occur during an ongoing procedure. If the problem occurs, the system cannot be operated normally. It may be necessary to cancel or restart the treatment or transfer the patient to an alternate or another system..<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Malvern, PA on 5/1/2018. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
73<p>
DISTRIBUTION
Nationwide and Internationally <p>

7/4/2018 Siemens Artis zee biplane MN, Cl II
Company:Siemens Medical Solutions USA, Inc
Date of Enforcement Report 7/4/2018
Class II:<p>
PRODUCT
Artis zee biplane MN, Material no. 10094143, for angiography and whole body radiographic/fluoroscopic procedures.
Recall Number: Z-2309-2018<p>
REASON
After the Large Display returns from power save mode, it may not show an image, and stay black without showing an error message although X-ray is still possible. The problem does not occur during an ongoing procedure. If the problem occurs, the system cannot be operated normally. It may be necessary to cancel or restart the treatment or transfer the patient to an alternate or another system..<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Malvern, PA on 5/1/2018. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
2<p>
DISTRIBUTION
Nationwide and Internationally <p>

7/4/2018 Siemens Artis zee biplane, Cl II
Company:Siemens Medical Solutions USA, Inc
Date of Enforcement Report 7/4/2018
Class II:<p>
PRODUCT
Artis zee biplane, Material no. 10094141, for angiography and whole body radiographic/fluoroscopic procedures.

Recall Number: Z-2308-2018<p>
REASON
After the Large Display returns from power save mode, it may not show an image, and stay black without showing an error message although X-ray is still possible. The problem does not occur during an ongoing procedure. If the problem occurs, the system cannot be operated normally. It may be necessary to cancel or restart the treatment or transfer the patient to an alternate or another system..<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Malvern, PA on 5/1/2018. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
68<p>
DISTRIBUTION
Nationwide and Internationally <p>

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7/4/2018 Siemens Artis Q zen floor, Cl II
Company:Siemens Medical Solutions USA, Inc
Date of Enforcement Report 7/4/2018
Class II:<p>
PRODUCT
Artis Q.zen floor, Material no. 10848353, for angiography and whole body radiographic/fluoroscopic procedures.
Recall Number: Z-2307-2018<p>
REASON
After the Large Display returns from power save mode, it may not show an image, and stay black without showing an error message although X-ray is still possible. The problem does not occur during an ongoing procedure. If the problem occurs, the system cannot be operated normally. It may be necessary to cancel or restart the treatment or transfer the patient to an alternate or another system..<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Malvern, PA on 5/1/2018. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
1<p>
DISTRIBUTION
Nationwide and Internationally <p>

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7/4/2018 Siemens Artis Q zeego, Cl II
Company:Siemens Medical Solutions USA, Inc
Date of Enforcement Report 7/4/2018
Class II:<p>
PRODUCT
Artis Q.zeego, Material no. 10848283, for angiography and whole body radiographic/fluoroscopic procedures.
Recall Number: Z-2306-2018<p>
REASON
After the Large Display returns from power save mode, it may not show an image, and stay black without showing an error message although X-ray is still possible. The problem does not occur during an ongoing procedure. If the problem occurs, the system cannot be operated normally. It may be necessary to cancel or restart the treatment or transfer the patient to an alternate or another system..<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Malvern, PA on 5/1/2018. Voluntary: Firm Initiated recall is

ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
4<p>
DISTRIBUTION
Nationwide and Internationally <p>

7/4/2018 Siemens Artis Q zen biplane, Cl II
Company:Siemens Medical Solutions USA, Inc
Date of Enforcement Report 7/4/2018
Class II:<p>
PRODUCT
Artis Q.zen biplane, Material no. 10848355, for angiography and whole body radiographic/fluoroscopic procedures.
Recall Number: Z-2305-2018<p>
REASON
After the Large Display returns from power save mode, it may not show an image, and stay black without showing an error message although X-ray is still possible. The problem does not occur during an ongoing procedure. If the problem occurs, the system cannot be operated normally. It may be necessary to cancel or restart the treatment or transfer the patient to an alternate or another system..<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Malvern, PA on 5/1/2018. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
2<p>
DISTRIBUTION
Nationwide and Internationally <p>

7/4/2018 Siemens Artis Q ceiling, Cl II
Company:Siemens Medical Solutions USA, Inc
Date of Enforcement Report 7/4/2018
Class II:<p>
PRODUCT
Artis Q ceiling, Material no. 10848281, for angiography and whole body radiographic/fluoroscopic procedures.
Recall Number: Z-2304-2018<p>
REASON
After the Large Display returns from power save mode, it may not show an image, and stay black without showing an error message although X-ray is still possible. The problem does not occur during an ongoing procedure. If the problem occurs, the system cannot be operated normally. It may be necessary to cancel or restart the treatment or transfer the patient to an alternate or another system..<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Malvern, PA on 5/1/2018. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
5<p>
DISTRIBUTION
Nationwide and Internationally <p>

7/4/2018 Siemens Artis Q biplane, Cl II
Company:Siemens Medical Solutions USA, Inc
Date of Enforcement Report 7/4/2018
Class II:<p>
PRODUCT
Artis Q biplane, Material no. 10848282, for angiography and whole body radiographic/fluoroscopic procedures.
Recall Number: Z-2303-2018<p>
REASON
After the Large Display returns from power save mode, it may not show an image, and stay black without showing an error message although X-ray is still possible. The problem does not occur during an ongoing procedure. If the problem occurs, the system cannot be operated normally. It may be necessary to cancel or restart the treatment or transfer the patient to an alternate or another system..<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Malvern, PA on 5/1/2018. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
5<p>
DISTRIBUTION
Nationwide and Internationally <p>

7/4/2018 RayStation Radiation Treatment Planning Sys, Cl II
Company: RAYSEARCH LABORATORIES AB.
Date of Enforcement Report 7/4/2018
Class II:<p>
PRODUCT
RayStation Radiation Therapy Treatment Planning System; 6.0, 6.1, 6.2, 7.0 Product Usage: Usage: RayStation is a software system designed for treatment planning and analysis of radiation therapy. The treatment plans provide treatment unit set-up parameters and estimates of dose distributions expected during the proposed treatment, and may be used to administer treatments after review and approval by the intended user
Recall Number: Z-2290-2018<p>
REASON
The dose calculation accuracy may in some situations be less than expected. The user must be aware in order to avoid incorrect dose calculations during treatment planning.<p>
RECALLING FIRM/MANUFACTURER
IRAYSEARCH LABORATORIES AB, Stockholm, Sweden on 3/22/2018. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
728<p>
DISTRIBUTION
Nationwide. <p>

7/4/2018 Proteus Plus and Proteus ONE, Cl II
Company: Ion Beam Applications S.A.
Date of Enforcement Report 7/4/2018
Class II:<p>
PRODUCT
The Proton Therapy System - Proteus 235 (brand names: Proteus Plus and Proteus ONE) Proteus 235, Beam Management System (PBS)
Recall Number: Z-2284-2018<p>

REASON
TBA is conducting a voluntary recall to address a PTS (Proton Therapy System) software issue and to reduce the risk related to this issue.<p>
RECALLING FIRM/MANUFACTURER
Ion Beam Applications S.A.., Louvain La Neuve, Belgium on 4/11/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
2<p>
DISTRIBUTION
Korea and Jacksonville, FL. <p>

6/27/2018 Perseus A500 Anesthesia Machine, Cl II
CompanyDraeger Medical, Inc.
Date of Enforcement Report 6/27/2018
Class II:<p>
PRODUCT
Perseus A500 Anesthesia Machine; Cat. no. MK06000Product VProduct Usage:Intended for use in anesthetizing adults, children, and neonates and can be used for automatic and manual ventilation, pressuresupported spontaneous breathing, and spontaneous breathing. Perseus is equipped with airway monitoring, gas measurement and device monitoring,
Recall Number: Z-2254-2018<p>
REASON
The Draeger anesthesia device may be able to dose 100% N2O. In the event of a fault, the S-ORC module would not prevent setting an N2O flow that would result in a hypoxic mixture from being dosed to the patient. Potential adverse outcomes include death of the patient.<p>
RECALLING FIRM/MANUFACTURER
Draeger Medical, Inc., Telford PA. on 5/24/2018. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
33<p>
DISTRIBUTION
Nationwide <p>

6/27/2018 Apollo Anesthesia Machine, Cl II
CompanyDraeger Medical, Inc.
Date of Enforcement Report 6/27/2018
Class II:<p>
PRODUCT
Apollo Anesthesia Machine; Cat. no. 8605310Product Usage:Indicated as a continuous flow anesthesia system. The Apollo may be used for manually assisted or automatic ventilation, delivery of gases and anesthetic vapor, and monitoring of oxygen and CO2 concentration, breathing pressure, respiratory volume, and anesthetic agent concentration and identification.
Recall Number: Z-2253-2018<p>
REASON
The Draeger anesthesia device may be able to dose 100% N2O. In the event of a fault, the S-ORC module would not prevent setting an N2O flow that would result in a hypoxic mixture from being dosed to the patient. Potential adverse outcomes include death of the patient.<p>
RECALLING FIRM/MANUFACTURER
Draeger Medical, Inc., Telford PA. on 5/24/2018. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
72<p>
DISTRIBUTION
Nationwide <p>

6/27/2018 Fabius GS MRI Anesthesia Machine; Cl II
CompanyDraeger Medical, Inc.
Date of Enforcement Report 6/27/2018
Class II:<p>
PRODUCT
Fabius GS MRI Anesthesia Machine; Cat. no. 8607300 Product Usage: Inhalation anesthesia machines for use in operating, induction and recovery rooms. They may be used with O2, N2O, and AIR supplied by a medical gas pipeline system or by externally mounted gas cylinders. Fabius series machines are equipped with a compact breathing system; providing fresh gas decoupling, PEEP, and pressure limitation. The following ventilation options are available: Volume Controlled Ventilation Pressure Controlled Ventilation Pressure Support (Optional) SIMV/PS (Optional) Manual Ventilation Spontaneous Breathing Fabius series anesthesia machines are equipped with an electrically driven and electronically controlled ventilator and monitors for airway pressure (P), volume (V), and inspiratory oxygen concentration (FiO2). As per IEC 60601-2-13 (Anesthetic Workstations and their Modules-Particular Requirements), additional monitoring of the concentrations of CO2 and anesthetic agent is required when the machine is in use
Recall Number: Z-2252-2018<p>
REASON
The Draeger anesthesia device may be able to dose 100% N2O. In the event of a fault, the S-ORC module would not prevent setting an N2O flow that would result in a hypoxic mixture from being dosed to the patient. Potential adverse outcomes include death of the patient.<p>
RECALLING FIRM/MANUFACTURER
Draeger Medical, Inc., Telford PA. on 5/24/2018. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
4<p>
DISTRIBUTION
Nationwide <p>

6/27/2018 Fabius GS Tiro Anesthesia Machine; Cl II
CompanyDraeger Medical, Inc.
Date of Enforcement Report 6/27/2018
Class II:<p>
PRODUCT
Fabius GS Tiro Anesthesia Machine; Cat. no. 8606000 Product Usage: Inhalation anesthesia machines for use in operating, induction and recovery rooms. They may be used with O2, N2O, and AIR supplied by a medical gas pipeline system or by externally mounted gas cylinders. Fabius series machines are equipped with a compact breathing system; providing fresh gas decoupling, PEEP, and pressure limitation. The following ventilation options are available: Volume Controlled Ventilation Pressure Controlled Ventilation Pressure Support (Optional) SIMV/PS (Optional) Manual Ventilation Spontaneous Breathing Fabius series anesthesia machines are equipped with an electrically driven and electronically controlled ventilator and monitors for airway pressure (P), volume (V), and inspiratory oxygen concentration (FiO2). As per IEC 60601-2-13 (Anesthetic Workstations and their Modules-Particular Requirements), additional monitoring of the concentrations of CO2 and anesthetic agent is required when the machine is in use
Recall Number: Z-2251-2018<p>
REASON
The Draeger anesthesia device may be able to dose 100% N2O. In the event of a fault, the S-ORC module would not prevent setting an N2O flow that would result in a hypoxic mixture from being dosed to the patient. Potential adverse outcomes include death of the patient.<p>
RECALLING FIRM/MANUFACTURER
Draeger Medical, Inc., Telford PA. on 5/24/2018. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
31<p>

DISTRIBUTION
Nationwide <p>

6/27/2018 Fabius GS Premium Anesthesia Machine; Cl II

CompanyDraeger Medical, Inc.
Date of Enforcement Report 6/27/2018
Class II:<p>
PRODUCT
Fabius GS Premium Anesthesia Machine; Cat. no. 8607000 Product Usage: Inhalation anesthesia machines for use in operating, induction and recovery rooms. They may be used with O2, N2O, and AIR supplied by a medical gas pipeline system or by externally mounted gas cylinders. Fabius series machines are equipped with a compact breathing system; providing fresh gas decoupling, PEEP, and pressure limitation. The following ventilation options are available: Volume Controlled Ventilation Pressure Controlled Ventilation Pressure Support (Optional) SIMV/PS (Optional) Manual Ventilation Spontaneous Breathing Fabius series anesthesia machines are equipped with an electrically driven and electronically controlled ventilator and monitors for airway pressure (P), volume (V), and inspiratory oxygen concentration (FiO2). As per IEC 60601-2-13 (Anesthetic Workstations and their Modules-Particular Requirements), additional monitoring of the concentrations of CO2 and anesthetic agent is required when the machine is in use
Recall Number: Z-2250-2018<p>
REASON
The Draeger anesthesia device may be able to dose 100% N2O. In the event of a fault, the S-ORC module would not prevent setting an N2O flow that would result in a hypoxic mixture from being dosed to the patient. Potential adverse outcomes include death of the patient.<p>
RECALLING FIRM/MANUFACTURER
Draeger Medical, Inc., Telford PA. on 5/24/2018. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
62<p>
DISTRIBUTION
Nationwide <p>

6/27/2018 CARESCAPE R860 ventilators Cl II

Company:Datex-Ohmeda, Inc.
Date of Enforcement Report 6/27/2018
Class II:<p>
PRODUCT
CARESCAPE R860 ventilators with software version 10SP05 Product Usage: The CARESCAPE R860 ventilator is designed to provide mechanical ventilation or support to neonatal, pediatric, and adult patients weighing 0.25 kg and above. The CARESCAPE R860 ventilator is a microprocessor based, electronically controlled, pneumatically driven ventilator that includes integrated monitoring of FiO2, airway pressure, flow, and volume. Additional respiratory gas monitoring capabilities are supported through the use of optional GE patient monitoring modules. Not all features are available for all patient types or product configurations. The CARESCAPE R860 ventilator is not a pulmonary function calculation device. The system is designed for facility use, including within facility transport, and should only be used under the orders of a clinician.
Recall Number: Z-2266-2018<p>
REASON
Issues identified with the monitor including urine output measurement errors, temperature measurement errors and undesired alarms..<p>
RECALLING FIRM/MANUFACTURER
Datex-Ohmeda, Inc. on 12/8/2017. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE

349 (US) + 2,051 (OUS)<p>
DISTRIBUTION
Nationwide and Internationally<p>

6/27/2018 CritiCore Automated Urine Monitor, Cl II
Company:C.R. Bard, Inc.
Date of Enforcement Report 6/27/2018
Class II:<p>
PRODUCT
CritiCore Automated Urine Output and Temperature Monitor
Recall Number: Z-2243-2018<p>
REASON
Issues identified with the monitor including urine output measurement errors, temperature measurement errors and undesired alarms..<p>
RECALLING FIRM/MANUFACTURER
C.R. Bard, Inc. Covington, GA on 11/10/2017. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
<p>
DISTRIBUTION
Nationwide<p>

6/27/2018 Cyberonics VNS Therapy Programmer, Cl II
Company:Cyberonics, Inc.
Date of Enforcement Report 6/27/2018
Class II:<p>
PRODUCT
VNS Therapy Programmer, Model 3000, v1.0 System
Recall Number: Z-2255-2018<p>
REASON
Certain Model 3000 programming events can result in miscalculation of parameters stored in the Models 103, 104, 105, and 106 generators. During these programming events, the miscalculations can lead to: " Delivery of more stimulation than intended, resulting in painful stimulation or other common side effects (Model 106 only); " No stimulation in the case of device disablement (Burst Watchdog Timeout), resulting in no therapy to the patient (Model 106 only); " Delivery of less stimulation than intended, resulting in therapeutic settings not being achieved within device specification (Models 103, 104, 105, or 106); and/or " Delays or absence of the 75% and 50% battery life indicators displayed by the programming software (Models 103, 104, 105, or 106).<p>
RECALLING FIRM/MANUFACTURER
Cyberonics, Inc., Houston TX on 11/13/2017. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
252 <p>
DISTRIBUTION
UAL, CA, CO, DE, FL, GA, ID, IL, IN, ME, MO, MS, NC, NJ, NY, PA, TN, TN, TX, UT, WA and WI<p>

6/20/2018 CellaVision DM Software, Cl II
Company:CellaVision AB.
Date of Enforcement Report 6/20/2018
Class II:<p>
PRODUCT
CellaVision DM Software versions 6.0.1 or 6.0.2 installed on the following products: CellaVision DM96, DM1200, DM9600 and DI-60 Product Usage: The devices are automated cell-locating devices. The devices automatically locates and presents images of blood cells on peripheral blood smears. The operator identifies and verifies the suggested classification of each cell according to type. The devices

are intended to be used by skilled operators, trained in the use of the device and in recognition of blood cells
Recall Number: Z-2184-2018<p>
REASON
A software malfunction was found where WBC, RBC and PLT comments added after a slide is signed, are not sent to the LIS. This can only occur where customers process multiple slides per blood sample.<p>
RECALLING FIRM/MANUFACTURER
CellaVision AB, Lund, Sweden on 12/4/2017. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
Instruments: 224 Software: 99 (US) <p>
DISTRIBUTION
US Nationwide in the states of FL, IL NY NC.<p>

6/20/2018 Sonialvision Safire II, Cl II
Company:Shimadzu Medical Systems.
Date of Enforcement Report 6/20/2018
Class II:<p>
PRODUCT
Sonialvision Safire II, Model #: DAR-8000f Product Usage: This angiographic x-ray system device intended to be used for the radiography in the hospital with X-ray devices. This device is operated and used by the physicians and X-ray technologist. The object of this device is total patient population.
Recall Number: Z-2060-2018<p>
REASON
When selecting serial radiography with a pulse rate of 7.5fps (including selecting a preset or changing the pulse rate using a temporary edit function) it was observed the indicated "irradiation time" on the X-ray Generator Console, as well as the "integral dose" on the external console of fluoroscopy, were reset to 0. There has been one report of this event..<p>
RECALLING FIRM/MANUFACTURER
IShimadzu Medical Systems, Torrence, CA on 1/12/2018. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
17 <p>
DISTRIBUTION
US Nationwide in the states of IL, WA, MI, TX, AZ, CA, LA, FL, SC, and NJ..<p>

6/13/2018 AdaPTinsight software: Cl II
Company:Ion Beam Applications S.A..
Date of Enforcement Report 6/13/2018
Class II:<p>
PRODUCT
12C (AdaPTinsight) Affected component: AdaPTinsight software Product Usage: 12C is used with a charged particle or photon radiation therapy system for localization of the patient position with respect to the therapy equipment and to provide correction feedback to the radiation therapy system.
Recall Number: Z-2109-2018<p>
REASON
IBA is initiating this recall to address an issue identified with AdaPTinsight software and to reduce risk related to this problem.<p>
RECALLING FIRM/MANUFACTURER
Ion Beam Applications S.A., Louvain La Neuve, Belgium on 10/28/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
5 units (12C) <p>

DISTRIBUTION
Worldwide Distribution - US Nationwide in the states of LA, TX, Italy, Sweden and France. Each country's National Competent Authorities were notified of the firm's Field Safety Notice.<p>

6/13/2018 GE Centricity Universal Viewer, CI II
Company:GE Healthcare
Date of Enforcement Report 6/13/2018
Class II:<p>
PRODUCT
Centricity PACS-IW with Universal Viewer Product Usage: Usage: Centricity PACS-IW with Universal Viewer is a device that displays medical images (including mammograms) and data from various imaging sources. Images and data can be viewed, communicated, processed and displayed within the system or across computer networks at distributed locations. Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using an FDA approved monitor that offers at least 5 Megapixel resolution and meet other technical specifications reviewed and accepted by the FDA.
Recall Number: 1) Z-2101-2018
2) Z-2012-2018
<p>
REASON
Potential that one or more image series may be missing from an exam without a user warning displayed in the Viewer..<p>
RECALLING FIRM/MANUFACTURER
GE Healthcare, chicago, IL Bergen Norway on 1/25/2018. Voluntary: Firm Initiated recall is ongoing.
<p>
VOLUME OF PRODUCT IN COMMERCE
1) 44
2) 252 <p>
DISTRIBUTION
Nationwide and Internationally<p>

6/13/2018 Xper Flex Cardio Physiomonitoring System:
CI II
Company:Invivo Corporation.
Date of Enforcement Report 6/13/2018
Class II:<p>
PRODUCT
Xper Flex Cardio Physiomonitoring System The Xper Flex Cardio physiomonitoring system is used to facilitate invasive investigation of heart and vascular, disease when non-invasive indicators warrant such.
Recall Number: Z-2115-2018<p>
REASON
While in Full Disclosure playback, a user may inadvertently close the Full Disclosure Control Window using the ESC key function, instead of pressing the X icon in the upper right corner of this window..<p>
RECALLING FIRM/MANUFACTURER
Invivo Corporation, Orlando, FL on 11/20/2017. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
1,040 units (USA) and 7 units (Foreign) <p>
DISTRIBUTION
Nationwide and Internationally<p>

6/13/2018 Draeger Jaundice Meter JM-105, Class I
Company:Draeger Medical Systems, Inc.
Date of Enforcement Report 6/13/2018
Class I:<p>
PRODUCT
Draeger Jaundice Meter JM-105 The device is intended for use in hospitals, clinics or doctor s offices under a physician s supervision / direction to assist clinicians in monitoring of newborn infants. The device is not intended as a standalone for diagnosis of hyperbilirubinemia. It is to be used in conjunction with other clinical signs and laboratory measurements.
Recall Number: Z-2047-2018<p>
REASON
Users have misinterpreted the display for out of range measurement indicated by the blinking" ---" to mean a zero measurement.<p>
RECALLING FIRM/MANUFACTURER
Draeger Medical Systems, Inc., Telford, PA on 5/15/2018. Voluntary: Firm Initiated recall is ongoing.
<p>
VOLUME OF PRODUCT IN COMMERCE
6711 <p>
DISTRIBUTION
Nationwide and Internationally<p>

6/13/2018 Draeger Jaundice Meter JM-103, Class I
Company:Draeger Medical Systems, Inc.
Date of Enforcement Report 6/13/2018
Class I:<p>
PRODUCT
Draeger Jaundice Meter JM-103 The device is intended for use in hospitals, clinics or doctor s offices under a physician s supervision / direction to assist clinicians in monitoring of newborn infants. The device is not intended as a standalone for diagnosis of hyperbilirubinemia. It is to be used in conjunction with other clinical signs and laboratory measurements.
Recall Number: Z-2046-2018<p>
REASON
Users have misinterpreted the display for out of range measurement indicated by the blinking" ---" to mean a zero measurement.<p>
RECALLING FIRM/MANUFACTURER
Draeger Medical Systems, Inc., Telford, PA on 5/15/2018. Voluntary: Firm Initiated recall is ongoing.
<p>
VOLUME OF PRODUCT IN COMMERCE
8318 <p>
DISTRIBUTION
Nationwide and Internationally<p>

6/13/2018 nordicICE v 2.3.14, Cl II
Company:NordicNeuroLab AS
Date of Enforcement Report 6/13/2018
Class II:<p>
PRODUCT
nordicICE v 2.3.14 nordicICE is an image processing software package to be used by trained professionals including but not limited to physicians and medical technicians. The software runs on a standard off-the-shelf PC workstation and can be used to perform image viewing, processing and analysis of medical images. Data and images are acquired through DICOM compliant imaging devices and modalities. nordicICE provides both viewing and analysis capabilities of functional and dynamic imaging datasets acquired with MRI or other relevant modalities, including blood oxygen level

dependent (BOLD) fMRI, diffusion weighted MRI (DWI) / fiber tracking and dynamic analysis.
Recall Number: Z-2061-2018<p>
REASON
The bug causes BOLD activation maps to be visualized as overlays without taking the coregistration into account. Any output created from these activation maps as overlays will not be adjusted according to the coregistration.<p>
RECALLING FIRM/MANUFACTURER
NordicNeuroLab AS, Bergen Norway on 7/3/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
121 licenses <p>
DISTRIBUTION
Nationwide and Internationally<p>

6/13/2018 nordicBrainEx 2.0 Cl II
Company:NordicNeuroLab AS
Date of Enforcement Report 6/13/2018
Class II:<p>
PRODUCT
nordicBrainEx 2.0 provides analysis and visualization capabilities of dynamic MRI data of the brain, presenting the derived properties and parameters in a clinically useful context..
Recall Number: Z-2050-2018<p>
REASON
An error was discovered in the interpretation of certain DICOM header tags that may lead to incorrect orientation labeling, and thus and indirect left-right, up-down or anterior-posterior flipping of images.<p>
RECALLING FIRM/MANUFACTURER
NordicNeuroLab AS, Bergen Norway on 9/17/2014. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
22 licenses <p>
DISTRIBUTION
Nationwide and Internationally<p>

6/6/2018 nordicBrainEx Cl II
Company:NordicNeuroLab AS
Date of Enforcement Report 6/6/2018
Class II:<p>
PRODUCT
nordicBrainEXProduct Usage:nordicBrainEx is an image processing software package to be used by trained professionals including but not limited to physicians and medical technicians. The software runs on a standard off-the-shelf PC workstation and can be used to perform image viewing, processing and analysis of medical images.
Recall Number: Z-2045-2018<p>
REASON
There is an error related to the relative geometry between fiber tracts in a fiber group and images. The error occurs in the following situations: A group of fibers has been selected using the VOI functionality and put into a fiber group. This is done with images series A visualized in the 3D viewer. Then a new images series B is visualized in the 3D viewer. If image series A and B have the same geometrical resolution (pixel sizes and slice distances), the coregistration matrix taking A to B will not be applied to the fiber group, and therefore the fiber group will in general not be positioned correctly on B in the 3D viewer. Furthermore, if the fiber group is exported as a new image series the fibers could be misplaced, and similarly if the fibers are visualized in the MPR on B, the positioning will not be correct. The misalignment will be equal to the rotations/translations necessary to align A with B.<p>
RECALLING FIRM/MANUFACTURER
NordicNeuroLab AS, Bergen Norway on 12/21/2012. Voluntary: Firm Initiated recall is ongoing. <p>

VOLUME OF PRODUCT IN COMMERCE
36 licenses <p>
DISTRIBUTION
Nationwide and Internationally<p>

6/6/2018 Siemens SOMATOM go.Now Cl II
Company:Siemens Medical Solutions USA, Inc
Date of Enforcement Report 6/62018
Class II:<p>
PRODUCT
SOMATOM Go.Now, Material Number 11061628 There is a potential for a software issue that may cause the need for necessary patient rescans.
Recall Number: Z-1939-2018<p>
REASON
There is a potential for a software issue that may cause the need for necessary patient rescans.<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Malvern, PA on 4/20/2018. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
4 units in US <p>
DISTRIBUTION
Nationwide and Internationally <p>

6/6/2018 Siemens SOMATOM Go.Up Cl II
Company:Siemens Medical Solutions USA, Inc
Date of Enforcement Report 6/62018
Class II:<p>
PRODUCT
SOMATOM Go.Up, Material Number 11061628 There is a potential for a software issue that may cause the need for necessary patient rescans.
Recall Number: Z-1940-2018<p>
REASON
There is a potential for a software issue that may cause the need for necessary patient rescans.<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Malvern, PA on 4/20/2018. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
33 units in US <p>
DISTRIBUTION
Nationwide and Internationally <p>

6/6/2018 nordicICE 2.3.14 image processing software, Cl II
Company:NordicNeuroLab AS
Date of Enforcement Report 6/6/2018
Class II:<p>
PRODUCT
nordicICE 2.3.14 Image processing software package used by trained professionals, including physicians and medical technicians.
Recall Number: Z-2044-2018<p>
REASON
An error was discovered in the interpretation of certain DICOM header tags that may lead to incorrect orientation labeling, and thus and indirect left-right, up-down or anterior-posterior flipping of images.<p>

RECALLING FIRM/MANUFACTURER
NordicNeuroLab AS, Bergen Norway on 9/12/2014. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
97 licenses <p>
DISTRIBUTION
Nationwide and Internationally<p>

6/6/2018 nordicTumorEx 1.0 Cl II
Company:NordicNeuroLab AS
Date of Enforcement Report 6/6/2018
Class II:<p>
PRODUCT
nordicTumorEx 1.0nordicTumorEx is an image processing software package to be used by trained professionals including but not limited to physicians and medical technicians. The software runs on a standard off-the-shelf PC workstation and can be used to perform image viewing, processing and analysis of medical images
Recall Number: Z-2042-2018<p>
REASON
An error was discovered in the interpretation of certain DICOM header tags that may lead to incorrect orientation labeling, and thus and indirect left-right, up-down or anterior-posterior flipping of images.<p>
RECALLING FIRM/MANUFACTURER
NordicNeuroLab AS, Bergen Norway on 12/15/2014. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
16 licenses <p>
DISTRIBUTION
Nationwide and Internationally<p>

5/30/2018 Siemens Biograph Horizon, PET/CT System
Cl II
Company:Siemens Medical Solutions USA, Inc
Date of Enforcement Report 5/30/2018
Class II:<p>
PRODUCT
 Biograph Horizon, PET/CT System using VJ10A, VJ10B, VJ20A scanners that provide registration and fusion of high resolution physiologic and anatomic information.SOMATOM Force (Model 10742326) Computed tomography x-ray diagnostic system
Recall Number: Z-1930-2018<p>
REASON
Possibility that the Biograph Horizon systems performing CT retrospective cardiac gating or PET cardiac gating examinations may experience a waveform sampling issue caused by a firmware change within the Universal Physiological Measurement Module.<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Hoffman Estates, IL on 2/21/2018. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
14 units <p>
DISTRIBUTION
Nationwide and Internationally<p>

5/30/2018 Baxter Prismaflex 7.20 US Cl II
Company:Baxter Healthcare Corporation
Date of Enforcement Report 5/30/2018
Class II:<p>
PRODUCT

Prismaflex 7.20 US: The Prismaflex Control Unit is intended for: " Continuous Renal Replacement Therapy (CRRT) for patients weighing 20 kilograms or more with acute renal failure and/or fluid overload. " Therapeutic Plasma Exchange (TPE) therapy for patients weighing 20 kilograms or more with diseases where removal of plasma components is indicated.
Recall Number: Z-1926-2018<p>
REASON
Baxter Healthcare will be installing new firmware on all Prismaflex control units to address the potential for a small number of these units to exhibit a failure mode with the pump module electronics. The failure mode may result in a Voltage Out of Range malfunction alarm, which causes the device to enter a safe state and become inoperable until it is serviced. Baxter will be releasing new firmware that will prevent the malfunction from occurring<p>
RECALLING FIRM/MANUFACTURER
Baxter Healthcare Corporation, Deerfield, IL on 4/24/2018. Voluntary: Firm Initiated recall is ongoing.
<p>
VOLUME OF PRODUCT IN COMMERCE
231 units <p>
DISTRIBUTION
Nationwide and Internationally <p>

5/30/2018 Baxter Prismaflex 7.XX ROW Cl II
Company:Baxter Healthcare Corporation
Date of Enforcement Report 5/30/2018
Class II:<p>
PRODUCT
Prismaflex 7.XX ROW, Product Code 114870: The Prismaflex Control Unit is intended for: " Continuous Renal Replacement Therapy (CRRT) for patients weighing 20 kilograms or more with acute renal failure and/or fluid overload. " Therapeutic Plasma Exchange (TPE) therapy for patients weighing 20 kilograms or more with diseases where removal of plasma components is indicated.
Recall Number: Z-1924-2018<p>
REASON
Baxter Healthcare will be installing new firmware on all Prismaflex control units to address the potential for a small number of these units to exhibit a failure mode with the pump module electronics. The failure mode may result in a Voltage Out of Range malfunction alarm, which causes the device to enter a safe state and become inoperable until it is serviced. Baxter will be releasing new firmware that will prevent the malfunction from occurring<p>
RECALLING FIRM/MANUFACTURER
Baxter Healthcare Corporation, Deerfield, IL on 4/24/2018. Voluntary: Firm Initiated recall is ongoing.
<p>
VOLUME OF PRODUCT IN COMMERCE
2772 units <p>
DISTRIBUTION
Nationwide and Internationally <p>

5/30/2018 Baxter Prismaflex System Cl II
Company:Baxter Healthcare Corporation
Date of Enforcement Report 5/30/2018
Class II:<p>
PRODUCT
Prismaflex System, Product Code 107493 Intended Use: The Prismaflex Control Unit is intended for: " Continuous Renal Replacement Therapy (CRRT) for patients weighing 20 kilograms or more with acute renal failure and/or fluid overload. " Therapeutic Plasma Exchange (TPE) therapy for patients weighing 20 kilograms or more with diseases where removal of plasma components is indicated.
Recall Number: Z-1922-2018<p>

REASON
Baxter Healthcare will be installing new firmware on all Prismaflex control units to address the potential for a small number of these units to exhibit a failure mode with the pump module electronics. The failure mode may result in a Voltage Out of Range malfunction alarm, which causes the device to enter a safe state and become inoperable until it is serviced. Baxter will be releasing new firmware that will prevent the malfunction from occurring<p>
RECALLING FIRM/MANUFACTURER
Baxter Healthcare Corporation, Deerfield, IL on 4/24/2018. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
5880 units <p>
DISTRIBUTION
Nationwide and Internationally <p>

5/23/2018 Siemens SOMATOM Force CT diagnostic system Cl II

Company:Siemens Medical Solutions USA, Inc
Date of Enforcement Report 5/23/2018
Class II:<p>
PRODUCT
SOMATOM Force (Model 10742326) Computed tomography x-ray diagnostic system
Recall Number: Z-1748-2018<p>
REASON
There is a potential risk of unnecessary radiation exposure due to a software issue found in the CARE Dose4D algorithm implemented in Siemens Healthineers CT scanners of types SOMATOM Definition AS, SOMATOM Definition DS, SOMATOM Definition Edge, SOMATOM Definition Flash and SOMATOM Force..<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Malvern, PA on 11/8/2017. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
91 <p>
DISTRIBUTION
Nationwide, Puerto Rico and Guam <p>

5/23/2018 Draeger Infinity Acute Care System, Cl II

Company:Draegar Medical Systems, Inc.
Date of Enforcement Report 5/23/2018
Class II:<p>
PRODUCT
Infinity Acute Care System (IACS) Monitoring Solution; Catalog Numbers:MS20401, MS20724, MS22956, MS25510, MS25520, MS25643, MS26196, MS26372, MS31818; UDI Information: 4049098054454, 4049098054447, 4049098054409, 4049098009799, 4049098009751.
Multi-parameter, physiologic patient monitoring of adult, pediatric and neonatal patients in environments where patient care is provided by trained healthcare professionals. The IACS obtains the physiologic, multi-parameter data from the connection to the M540 monitor and optional medical devices and displays. The transfer of this data is accomplished by the Infinity network. The M540 is intended to monitor one patient at a time.
Recall Number: Z-1813-2018<p>
REASON
Software anomaly resulting in the loss of patient settings and stored patient data.<p>
RECALLING FIRM/MANUFACTURER
Draegar Medical Systems, Inc., Andover, MA on 3/28/2018 Voluntary: Firm Initiated recall is ongoing.

<p>
VOLUME OF PRODUCT IN COMMERCE
25, 629 <p>
DISTRIBUTION
Nationwide and Internationally <p>

5/23/2018 PHILIPS Xper Flex Cl II
Company:Invivo Corporation
Date of Enforcement Report 5/23/2018
Class II:<p>
PRODUCT
PHILIPS Xper Flex Cardio Physiomonitoring System, Model Numbers: 453564241901, 453564483321, 453564621791, and 989803199561 (international only)The Xper Flex Cardio physiomonitoring system is used to facilitate invasive investigation of heart and vascular, disease when non-invasive indicators warrant such.
Recall Number: Z-1867-2018<p>
REASON
The real-time numeric value for ventricular end-diastolic pressure (EDP) displayed on the Live Display may be inaccurate. Because ventricular pressure monitoring is only performed in the cardiac catheterization procedure room using the FC2010 device, the FC2020 device, which is used in the Pre or Post-Op Holding Areas, is not impacted by this issue.<p>
RECALLING FIRM/MANUFACTURER
Invivo Corporation, Orlando FL on 3/14/2018. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
4375 units <p>
DISTRIBUTION
Nationwide and Internationally <p>

5/23/2018 Siemens SOMATOM Definition AS; Cl II
Company:Siemens Medical Solutions USA, Inc
Date of Enforcement Report 5/23/2018
Class II:<p>
PRODUCT
SOMATOM Definition AS (Model 8098027) Computed tomography x-ray diagnostic system
Recall Number: Z-1745-2018<p>
REASON
There is a potential risk of unnecessary radiation exposure due to a software issue found in the CARE Dose4D algorithm implemented in Siemens Healthineers CT scanners of types SOMATOM Definition AS, SOMATOM Definition DS, SOMATOM Definition Edge, SOMATOM Definition Flash and SOMATOM Force..<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Malvern, PA on 11/8/2017. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
1385 <p>
DISTRIBUTION
Nationwide, Puerto Rico and Guam <p>

5/16/2018 Siemens Syngo.plaza software : Cl II
Company:Siemens Medical Solutions USA, Inc
Date of Enforcement Report 5/16/2018
Class II:<p>
PRODUCT

Syngo.plaza software Syngo.Plaza is a Picture Archiving and Communication System (PACS) intended to display, process, read, report, communicate, distribute, store and archive digital medical images. It supports the physician in diagnosis and treatment planning. Syngo.plaza also supports storage and archiving of DICOM Structured reports
Recall Number: Z-1700-2018<p>
REASON
Software upgrade to correct format of study dates and issues with Legacy Presentation States (annotations) in order to prevent potential patient misdiagnosis.<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Malvern, PA on 2/20/2018. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
92 <p>
DISTRIBUTION
Nationwide <p>

5/16/2018 Siemens Syngo.plaza software VB10A : Cl II
Company:Siemens Medical Solutions USA, Inc
Date of Enforcement Report 5/16/2018
Class II:<p>
PRODUCT
Syngo.plaza software VB10A model numbers: 10863171, 10863172, 10863173 Syngo.Plaza is a Picture Archiving and Communication System (PACS) intended to display, process, read, report, communicate, distribute, store and archive digital medical images. It supports the physician in diagnosis and treatment planning. Syngo.plaza also supports storage and archiving of DICOM Structured reports. In a comprehensive imaging syngo.plaza integrates Hospital/Radiology Information Systems (HIS/RIS) to enable customer specific workflows. Syngo.plaza optionally uses a variety of advanced postprocessing applications
Recall Number: Z-1699-2018<p>
REASON
Software upgrade to correct format of study dates and issues with Legacy Presentation States (annotations) in order to prevent potential patient misdiagnosis.<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Malvern, PA on 2/20/2018. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
92 <p>
DISTRIBUTION
Nationwide <p>

5/16/2018 FlexLab Laboratory Automation System Cl II
Company:Inpeco S.A.
Date of Enforcement Report 5/16/2018
Class II:<p>
PRODUCT
FlexLab (FLX), Accelerator a3600 (ACP), Aptio Automation (AP2), Laboratory Automation System
Recall Number: Z-1798-2018<p>
REASON
Module may freeze without generating user warning. There is a potential risk in delay of sample processing, leading to delayed delivery of test results to patients<p>
RECALLING FIRM/MANUFACTURER
Inpeco S.A. Lugano Switzerlandon 2/13/2018. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE

NY and IL <p>
DISTRIBUTION
NY and IL <p>

5/16/2018 Siemens ACUSON SC2000 Ultrasound Cl II
Company:Siemens Medical Solutions USA, Inc
Date of Enforcement Report 5/16/2018
Class II:<p>
PRODUCT
ACUSON SC2000 Ultrasound System. The firm name on the label is Siemens Medical Solutions USA, Inc., Buffalo Grove, IL..
Recall Number: Z-1200-2018<p>
REASON
The ECG signal may flatline due to electromagnetic interference during the use of electrosurgical equipment. <p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Mountain View, CA on 3/5/2018. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
229 systems <p>
DISTRIBUTION
Nationwide and internationally <p>

5/9/2018 Siemens Biograph Horizon - PET/CT, PET : Cl II
Company:Siemens Medical Solutions USA, Inc
Date of Enforcement Report 5/9/2018
Class II:<p>
PRODUCT
Biograph Horizon - PET/CT, PETsyngo VJ20A Software Nuclear medicine/ xray diagnostic scanner.
Recall Number: Z-15972018<p>
REASON
Error introduced into PET images acquired and reconstructed with VJ20A software. Array values are indexed improperly when the norm file is created during QC. During data reconstruction, incorrect values are being applied. This can lead to a gradient in the image. The severity of the error is directly related to the positioning of the PET QC phantom relative to the center of the field of view. <p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Hoffman Estates, IL on 1/26/2018. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
42 units <p>
DISTRIBUTION
Nationwide and internationally <p>

5/9/2018 Philips Allura Xper R8.x.25.5 and UNIZ , Cl II
Company:Philips Electronics North America Corporation
Date of Enforcement Report 5/9/2018
Class II:<p>
PRODUCT
Allura Xper R8.x.25.5 and UNIZ systems (only with a FlexVision large screen monitor), Interventional fluoroscopic x-ray system Product Usage: The Allura Xper ED series is intended for use on human patients to perform: Vascular, cardiovascular and neurovascular imaging applications, including diagnostic, interventional and minimally invasive procedures.

Recall Number Z-15894-2018<p>
REASON
After continuous operation for more than one and a half days, the image on the large screen monitor may freeze for approximately 15 seconds after which the system will restore itself.<p>
RECALLING FIRM/MANUFACTURER
Philips Electronics North America Corporation, Andover, MA on 3/14/2018. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
2<p>
DISTRIBUTION
Nationwide and Internationally<p>

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5/9/2018 Cobas b 221<6>Roche OMNI S4 system Cl II

Company:Roche Diagnostics Corporation
Date of Enforcement Report 5/9/2018
Class II:<p>
PRODUCT
cobas b 221<6>Roche OMNI S2 system catalog numbers: 3337111001 and 3337111692 The Roche Diagnostics Omni S Analyzer is a fully automated critical care analyzer intended to be used for the measurement of pH, PCO2, PO2, sodium, potassium, ionized calcium, chloride, hematocrit, glucose, lactate, urea/BUN, total hemoglobin, oxygen saturation, oxyhemoglobin, deoxyhemoglobin, carboxyhemoglobin, and methemoglobin in samples of whole blood, serum, plasma, and aqueous solutions as appropriate.
Recall Number: Z-1612-2018<p>
REASON
The software responsible for starting scheduled AutoQC measurements (scheduler) will not activate..<p>
RECALLING FIRM/MANUFACTURER
HRoche Diagnostics Corporation, Indianapolis, IN 2/22/2018. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
1026 total products <p>
DISTRIBUTION
Nationwide <p>

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5/9/2018 Cobas b 221<4>Roche OMNI S4 system Cl II

Company:Roche Diagnostics Corporation
Date of Enforcement Report 5/9/2018
Class II:<p>
PRODUCT
cobas b 221<4>Roche OMNI S2 system catalog numbers: 3337111001 and 3337111692 The Roche Diagnostics Omni S Analyzer is a fully automated critical care analyzer intended to be used for the measurement of pH, PCO2, PO2, sodium, potassium, ionized calcium, chloride, hematocrit, glucose, lactate, urea/BUN, total hemoglobin, oxygen saturation, oxyhemoglobin, deoxyhemoglobin, carboxyhemoglobin, and methemoglobin in samples of whole blood, serum, plasma, and aqueous solutions as appropriate.
Recall Number: Z-1611-2018<p>
REASON
The software responsible for starting scheduled AutoQC measurements (scheduler) will not activate..<p>
RECALLING FIRM/MANUFACTURER
HRoche Diagnostics Corporation, Indianapolis, IN 2/22/2018. Voluntary: Firm Initiated recall is ongoing. <p>

VOLUME OF PRODUCT IN COMMERCE
1026 total products <p>
DISTRIBUTION
Nationwide <p>

5/9/2018 cobas b 221<2>Roche OMNI S2 system Cl II
Company:Roche Diagnostics Corporation
Date of Enforcement Report 5/9/2018
Class II:<p>
PRODUCT
cobas b 221<2>Roche OMNI S2 system catalog numbers: 3337111001 and 3337111692 The Roche Diagnostics Omni S Analyzer is a fully automated critical care analyzer intended to be used for the measurement of pH, PCO2, PO2, sodium, potassium, ionized calcium, chloride, hematocrit, glucose, lactate, urea/BUN, total hemoglobin, oxygen saturation, oxyhemoglobin, deoxyhemoglobin, carboxyhemoglobin, and methemoglobin in samples of whole blood, serum, plasma, and aqueous solutions as appropriate.
Recall Number: Z-1610-2018<p>
REASON
The software responsible for starting scheduled AutoQC measurements (scheduler) will not activate..<p>
RECALLING FIRM/MANUFACTURER
HRoche Diagnostics Corporation, Indianapolis, IN 2/22/2018. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
1026 total products <p>
DISTRIBUTION
Nationwide <p>

5/9/2018 Hitachi MHI-TM2000 Linear Accelerator System
Cl II
Company:Hitachi Ltd., Medical System Operations Group
Date of Enforcement Report 5/9/2018
Class II:<p>
PRODUCT
MHI-TM2000 Linear Accelerator System Product Usage: MHI-TM2000 Linear Accelerator System is intended for radiation therapy of lesions, tumors and conditions anywhere in the body where radiation treatment is indicated.
Recall Number: Z-1585-2018<p>
REASON
Due to a system controller software anomaly, the patient positioning deviation correction may not be applied and may result in the wrong part of the patient being irradiated.<p>
RECALLING FIRM/MANUFACTURER
Hitachi Ltd., Medical System Operations Group, Kashiwa, Japanon 12/8/2017. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
1 <p>
DISTRIBUTION
New York <p>

**5/9/2018 Siemens SOMATOM Sensation Emotion Duo (
: Cl II**
Company:Siemens Medical Solutions USA, Inc
Date of Enforcement Report 5/9/2018
Class II:<p>
PRODUCT
SOMATOM Sensation Emotion Duo (2003) Intended to produce cross-sections images of the body by computer reconstruction of x-ray transmission data.
Recall Number: Z-1459-2018<p>
REASON
To inform customers of possible incorrect tube current calculations by the CARE Dose4D algorithm for head scans based on p.a. (posterior-anterior) or a.p. (anterior-posterior) topograms. Depending on the geometrical shape of the skull bone, it may happen in rare cases that the calculated dose distribution is not appropriate and could lead to unnecessary radiation exposure<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Malvern, PA on 2/15/2018. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
1301 <p>
DISTRIBUTION
Nationwide <p>

5/9/2018 Siemens SOMATOM Sensation 40 : Cl II
Company:Siemens Medical Solutions USA, Inc
Date of Enforcement Report 5/9/2018
Class II:<p>
PRODUCT
SOMATOM Sensation 40 Intended to produce cross-sections images of the body by computer reconstruction of x-ray transmission data.
Recall Number: Z-1458-2018<p>
REASON
To inform customers of possible incorrect tube current calculations by the CARE Dose4D algorithm for head scans based on p.a. (posterior-anterior) or a.p. (anterior-posterior) topograms. Depending on the geometrical shape of the skull bone, it may happen in rare cases that the calculated dose distribution is not appropriate and could lead to unnecessary radiation exposure<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Malvern, PA on 2/15/2018. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
1301 <p>
DISTRIBUTION
Nationwide <p>

5/9/2018 Siemens SOMATOM Sensation Open : Cl II
Company:Siemens Medical Solutions USA, Inc
Date of Enforcement Report 5/9/2018
Class II:<p>
PRODUCT
SOMATOM Sensation Open Intended to produce cross-sections images of the body by computer reconstruction of x-ray transmission data.
Recall Number: Z-1457-2018<p>
REASON
To inform customers of possible incorrect tube current calculations by the CARE Dose4D algorithm for

head scans based on p.a. (posterior-anterior) or a.p. (anterior-posterior) topograms. Depending on the geometrical shape of the skull bone, it may happen in rare cases that the calculated dose distribution is not appropriate and could lead to unnecessary radiation exposure<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Malvern, PA on 2/15/2018. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
1301 <p>
DISTRIBUTION
Nationwide <p>

5/9/2018 Siemens SOMATOM Sensation 64 : Cl II
Company:Siemens Medical Solutions USA, Inc
Date of Enforcement Report 5/9/2018
Class II:<p>
PRODUCT
SOMATOM Sensation 64 Intended to produce cross-sections images of the body by computer reconstruction of x-ray transmission data.
Recall Number: Z-1456-2018<p>
REASON
To inform customers of possible incorrect tube current calculations by the CARE Dose4D algorithm for head scans based on p.a. (posterior-anterior) or a.p. (anterior-posterior) topograms. Depending on the geometrical shape of the skull bone, it may happen in rare cases that the calculated dose distribution is not appropriate and could lead to unnecessary radiation exposure<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Malvern, PA on 2/15/2018. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
1301 <p>
DISTRIBUTION
Nationwide <p>

5/9/2018 Siemens SOMATOM Sensation Cardiac : Cl II
Company:Siemens Medical Solutions USA, Inc
Date of Enforcement Report 5/9/2018
Class II:<p>
PRODUCT
SOMATOM Sensation Cardiac Intended to produce cross-sections images of the body by computer reconstruction of x-ray transmission data.
Recall Number: Z-1455-2018<p>
REASON
To inform customers of possible incorrect tube current calculations by the CARE Dose4D algorithm for head scans based on p.a. (posterior-anterior) or a.p. (anterior-posterior) topograms. Depending on the geometrical shape of the skull bone, it may happen in rare cases that the calculated dose distribution is not appropriate and could lead to unnecessary radiation exposure<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Malvern, PA on 2/15/2018. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
1301 <p>
DISTRIBUTION
Nationwide <p>

5/9/2018 Siemens SOMATOM Sensation 16 : Cl II
Company:Siemens Medical Solutions USA, Inc
Date of Enforcement Report 5/9/2018
Class II:<p>
PRODUCT
SOMATOM Sensation 16 Intended to produce cross-sections images of the body by computer reconstruction of x-ray transmission data.
Recall Number: Z-1454-2018<p>
REASON
To inform customers of possible incorrect tube current calculations by the CARE Dose4D algorithm for head scans based on p.a. (posterior-anterior) or a.p. (anterior-posterior) topograms. Depending on the geometrical shape of the skull bone, it may happen in rare cases that the calculated dose distribution is not appropriate and could lead to unnecessary radiation exposure<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Malvern, PA on 2/15/2018. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
1301 <p>
DISTRIBUTION
Nationwide <p>

5/9/2018 Siemens SOMATOMSensation 10 : Cl II
Company:Siemens Medical Solutions USA, Inc
Date of Enforcement Report 5/9/2018
Class II:<p>
PRODUCT
SOMATOM Sensation 10 Intended to produce cross-sections images of the body by computer reconstruction of x-ray transmission data.
Recall Number: Z-1453-2018<p>
REASON
To inform customers of possible incorrect tube current calculations by the CARE Dose4D algorithm for head scans based on p.a. (posterior-anterior) or a.p. (anterior-posterior) topograms. Depending on the geometrical shape of the skull bone, it may happen in rare cases that the calculated dose distribution is not appropriate and could lead to unnecessary radiation exposure<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Malvern, PA on 2/15/2018. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
1301 <p>
DISTRIBUTION
Nationwide <p>

5/9/2018 Siemens SOMATOM Emotion (2003) : Cl II
Company:Siemens Medical Solutions USA, Inc
Date of Enforcement Report 5/9/2018
Class II:<p>
PRODUCT
SOMATOM Emotion (2003) Intended to produce cross-sections images of the body by computer reconstruction of x-ray transmission data.
Recall Number: Z-1452-2018<p>
REASON
To inform customers of possible incorrect tube current calculations by the CARE Dose4D algorithm for head scans based on p.a. (posterior-anterior) or a.p. (anterior-posterior) topograms. Depending on the

geometrical shape of the skull bone, it may happen in rare cases that the calculated dose distribution is not appropriate and could lead to unnecessary radiation exposure<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Malvern, PA on 2/15/2018. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
1301 <p>
DISTRIBUTION
Nationwide <p>

5/9/2018 Siemens SOMATOM Spirit : Cl II
Company:Siemens Medical Solutions USA, Inc
Date of Enforcement Report 5/9/2018
Class II:<p>
PRODUCT
SOMATOM Spirit Intended to produce cross-sections images of the body by computer reconstruction of x-ray transmission data.
Recall Number: Z-1451-2018<p>
REASON
To inform customers of possible incorrect tube current calculations by the CARE Dose4D algorithm for head scans based on p.a. (posterior-anterior) or a.p. (anterior-posterior) topograms. Depending on the geometrical shape of the skull bone, it may happen in rare cases that the calculated dose distribution is not appropriate and could lead to unnecessary radiation exposure<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Malvern, PA on 2/15/2018. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
1301 <p>
DISTRIBUTION
Nationwide <p>

5/9/2018 Siemens SOMATOM Scope Power : Cl II
Company:Siemens Medical Solutions USA, Inc
Date of Enforcement Report 5/9/2018
Class II:<p>
PRODUCT
SOMATOM Scope Power Intended to produce cross-sections images of the body by computer reconstruction of x-ray transmission data.
Recall Number: Z-1450-2018<p>
REASON
To inform customers of possible incorrect tube current calculations by the CARE Dose4D algorithm for head scans based on p.a. (posterior-anterior) or a.p. (anterior-posterior) topograms. Depending on the geometrical shape of the skull bone, it may happen in rare cases that the calculated dose distribution is not appropriate and could lead to unnecessary radiation exposure<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Malvern, PA on 2/15/2018. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
1301 <p>
DISTRIBUTION
Nationwide <p>

5/9/2018 Siemens SOMATOM Scope : Cl II
Company:Siemens Medical Solutions USA, Inc
Date of Enforcement Report 5/9/2018
Class II:<p>
PRODUCT
SOMATOM Scope Intended to produce cross-sections images of the body by computer reconstruction of x-ray transmission data.
Recall Number: Z-1449-2018<p>
REASON
To inform customers of possible incorrect tube current calculations by the CARE Dose4D algorithm for head scans based on p.a. (posterior-anterior) or a.p. (anterior-posterior) topograms. Depending on the geometrical shape of the skull bone, it may happen in rare cases that the calculated dose distribution is not appropriate and could lead to unnecessary radiation exposure<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Malvern, PA on 2/15/2018. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
1301 <p>
DISTRIBUTION
Nationwide <p>

5/9/2018 Siemens SOMATOM Perspective 16 : Cl II
Company:Siemens Medical Solutions USA, Inc
Date of Enforcement Report 5/9/2018
Class II:<p>
PRODUCT
SOMATOM Perspective 16 Intended to produce cross-sections images of the body by computer reconstruction of x-ray transmission data.
Recall Number: Z-1448-2018<p>
REASON
To inform customers of possible incorrect tube current calculations by the CARE Dose4D algorithm for head scans based on p.a. (posterior-anterior) or a.p. (anterior-posterior) topograms. Depending on the geometrical shape of the skull bone, it may happen in rare cases that the calculated dose distribution is not appropriate and could lead to unnecessary radiation exposure<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Malvern, PA on 2/15/2018. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
1301 <p>
DISTRIBUTION
Nationwide <p>

5/9/2018 Siemens Perspective 16 : Cl II
Company:Siemens Medical Solutions USA, Inc
Date of Enforcement Report 5/9/2018
Class II:<p>
PRODUCT
SOMATOM Perspective 16 Intended to produce cross-sections images of the body by computer reconstruction of x-ray transmission data.
Recall Number: Z-1448-2018<p>
REASON
To inform customers of possible incorrect tube current calculations by the CARE Dose4D algorithm for head scans based on p.a. (posterior-anterior) or a.p. (anterior-posterior) topograms. Depending on the

geometrical shape of the skull bone, it may happen in rare cases that the calculated dose distribution is not appropriate and could lead to unnecessary radiation exposure<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Malvern, PA on 2/15/2018. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
1301 <p>
DISTRIBUTION
Nationwide <p>

5/9/2018 Siemens Perspective : Cl II
Company:Siemens Medical Solutions USA, Inc
Date of Enforcement Report 5/9/2018
Class II:<p>
PRODUCT
SOMATOM Perspective Intended to produce cross-sections images of the body by computer reconstruction of x-ray transmission data.
Recall Number: Z-1447-2018<p>
REASON
To inform customers of possible incorrect tube current calculations by the CARE Dose4D algorithm for head scans based on p.a. (posterior-anterior) or a.p. (anterior-posterior) topograms. Depending on the geometrical shape of the skull bone, it may happen in rare cases that the calculated dose distribution is not appropriate and could lead to unnecessary radiation exposure<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Malvern, PA on 2/15/2018. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
1301 <p>
DISTRIBUTION
Nationwide <p>

5/9/2018 Siemens SOMATOM Emotion 16 : Cl II
Company:Siemens Medical Solutions USA, Inc
Date of Enforcement Report 5/9/2018
Class II:<p>
PRODUCT
SOMATOM Emotion 16 Intended to produce cross-sections images of the body by computer reconstruction of x-ray transmission data.
Recall Number: Z-1446-2018<p>
REASON
To inform customers of possible incorrect tube current calculations by the CARE Dose4D algorithm for head scans based on p.a. (posterior-anterior) or a.p. (anterior-posterior) topograms. Depending on the geometrical shape of the skull bone, it may happen in rare cases that the calculated dose distribution is not appropriate and could lead to unnecessary radiation exposure<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Malvern, PA on 2/15/2018. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
1301 <p>
DISTRIBUTION
Nationwide <p>

5/9/2018 Siemens SOMATOM Emotion 6 : Cl II
Company:Siemens Medical Solutions USA, Inc
Date of Enforcement Report 5/9/2018
Class II:<p>
PRODUCT
SOMATOM Emotion 6 Intended to produce cross-sections images of the body by computer reconstruction of x-ray transmission data.
Recall Number: Z-1445-2018<p>
REASON
To inform customers of possible incorrect tube current calculations by the CARE Dose4D algorithm for head scans based on p.a. (posterior-anterior) or a.p. (anterior-posterior) topograms. Depending on the geometrical shape of the skull bone, it may happen in rare cases that the calculated dose distribution is not appropriate and could lead to unnecessary radiation exposure<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Malvern, PA on 2/15/2018. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
1301 <p>
DISTRIBUTION
Nationwide <p>

5/9/2018 PerkenElmer Specimen Gate Screening Center, Cl II
Company:PerkinElmer Life and Analytical Sciences, Wallac, OY
Date of Enforcement Report 5/9/2018
Class II:<p>
PRODUCT
Specimen Gate Screening Center, Part Number 5002-0500, All software versions from 1.0 to 1.8 (current software version) Specimen Gate Screening Center is used for data management of neonatal screening test results and demographics by qualified laboratory personnel in newborn screening programs.
Recall Number Z-1541-2018<p>
REASON
Potential errors in patient results generated by the Screening Center product that include both false negative and false positive results.<p>
RECALLING FIRM/MANUFACTURER
PerkinElmer Life and Analytical Sciences, Wallac, OY, Turku ,Finland on 11/17/2017. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
8<p>
DISTRIBUTION
Worldwide Distribution - US Distribution to the state of Georgia., and to the countries of : Belgium, Canada, Denmark, Italy, and United Kingdom.<p>

5/9/2018 AQURE system Cl II
Company:Radiometer Medical ApS
Date of Enforcement Report 5/9/2018
Class II:<p>
PRODUCT
AQURE, Software version 2.3.0 and 2.3.1 Product Usage: The AQURE system is intended to let allow the management of analytical devices and operator profiles. The user can associate patient data with test data. The system shows test results. The system receives data from connected devices at the point-of care or laboratory. It can send test results to the HIS/LIS. The system lets the user send

commands to selected devices. The system uses data related to the performance of devices, to tell users of issues to be managed. The AQURE system is intended for professional use.
Recall Number Z-1982-2018<p>
REASON
There is a potential problem relating to the AQURE System, versions 2.3.0 and 2.3.1, that may result in patient mix-up.<p>
RECALLING FIRM/MANUFACTURER
FRadiometer Medical ApS, Bronshoj , Denmark on 2/27/2018. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
2<p>
DISTRIBUTION
US Nationwide Distribution in the states to Georgia and Wisconsin.<p>

4/25/2018 Siemens PRIMUS HI : Cl II
Company:Siemens Medical Solutions USA, Inc
Date of Enforcement Report 4/25/2018
Class II:<p>
PRODUCT
PRIMUS HI, Digital Linear Accelerator, Model No. 07360717 Product Usage: The intended use of the device is to deliver x-ray radiation for therapeutic treatment of cancer
Recall Number: Z-1402-2018<p>
REASON
Control Console software has been updated to reduce the risk for collision when delivering automatically sequenced treatments with automatic movements of the gantry and/or the treatment table.<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Malvern, PA on 2/14/2018. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
18 <p>
DISTRIBUTION
Nationwide, PR and Nassau <p>

4/25/2018 Siemens ONCOR Impression Plus : Cl II
Company:Siemens Medical Solutions USA, Inc
Date of Enforcement Report 4/25/2018
Class II:<p>
PRODUCT
ONCOR Impression plus, Digital Linear Accelerator, Model No. 07360717 Product Usage: The intended use of the device is to deliver x-ray radiation for therapeutic treatment of cancer
Recall Number: Z-1401-2018<p>
REASON
Control Console software has been updated to reduce the risk for collision when delivering automatically sequenced treatments with automatic movements of the gantry and/or the treatment table.<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Malvern, PA on 2/14/2018. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
15 <p>
DISTRIBUTION
Nationwide, PR and Nassau <p>

4/25/2018 Siemens ONCOR Impression: Cl II
Company:Siemens Medical Solutions USA, Inc
Date of Enforcement Report 4/25/2018
Class II:<p>
PRODUCT
ONCOR Impression, Digital Linear Accelerator, Model No. 07360717 Product Usage: The intended use of the device is to deliver x-ray radiation for therapeutic treatment of cancer
Recall Number: Z-1400-2018<p>
REASON
Control Console software has been updated to reduce the risk for collision when delivering automatically sequenced treatments with automatic movements of the gantry and/or the treatment table.<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Malvern, PA on 2/14/2018. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
7 <p>
DISTRIBUTION
Nationwide, PR and Nassau <p>

4/25/2018 Siemens ONCOR Expression: Cl II
Company:Siemens Medical Solutions USA, Inc
Date of Enforcement Report 4/25/2018
Class II:<p>
PRODUCT
ONCOR Expression, Digital Linear Accelerator, Model No. 07360717 Product Usage: The intended use of the device is to deliver x-ray radiation for therapeutic treatment of cancer
Recall Number: Z-1399-2018<p>
REASON
Control Console software has been updated to reduce the risk for collision when delivering automatically sequenced treatments with automatic movements of the gantry and/or the treatment table.<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Malvern, PA on 2/14/2018. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
2 <p>
DISTRIBUTION
Nationwide, PR and Nassau <p>

4/25/2018 Siemens ONCOR Avant-garde: Cl II
Company:Siemens Medical Solutions USA, Inc
Date of Enforcement Report 4/25/2018
Class II:<p>
PRODUCT
ONCOR Avant-garde, Digital Linear Accelerator, Model No. 05863472 Product Usage: The intended use of the device is to deliver x-ray radiation for therapeutic treatment of cancer.
Recall Number: Z-1398-2018<p>
REASON
Control Console software has been updated to reduce the risk for collision when delivering automatically sequenced treatments with automatic movements of the gantry and/or the treatment table.<p>

RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Malvern, PA on 2/14/2018. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
1 <p>
DISTRIBUTION
Nationwide, PR and Nassau <p>

4/25/2018 Siemens MEVATRON M2 / PRIMUS: Cl II
Company:Siemens Medical Solutions USA, Inc
Date of Enforcement Report 4/25/2018
Class II:<p>
PRODUCT
MEVATRON M2 / PRIMUS Mid-Energy, Digital Linear Accelerator, Model No. 01940035 Product Usage: The intended use of the device is to deliver x-ray radiation for therapeutic treatment of cancer.
Recall Number: Z-1397-2018<p>
REASON
Control Console software has been updated to reduce the risk for collision when delivering automatically sequenced treatments with automatic movements of the gantry and/or the treatment table.<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Malvern, PA on 2/14/2018. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
18 <p>
DISTRIBUTION
Nationwide, PR and Nassau <p>

4/25/2018 GE Healthcare Prodigy: Cl II
Company:GE Medical Systems Ultrasound & Primary Care Diagnostics,
Date of Enforcement Report 4/25/2018
Class II:<p>
PRODUCT
GE Healthcare:a) Prodigy, Model Numbers: LU7248, LU8905, LU40427, LU40431, LU40626, LU40637, LU40626, LU40637, LU42021, LU42025, LU41730, LU41734, LU42344, LU42365 b) Prodigy Advanced, Model Numbers: LU42361, LU42397Provides an estimate of BMD (Bone Marrow Density) at the lumbar spine and proximal femur regions.
Recall Number Z-1395-2018 <p>
REASON
Under certain conditions, when using DICOM Worklist along with DICOM MPPS, a report for a bone density exam may be sent to PACS with the incorrect patient information in the DICOM header. The correct patient information will be listed on the DICOM report image; however, the report may appear under a different patients name in the PACS<p>
RECALLING FIRM/MANUFACTURER
GE Medical Systems Ultrasound & Primary Care Diagnostics, Madison, WI on 3/16/2018. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
303 units <p>
DISTRIBUTION
Worldwide <p>

4/25/2018 GE Healthcare Lunar: Cl II
Company:GE Medical Systems Ultrasound & Primary Care Diagnostics,
Date of Enforcement Report 4/25/2018
Class II:<p>
PRODUCT
1. GE Healthcare Lunar: a) DPX Duo, Model Number: LU41693 b) DPX Bravo, Model Number: LU41692 Provides an estimate of BMD (Bone Marrow Density) at the lumbar spine and proximal femur regions. This BMD value can then be compared to a reference population at the sole discretion of the physician.
2. GE Healthcare Lunar: a) DPX NT, Model Numbers: LU8230, LU40338, LU42357, LU42369 b) DPX MD+, Model Numbers: LU8230, LU40338, LU40352 Provides an estimate of BMD (Bone Marrow Density) at the lumbar spine and proximal femur regions. This BMD value can then be compared to a reference population at the sole discretion of the physician
Recall Number Z-1393-2018 and Z-1394-2018<p>
REASON
Under certain conditions, when using DICOM Worklist along with DICOM MPPS, a report for a bone density exam may be sent to PACS with the incorrect patient information in the DICOM header. The correct patient information will be listed on the DICOM report image; however, the report may appear under a different patients name in the PACS<p>
RECALLING FIRM/MANUFACTURER
GE Medical Systems Ultrasound & Primary Care Diagnostics, Madison, WI on 3/16/2018. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
1. 26 units
2. 43 units<p>
DISTRIBUTION
Worldwide <p>

4/25/2018 Ingenuity TF PET/CT, Cl II
Company:Philips Medical Systems (Cleveland) Inc
Date of Enforcement Report 4/25/2018
Class II:<p>
PRODUCT
ngenuity TF PET/CT, Model No. 882442 Product Usage: The device is an integrated diagnostic X-ray Computed Tomography (CT) and Positron Emission Tomography (PET) system suitable for a wide range of diagnostic applications. The device utilizes the CT technology to obtain anatomic images of the human body and PET technology to obtain functional images of the human body.
Recall Number Z-1392-2018<p>
REASON
Following a period of inactivity, the mass storage device may cause the acquisition console to become unresponsive. This may prevent an acquisition from proceeding.<p>
RECALLING FIRM/MANUFACTURER
PPhilips Medical Systems (Cleveland) Inc, Cleveland, OH on 2/15/2018. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
12<p>
DISTRIBUTION
Nationwide and Internationally <p>

4/18/2018 Fresenius Liberty Select Cycler (SW v.2.8.7)
Cl II
Company:Fresenius Medical Care Renal Therapies Group, LLC
Date of Enforcement Report 4/18/2018
Class II:<p>
PRODUCT
Liberty Select Cycler (SW v.2.8.7), Material Number RTLR108343 Product Usage: The device is indicated for acute and chronic peritoneal dialysis.
Recall Number Z-1365-2018<p>
REASON
The recalling firm identified a software issue related to the Patient Line Check (PLC) which may result in an increased risk of Overfill (also known as Increased Intraperitoneal Volume, IIPV). Overfill/IIPV may result in serious injury or death.<p>
RECALLING FIRM/MANUFACTURER
Fresenius Medical Care Renal Therapies Group, LLC, Waltham, MA on 1/24/2018. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
9293<p>
DISTRIBUTION
Nationwide<p>

4/18/2018 iQ200 Series Urine Microscopy Analyzer ; Cl II
Company:Beckman Coulter Inc.
Date of Enforcement Report 4/18/2018
Class II:<p>
PRODUCT
BECKMAN COULTER iQ200 Series Urine Microscopy Analyzer
Recall Number Z-1362-2018<p>
REASON
Beckman Coulter has determined that there is a potential for under-reporting casts. This can occur if per high-power field (/HPF) units of measurement for casts are selected in the iQ200 software, but the abnormal threshold and/or grading format is set up based on reporting per low-power field (/LPF)* or *per microliter. This may occur during initial method validation or if settings are altered after the initial validation.<p>
RECALLING FIRM/MANUFACTURER
Beckman Coulter Inc., Brea CA on 3/2/2018. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
5247 units<p>
DISTRIBUTION
Nationwide and Internationally <p>

4/18/2018 AQUIOS CL Flow Cytometer System Cl II
Company:Beckman Coulter Inc.
Date of Enforcement Report 4/18/2018
Class II:<p>
PRODUCT
AQUIOS CL Flow Cytometer System, Catalog #B30166. The AQUIOS CL Flow Cytometer system is an automated analyzer that use a no-wash sample preparation process.The firm name on the label is Beckman Coulter Ireland, Inc., Co. Clare, Ireland.
Recall Number Z-1341-2018<p>
REASON
The device may process the same sample with two different sample IDs and sample information while

using the single tube loader, which has the potential for erroneous results due to the mis-identification..<p>
RECALLING FIRM/MANUFACTURER
Beckman Coulter Inc., Brea CA on 1/29/2018. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
288 devices<p>
DISTRIBUTION
Nationwide and Internationally <p>

4/18/2018 iQ200 Series Urine Microscopy Analyzer Cl II
Company:Beckman Coulter Inc.
Date of Enforcement Report 4/18/2018
Class II:<p>
PRODUCT
iQ200 Series Urine Microscopy Analyzer with Barcode Reader Model NFT-2100.
Recall Number Z-1366-2018<p>
REASON
iQ200 Series Urine Microscopy Analyzer may intermittently fail to read urine sample dilution barcode labels causing erroneous results that could delay treatment for health conditions such as hematuria.<p>
RECALLING FIRM/MANUFACTURER
Beckman Coulter Inc., Brea CA on 11/10/2017. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
4350 total units (1713 in U.S.)<p>
DISTRIBUTION
Nationwide and Internationally <p>

4/18/2018 HomeSafe AutoAlert Pendant Cl II
Company:Lifeline Systems Company.
Date of Enforcement Report 4/18/2018
Class II:<p>
PRODUCT
HomeSafe AutoAlert Pendant works in conjunction with a compatible Lifeline communicator.
Recall Number Z-1316-2018<p>
REASON
A programing error in some Model FD100 HomeSafe AutoAlert Pendants will render the fall detection feature inoperable.<p>
RECALLING FIRM/MANUFACTURER
Lifeline Systems Company, Framingham, MA on 11/13/2017. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
20201<p>
DISTRIBUTION
US and Canada <p>

4/18/2018 IntelliVue X3 Patient Monitor., Cl II
Company:Philips Electronics North America Corporation
Date of Enforcement Report 4/18/2018
Class II:<p>
PRODUCT
IntelliVue X3 Patient Monitor..
Recall Number Z-1315-2018<p>
REASON
The NBP measurement of Intellivue X3 Patient Monitor shows intermittently only mean values instead

of the diastolic and systolic blood pressure values. This is caused by a falsely detected NBP cuff, which is leading to wrong internal NBP setting. Furthermore, occasionally the Monitor shows the Check Touch Input message and the monitor is inoperable with the touch interface. <p>
RECALLING FIRM/MANUFACTURER
Philips Electronics North America Corporation, Andover, MA on 11/17/2017. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
968<p>
DISTRIBUTION
48 Foreign Accounts <p>

4/11/2018 DynaCad software, Cl II
Company:Invivo Corporation.
Date of Enforcement Report 4/11/2018
Class II:<p>
PRODUCT
DynaCad software consist of an MR Analysis Server software and the viewer workstation software. The MR Analysis software consists of DynaCad Breast, DynaCad Prostate, and DynaCad Advanced PK for other MR analyses modules. Product Usage: Intended to be used as a post processing software package designed to provide a reliable means for analyzing MR datasets.
Recall Number Z-1289-2018<p>
REASON
Following update from 3.3 to 3.5 of the DynaCAD software it was noted that the Ktrans map was not rendered correctly on the DynaCad Client. The defect causes the pharmacokinetic (PK) color maps to display incorrectly when viewed from remote DynaCAD client computers and could result in visually underestimating calculated Ktrans, Kep, and iAUGC values. The defect also impacts DynaCAD s on-the-fly calculation of Apparent Diffusion Coefficient (ADC) maps. If the ADC values are computed on-the-fly by DynaCAD, the ADC values and colors will also display incorrectly if viewed on a remote DynaCAD client.<p>
RECALLING FIRM/MANUFACTURER
Invivo Corporation, Gainesville, FL on 1/24/2018. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
432<p>
DISTRIBUTION
UDevice is software. Customer notification letters recommended that users discontinue use of the Ktrans, Kep, and iAUGC colormaps when assessing studies from a remotely connected DynaCAD client computer. It is further advised that users refrain from using the colormaps and values derived from ADC maps calculated by DynaCAD. ADC maps originating natively from the MRI system should be used as an alternative as these values are unaffected. Firm will provide a v4.0 software update for the affected software versions (v3.4, v3.5) to correct the defect at no charge to the user. <p>

4/11/2018 GE Healthcare Centricity PACS-IW Cl II
Company:GE Healthcare
Date of Enforcement Report 4/11/2018
Class II:<p>
PRODUCT
GE Healthcare Centricity PACS-IW, Model Numbers: (a) 2052831-00X (b) 2049588-008 Product Usage: Centricity PACS-IW by GE Healthcare is a device that receives medical images (including mammograms) and data from various imaging sources. Images and data can be stored, communicated, processed and displayed within the system or across computer networks at distributed locations.
Recall Number Z-1302-2018<p>
REASON

A database handling error could occur during the image acquisition process affecting the completeness of acquired images with Centricity PACS-IW. There is a potential that one or more image series (i.e. all images within an image set) may be missing from an exam without indication to the user. While this is rare, this can occur with imaging studies that consist of a very small number of images per series. E.g. CR Thorax exam with 1 image per series.<p>
RECALLING FIRM/MANUFACTURER
PGE Healthcare, Barrington, IL on 2/23/2018. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
569 units<p>
DISTRIBUTION
Worldwide <p>

4/11/2018 Siemens Syngo.via. Medical Device Software
Cl II

Company:Siemens Medical Solutions USA, Inc.
Date of Enforcement Report 4/11/2018
Class II:<p>
PRODUCT
Syngo.via. Medical Device Software. Picture archiving and communications system
Recall Number Z-1303-2018<p>
REASON
A software functionality in the report sections Findings Information and Summary of Measured Findings is not performing properly. The system will use the original values instead of displaying and saving corrected/modified values. Outdated information could be sent to the referring physician when creating the formal report in the reporting system.<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc., Malvern, PA on 1/8/2018. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
236 units<p>
DISTRIBUTION
Device is software only. No products are distributed to wholesale dealers, distributers or retailers<p>

4/11/2018 Fresenius 2008 K2 Hemodialysis Machine Cl
II

Company:Fresenius Medical Care Renal Therapies Group, LLC
Date of Enforcement Report 4/11/2018
Class II:<p>
PRODUCT
2008 K2 Hemodialysis Machine with software version 5.40, Models: (1) Hemodialysis SYS OLC/Diasafe PLS 190610, UDI 00840861100859 (+Serial Number), (2) Machine Short Cap, OLC.DP HP 190630, UDI 00840861100866 (+Serial Number) ndicated for acute and chronic dialysis therapy.
Recall Number Z-1278-2018<p>
REASON
When the recirculation ultrafiltration (UF) Goal is set to a value greater than 200ml in service mode and the user starts a treatment using the SLED (Sustained Low Efficiency Dialysis) program the display will show an invalid message and the UF pump will run at the recirculation UF rate which may be up to 4000ml/hour. The SLED program is required to limit the UF rate to a maximum of 1000 ml/hour.<p>
RECALLING FIRM/MANUFACTURER
Fresenius Medical Care Renal Therapies Group, LLC, Waltham, MA on 12/14/2017. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
127<p>

DISTRIBUTION
US Distribution to the states of: AR, CA, CO, FL, GA, IL, MA, MD, MN, NC, NY, OH, PA, SC, TN, and TX.<p>

4/11/2018 Phadia Prime software Cl II
Company:Phadia Ab.
Date of Enforcement Report 4/11/2018
Class II:<p>
PRODUCT
Phadia Prime software, article number 12-4101-00, as used in combination with the Phadia 250 Instrument, article number 12-3900-01 and EliA Assays. This recall is for any Phadia Prime software version up to and including the current version, 2.1.4.
Recall Number Z-1276-2018<p>
REASON
We want to inform all Phadia 250 system operators performing EliA Assays not to use the function OK to All in any version of Phadia Prime, up to and including 2.1.4, when rejecting and retesting samples with any EliA assay (the OK function may be used for rejecting single tests and dilution of samples in accordance with product DfU)..<p>
RECALLING FIRM/MANUFACTURER
Phadia Ab, Uppsala , Sweden on 11/20/2017. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
2307<p>
DISTRIBUTION
US Distribution to the states of :TX, VA, NJ, MA, IN, GA, UT, TN, CA, MS, NC, ME and OR <p>

4/11/2018 Prismaflex Control Unit Cl II
Company:Baxter Healthcare Corporation
Date of Enforcement Report 4/11/2018
Class II:<p>
PRODUCT
Prismaflex Control Unit. Dialyzer, high permeability with or without sealed dialysate system.Continuous Renal Replacement Therapy (CRRT) for patients weighing 20 kilograms or more with acute renal failure and/or fluid overload.
Recall Number Z-1280-2018<p>
REASON
Firm has received reports of device operators failing to adhere to instructions for use pertaining to the safe unloading of disposable sets from the Prismaflex Control Unit. Additionally, for software versions 5.10 and 6.10, the programmed syringe size for the syringe pump may revert to safe default values unintentionally.<p>
RECALLING FIRM/MANUFACTURER
Baxter Healthcare Corporation, Deerfield, IL on 2/15/2017. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
3,440 units<p>
DISTRIBUTION
Nationwide and Internationally<p>

4/4/2018 Ray Station 4.9, 5, 6, 7 Software Cl II
Company:RAYSEARCH LABORATORIES AB
Date of Enforcement Report 4/4/2018
Class II:<p>
PRODUCT
Ray Station 4.9 Ray Station 5, Ray Station 6 and Ray Station 7 Software build numbers: 4.9.0.42,

5.0.0.37, 5.0.1.11, 5.0.2.35, 6.0.0.24, 6.1.0.26, 6.1.1.2, 6.2.0.7 or 7.0.0.19 UDI: 073500020100682017113O
Recall Number Z-1275-2018<p>
REASON
Software issue with Center Beam in Field functionality. Issue can result in incorrect treatment volume delivered to patient..<p>
RECALLING FIRM/MANUFACTURER
RAYSEARCH LABORATORIES AB, Stockholm, Sweden on 3/29/2018. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
2484<p>
DISTRIBUTION
Nationwide <p>

4/4/2018 Siemens ACUSON SC2000 Cl II
Company:Siemens Medical Solutions USA, Inc.
Date of Enforcement Report 4/4/2018
Class II:<p>
PRODUCT
ACUSON SC2000 Ultrasound System. The firm name on the label is Siemens Medical Solutions USA, Inc., Buffalo Grove, IL.
Recall Number Z-1200-2018<p>
REASON
The ECG signal may flatline due to electromagnetic interference during the use of electrosurgical equipment.<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc., Mountain View, CA on 3/5/2018. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
229 systems<p>
DISTRIBUTION
Nationwide and Internationally<p>

4/4/2018 St. Jude Proclaim DRG Implantable Pulse Gen.
Cl II
Company:St. Jude Medical, Inc..
Date of Enforcement Report 4/4/2018
Class II:<p>
PRODUCT
Proclaim DRG Implantable Pulse Generator, Model Number 3664
Recall Number Z-1170-2018<p>
REASON
The firm received complaints of error messages that occurred during routine impedance checks on Proclaim DRG IPGs, model 3664. Some complaints were also associated with transient over stimulation which created discomfort for the patients.<p>
RECALLING FIRM/MANUFACTURER
St. Jude Medical, Inc., Plano TX on 3/9/2018. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
17<p>
DISTRIBUTION
Nationwide <p>

4/4/2018 Siemens Syngo.via software Cl II
Company:Siemens Medical Solutions USA, Inc
Date of Enforcement Report 4/4/2018
Class II:<p>
PRODUCT
Syngo.via software is intended to be used for viewing, manipulation, communication, and storage of medical images. It can be used as a standalone device or together with a variety of cleared and unmodified syngo based software options.
Recall Number Z-1261-2018<p>
REASON
When the archiving configuration is changed, data received/created after the upgrade may be flagged as "Not to be archived". This is caused by the automatic function for cleaning up temporary data being disabled by the software upgrade. Due to the disabled cleanup function, disc capacity for free space decreases faster than usual. Unless the archiving configuration and the cleanup automatic function are reverted back to the original state (prior to the software upgrade), data that was incorrectly flagged "Not to be archived" must be manually prevented from being deleted by either clinical administrator or service engineer. <p>
Siemens Medical Solutions USA, Inc, Malvern PA.on 1/10/2018. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
165 units<p>
DISTRIBUTION
Medical device software which needs to be installed.<p>

3/28/2018 Medfusion Syringe Pumps Cl II
Company:Smiths Medical ASD Inc..
Date of Enforcement Report 3/28/2018
Class II:<p>
PRODUCT
The Medfusion Syringe Infusion Pumps are indicated for the following uses: 1) Administration of fluids requiring precisely controlled infusion rates including blood or blood products, lipids, drugs, antibiotics, enteral solutions and other therapeutic fluids; 2) By the following delivery routes: arterial, epidural, intravenous, intrathecal, subcutaneous, and enteral; 3)By the following delivery modes: continuous, volume/time, mass, body weight, intermittent, and bolus; 4) In critical care, anesthesia, neonatal, and pediatric applications or other healthcare settings where use of the syringe infusion pump can be monitored or supervised by a clinician; 5) Inside the MRI room mounted outside the 150 Gauss line and with shielded magnets of field strength of 1.5 Tesla
Recall Number Z-1134-2018Z-1135-2018 Z-1136-2018<p>
REASON
Certain Medfusion Syringe Pump Models, Series 3100, 3500, and 4000, may not recognize or may misidentify loaded medication syringes. The inability of a pump to recognize a syringe (i.e. the size of the syringe is unknown to the pump) results in an inability to complete pump programming. Misidentification of a syringe is where the pump misinterprets the syringe size.<p>
RECALLING FIRM/MANUFACTURER
Smiths Medical ASD Inc, Minneapolis, MN..on 11/30/2017. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
16,600 pumps total<p>
DISTRIBUTION
Nationwide and Internationally<p>

3/21/2018 Siemens ACUSON SC2000 Ultrasound System CI II

Company:Siemens Medical Solutions USA, Inc.
Date of Enforcement Report 3/21/2018
Class II:<p>
PRODUCT
ACUSON SC2000 Ultrasound System Product Usage: The SC2000 ultrasound imaging system is intended for the following applications: Cardiac, Neo-natal and Fetal Cardiac, Pediatric, Transespohageal, Adult Cephalic, Peripheral Vessel, Abdominal, Abdominal Intraoperative, Intraoperative Neurological, Musculo-skeletal Conventional, and Musculo-skeletal Superficial applications. The system also provides the ability to measure anatomical structures and calculation packages that provide information to the clinician that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes.
Recall Number Z-0978-2018<p>
REASON
The application may underestimate the EROA (Effective Regurgitant Orifice Area) in comparison to the same patient results obtained with the 4Z1c volume transthoracic echocardiography transducer..<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc., Mountain View, CA on 1/26/2018. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
564 systems<p>
DISTRIBUTION
Nationwide and Internationally<p>

3/21/2018 Philips HeartStart XL+ Defibrillator/Monitor CI II

Company:Philips Electronics North America Corporation
Date of Enforcement Report 3/21/2018
Class II:<p>
PRODUCT
HeartStart XL+ Defibrillator/MonitorThe HeartStart XL+ is intended for use in a hospital setting by qualified medical personnel trained in the operation of the device and qualified by training in basic life support, advanced life support, or defibrillation.
Recall Number Z-0978-2018<p>
REASON
Update XL¿ device software to version A.03. This includes enhancements to the Operational Checks, event logs, and troubleshooting messages that provide as complete of information as needed to users on device readiness.<p>
RECALLING FIRM/MANUFACTURER
Philips Electronics North America Corporation, Andover, MA on 2/7/2018. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
4315<p>
DISTRIBUTION
China<p>

3/14/2018 Medtronic Navigation O-arm Imaging CI II

Company:Medtronic Navigation, Inc.
Date of Enforcement Report 3/14/2018
Class II:<p>
PRODUCT
O-arm 1000 mobile image-intensified fluoroscopic x-ray system; (1) Model: BASE OARM

BI70000028100 SYS 100V, Product Number: BI70000028100 (UDI: 00643169354418); (2) Model: BASE OARM BI70000028120 SYS 120V, Product Number: BI70000028120 (UDI: 00643169353411); (3) Model: BASE OARM BI70000028120R SYS 120V RWK, Product Number: BI70000028120R (UDI: 00643169353459); (4) Model: BASE OARM BI70000028230 SYS 230V, Product Number: BI70000028230 (UDI: 00643169353992); (5) BASE OARM BI70000028230R SYS 230V RWK, Product Number: BI70000028230R (UDI: 00643169354081) Product Usage: The O-arm Imaging System is a mobile x-ray system designed for 2D fluoroscopic and 3D imaging and is intended to be used where a physician benefits from 2D and 3D information of anatomic structures and objects with high x-ray attenuation such as bony anatomy and metallic objects. The O-arm Imaging System is compatible with certain Image Guided Surgery Systems.
Recall Number Z-0928-2018<p>
REASON
Software update ("SW Update 3.2.1") is being implemented to address the following issues: Inability to power the system after shutdown, System stays in standalone mode, Image reconstruction, System/Pendant bootup, Dose display/report, Gantry motion, Network communication, System shutdown, and Early termination of 3D spin..<p>
ECALLING FIRM/MANUFACTURER
AMedtronic Navigation, Inc., Littleton, MA.on 1/25/2018. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
253<p>
DISTRIBUTION
Nationwide and Internationally<p>

3/14/2018 i-STAT DE handheld module, Cl II
Company:Abbott Point Of Care Inc.
Date of Enforcement Report 3/14/2018
Class II:<p>
PRODUCT
i-STAT DE handheld data processing module for clinical use, Software Version 2.8, List Number:08K46-01115200 (UDI: 00054749001255)
Recall Number Z-0946-2018<p>
REASON
Issues resulting from upgrade to software version 2.8: (1) Location, operator, stored patient lists will not update, and (2) Customized Reference Ranges, Action Ranges, and Custom Reportable Ranges are reset to factory default values. No erroneous results are generated as a result of this issue..<p>
RECALLING FIRM/MANUFACTURER
Abbott Point Of Care Inc., Princeton, NJ on 8/12/2017. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
894<p>
DISTRIBUTION
Nationwide and Internationally<p>

3/14/2018 Mindray Anesthesia Delivery Systems, Cl II
Company:Mindray DS USA, Inc. dba Mindray North America
Date of Enforcement Report 3/14/2018
Class II:<p>
PRODUCT
A-Series A3/A5 Anesthesia Delivery System; Model Numbers: 0633F-01000-0X (A3) and 0631F-01000-0X (A5) Product Usage: The A-Series Anesthesia System is a device used to administer to a patient, continuously or intermittently, a general inhalation anesthetic, and to maintain a patient s ventilation. The A-Series is intended for use by licensed clinicians, for patients requiring anesthesia within a health care facility, and can be used for adult, pediatric, and infant populations. Recall Number Z-0846-2018

A-Series A7 Anesthesia Delivery System; Model Number: 0632F-PA0000X (A7) Product Recall Number Z-0847-2018<p>
REASON
A software issue may result in the previous settings being applied instead of the default settings or the unit may skip the startup leak test.<p>
RECALLING FIRM/MANUFACTURER
Mindray DS USA, Inc. dba Mindray North America, Mahwah NJ on 7/14/2017. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
2875<p>
DISTRIBUTION
Nationwide <p>

3/14/2018 Philips Network Firewall, Cl II
Company:Philips Electronics North America Corporation
Date of Enforcement Report 3/14/2018
Class II:<p>
PRODUCT
Philips Network Firewall (Cisco ASA 5506)Product Usage:The Cisco ASA 5506-X provides IPv4 and IPv6 Routing and Network Address Translation (NAT) capabilities. It also provides the following: Port Filtering Stateful Packet Inspection Default Protection Policies These default policies trust all outgoing traffic and do not allow any incoming traffic. (Cisco ASA 5506)Product Usage:The Cisco ASA 5506-X provides IPv4 and IPv6 Routing and Network Address Translation (NAT) capabilities. It also provides the following: Port Filtering Stateful Packet Inspection Default Protection Policies These default policies trust all outgoing traffic and do not allow any incoming traffic.
Recall Number Z-0850-2018<p>
REASON
Firewall installed with Philips IntelliVue Information Center iX or Information Center Classic may have a defective component, which may result in loss of connection to the Information Center iX. The defect involves the clock signal component within the firewall. This component has a high probability of failing in appliances that have been running for greater than 18 months. If the clock signal component were to fail, the firewall will stop functioning, will not boot, and is not recoverable. This failure will result in loss of communication between devices that are separated by the firewall, which may cause the Information Center to reboot.<p>
RECALLING FIRM/MANUFACTURER
Philips Electronics North America Corporation, Andover, MA on 3/2/2018. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
331<p>
DISTRIBUTION
Nationwide and Internationally<p>

3/7/2018 Zoll 731 Series Ventilators , Cl II
Company:ZOLL Medical Corporation
Date of Enforcement Report 3/7/2018
Class II:<p>
PRODUCT
731 Series Ventilators running software version 05.20.00 The devices in the ZOLL ventilator are indicated for use in the management of infant through adult patients weighing ;:: 5 kg with acute or chronic respiratory failure or during resuscitation by providing continuous positive-pressure ventilation.
Recall Number Z-0812-2018<p>
REASON
A software anomaly in the 731 software version 05/20/00, was identified, which can lead to a user

inadvertently changing device settings.<p>
RECALLING FIRM/MANUFACTURER
ZOLL Medical Corporation, Chelmsford, MA on 6/30/2017. Voluntary: Firm Initiated recall is ongoing.
<p>
VOLUME OF PRODUCT IN COMMERCE
46<p>
DISTRIBUTION
Outside US <p>

3/7/2018 Fresenius 2008T, Hemodialysis Delivery Syst,
Cl II
Company:Fresenius Medical Care Renal Therapies Group, LLC
Date of Enforcement Report 3/7/2018
Class II:<p>
PRODUCT
Intellivue iX Information Center Software - All PIIC iX Surveillance stations including: 866023 2008T, Hemodialysis Delivery System Product Indicated for acute and chronic dialysis therapy.
Recall Number Z-0829-2018<p>
REASON
While reviewing documentation for the next software release of the 2008T, an R&D technician identified that setting the UF goal to '0' introduces a discrepancy between the UF rate displayed and the actual UF pump rate. The software anomaly is also applicable to the 2008T Machines that contained the 2.63 Bug Fix per DCAF 17-088. 2008T Upgrade kits that contained the 2.63 Bug Fix are also affected. Additionally, SW version 2.64 (in design freeze) is also impacted by this anomaly.<p>
RECALLING FIRM/MANUFACTURER
Fresenius Medical Care Renal Therapies Group, LLC, Waltham, MA on 10/5/2017. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
15 machines<p>
DISTRIBUTION
Nationwide <p>

3/7/2018 Philips digital x-ray detectorProGrade R1, Cl II
Company:Philips Electronics North America Corporation
Date of Enforcement Report 3/7/2018
Class II:<p>
PRODUCT
digital x-ray detector ProGrade R1 - solid state X ray imager (flat panel/digital imager) As a part of a radiographic system, the Philips ProGrade is intended to acquire, process, store, display, and export digital radiographic images. The Philips ProGrade is suitable for all routine radiographic examinations, including specialist area like intensive care, trauma, or pediatric work, excluding mammography. United States only: The Eleva Workspot is not intended for fluoroscopy and angiography.
Recall Number Z-0704-2018<p>
REASON
It the WiFi connection between the SkyPlate detector and HP transfer point is weak, an image may fail to transfer from the SkyPlate detector to the system. The image remains in the memory of the detector, but cannot be transferred wirelessly or by use of the backup cable. To continue, the operator can reset the SkyPlate detector by removing its batteries, but the acquired image is lost and a re-take is necessary.<p>
RECALLING FIRM/MANUFACTURER
Philips Electronics North America Corporation, Andover, MA on 12/11/2017. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE

157<p>
DISTRIBUTION
Nationwide and Canada<p>

3/7/2018 Philips All PIIC iX Surveillance stations, Cl II
Company:Philips Electronics North America Corporation
Date of Enforcement Report 3/7/2018
Class II:<p>
PRODUCT
Intellivue iX Information Center Software - All PIIC iX Surveillance stations including: 866023 IntelliVue Info Center iX A.0 866117 PIIC Classic Upgrade 866389 IntelliVue Info Center iX B.0, C.0 867141 IntelliVue Info Center iX B.0 866025 IntelliVue Server IX A.0 866118 Database Server Upgrade A.0
Recall Number Z-0776-2018<p>
REASON
Once a surveillance station is restarted on January 1, 2018 or later, the station will be unable to perform patient discharge and transfer operations. Any subsequent attempt to perform these operations will cause the station to restart, resulting in a short period of loss of monitoring at the Surveillance station during such restart. Until this issue can be corrected, users should avoid intentionally restarting their Surveillance stations in 2018.<p>
RECALLING FIRM/MANUFACTURER
Philips Electronics North America Corporation, Andover, MA on 1/3/2018. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
20357<p>
DISTRIBUTION
Nationwide and Internationally<p>

2/28/2018 Protura Software with Eleckta interface Cl II
Company:Med Tec Inc
Date of Enforcement Report 2/28/2018
Class II:<p>
PRODUCT
Protura Software which utilizes Elekta's iCOM interface: MT6XSM1.4.0, MT6XSM1.4.0-1, MT6XSM1.4.0-2, MT6SXM1.4.0-3, MT6XSM1.5.0-2, MT6XSM1.6.0-1, MT6XSM1.7.2, MT6XSM1.7.2-1, MT6XSM1.7.2-3, MT6XSM1.7.3, MT6XSM1.7.3-1, MT6XSM1.7.3-3. The Protura Software is intended to interface between record and verify systems, linear accelerator (Linac) software systems, and/or image guidance systems and the Protura Couch..
Recall Number Z- 0671-2018 <p>
REASON
When an error message remains displayed and is not cleared in the Protura software with the Elekta pedestal coordinates, moving the pedestal could cause the Protura software to not update with the pedestal location and buffers the pedestal movement history.<p>
RECALLING FIRM/MANUFACTURER
Med Tec Inc., Orange City, IA on 11/8/2017. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
5 installations<p>
DISTRIBUTION
US Distribution to Iowa and South Dakota. Shipped internationally to the Netherlands. <p>

2/28/2018 Fuji Computed Radiography Mammography Suite CI II
Company:Fujifilm Medical Systems U.S.A., Inc.
Date of Enforcement Report 2/28/2018
Class II:<p>
PRODUCT
Fuji Computed Radiography Mammography Suite, FCRMS (for CR-IR363AWS) The Fuji Computed Radiography Mammography Suite (FCRMS) is a software device that, in conjunction with a specified Fuji Computed Radiography system forms the Fuji Computed Radiography for mammography (FCRm) device. FCRm with a dedicated mammographic x-ray machine generates digital mammographic images that can be used for screening and diagnosis of breast cancer.
Recall Number Z- 0662-2018 <p>
REASON
FUJIFILM Medical Systems U.S.A., Inc. (FMSU) identified a potential failure with our Mammography system. The acquisition workstations, FDR¿1000AWS, FDR-2000AWS, FDR-3000AWS, and CR¿IR363AWS assign a unique ID number to every image study but very rarely, with the acquisition workstation software versions, VS.O, VS.1, VS.2 , V6.0, V6.1, and V7.0, the system may assign the same ID number to a new set of images that was already assigned to the previous set of images due to the error in ID number generation logic. If an Image with this error (with duplicate ID number) Is transmitted to PACS, it may overwrite the image already stored on PACS. <p>
RECALLING FIRM/MANUFACTURER
Fujifilm Medical Systems U.S.A., Inc., Stamford, CT on 8/4/2017. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
71 units total<p>
DISTRIBUTION
Worldwide <p>

2/28/2018 Fujifilm Medical Aspire Systems CI II
Company:Fujifilm Medical Systems U.S.A., Inc.
Date of Enforcement Report 2/28/2018
Class II:<p>
PRODUCT
Aspire HD Plus, Aspire HD-s (for FDR-2000AWS) The Fujifilm Digital Mammography Systems, Aspire HD Plus (FDR MS-2500) and Aspire ND-s (FDR MS-2000), generate full-field digital mammography images that can, as other full-field digital mammography systems, be used for screening and diagnosis of breast cancer and are intended for use in the same clinical applications as traditional screen-film mammography systems.
Recall Number Z- 0669-2018 , Z-0660-2018, Z-0661-2018<p>
REASON
FUJIFILM Medical Systems U.S.A., Inc. (FMSU) identified a potential failure with our Mammography system. The acquisition workstations, FDR¿1000AWS, FDR-2000AWS, FDR-3000AWS, and CR¿IR363AWS assign a unique ID number to every image study but very rarely, with the acquisition workstation software versions, VS.O, VS.1, VS.2 , V6.0, V6.1, and V7.0, the system may assign the same ID number to a new set of images that was already assigned to the previous set of images due to the error in ID number generation logic. If an Image with this error (with duplicate ID number) Is transmitted to PACS, it may overwrite the image already stored on PACS. <p>
RECALLING FIRM/MANUFACTURER
Fujifilm Medical Systems U.S.A., Inc., Stamford, CT on 8/4/2017. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
71 units total<p>
DISTRIBUTION

Worldwide <p>

2/28/2018 Roche Cobas 8000 Modular Series, Cl II
Company: Roche Diagnostics Corporation
Date of Enforcement Report 2/28/2018
Class II:<p>
PRODUCT
Cobas 8000 Modular Series system; Software Version 05-02 and 06-03; UDI: 05641446001
Recall Number Z-0675-2018<p>
REASON
A software failure may incorrectly set the system settings to "default" settings, creating a risk of incorrect results.<p>
RECALLING FIRM/MANUFACTURER
Roche Diagnostics Corporation, Indianapolis, IN on 4/28/2017. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
399<p>
DISTRIBUTION
Nationwide and Puerto Rico<p>

2/28/2018 ROSA Spine 1.0.2 Cl II
Company:Zimmer Biomet, Inc.
Date of Enforcement Report 2/28/2018
Class II:<p>
PRODUCT
ROSA Spine 1.0.2 Stereotaxic instrument Computer-assisted surgical device. Intended for the spatial positioning and orientation of instrument holders to be used by neurosurgeons.
Recall Number Z- 0638-2018 <p>
REASON
Robot arm being sent to the wrong position-2018<p>
RECALLING FIRM/MANUFACTURER
Zimmer Biomet, Inc.Warsaw, IN on 5/1/2017. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
16<p>
DISTRIBUTION
Nationwide <p>

2/28/2018 ROSA Brain 3.0 Cl II
Company:Zimmer Biomet, Inc.
Date of Enforcement Report 2/28/2018
Class II:<p>
PRODUCT
ROSA Brain 3.0 Stereotaxic instrument Computer-assisted surgical device. Intended for the spatial positioning and orientation of instrument holders to be used by neurosurgeons.
Recall Number Z- 0637-2018 <p>
REASON
Robot arm being sent to the wrong position-2018<p>
RECALLING FIRM/MANUFACTURER
Zimmer Biomet, Inc.Warsaw, IN on 5/1/2017. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
16<p>
DISTRIBUTION
Nationwide <p>

2/28/2018 OCULUS Pentacam AXL, Model 70100, software Cl II

Company:Oculus Optikgeraete GMBH
Date of Enforcement Report 2/28/2018
Class II:<p>
PRODUCT
OCULUS Pentacam AXL, Model 70100, software versions 1.21r01, 1.21r03, 1.21r11, and 1.21r13. The firm name on the label is OCULUS Optikgerate GmbH, Made in Germany. The Pentacam AXL is designed to take photos of the anterior segment of the eye
Recall Number Z-0635-2018<p>
REASON
The device software versions have an anomaly which may produce an erroneous marking for the quality specification value<p>
RECALLING FIRM/MANUFACTURER
Oculus Optikgeraete GMBH, Wetzler, Germany on 11/21/2017. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
83 devices<p>
DISTRIBUTION
US Distribution to the states of : CA and FL. There were no foreign/military/government accounts. <p>

2/21/2018 Philips Ingenuity TF PET/CT Cl II

Company:Philips Medical Systems (Cleveland) Inc
Date of Enforcement Report 2/21/2018
Class II:<p>
PRODUCT
Ingenuity TF PET/CT (model 882442) running software version 4.0.2This device is a diagnostic imaging system that combines Positron Emission Tomography (PET) and X-ray Computed Tomography (CT) systems. The CT subsystem produces cross-sectional images of the body by computer reconstruction of x-ray transmission data.
Recall Number Z-0562-2018<p>
REASON
A software issue causes PET reconstructions to fail intermittently. It was determined that reconstructions fail due to a negative table position (-1 value is inserted) in the raw data list file, rather than the actual table position. This error has been found to occur in two scenarios: 1) When the system operator cancels an acquisition a. The error will occur every time a scan is cancelled by the operator. 2) Couch position requests within the software sequence were delayed a. The error occurs intermittently, but has been found to occur more frequently when the gantry s network is heavily loaded with multiple retrospective reconstructions running in parallel. b. The error manifests to the technologist by an error message and Failed status on the Reconstruction Monitor and the error message Result {0} failed to reconstruct" on the Acquisition Workflow window during reconstruction after the patient scan has been completed. In both scenarios, the acquisition data will not be able to be reconstructed and will therefore be unusable<p>
RECALLING FIRM/MANUFACTURER
Philips Medical Systems (Cleveland) Inc, Cleveland, OH on 12/11/2017. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
24<p>
DISTRIBUTION
Worldwide Distribution - US Distribution to the states of : CA, OH, IL, PA and NY. <p>

2/21/2018 Accu-Chek Connect Diabetes Management App, Cl II
Company:Roche Diabetes Care, Inc.
Date of Enforcement Report 2/21/2018
Class II:<p>
PRODUCT
Accu-Chek Connect Diabetes Management App, Catalog number 07562462001 / GTIN number 00365702700000 & Catalog number 07250452001 / GTIN number 00365702700017
Recall Number Z-0625-2018<p>
REASON
Certain iOS and Android App versions contain a program error (bug) in the Bolus Advisor feature. Due to a software bug, when the OS region of the phone setting is changed, the unit of measure within the app may unexpectedly change. This creates a risk the app might not transfer the blood glucose result or the user might not correctly input numerical values for carbohydrate used for bolus advice. .<p>
RECALLING FIRM/MANUFACTURER
Roche Diabetes Care, Inc., Indianapolis, IN on 6/8/2017. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
67,040 unique users of version 2.1.0<p>
DISTRIBUTION
Nationwide<p>

2/14/2018 Spacelabs Healthcare Xhibit Telemetry Receiv Cl II
Company:Spacelabs Healthcare
Date of Enforcement Report 2/14/2018
Class II:<p>
PRODUCT
Spacelabs Healthcare Xhibit Telemetry Receiver, Model 96280, software version 1.1,
Recall Number Z-0532-2018<p>
REASON
Spacelabs has received multiple complaints reporting telemetry beds dropping off the Spacelabs Central Station resulting in a loss of monitoring.<p>
RECALLING FIRM/MANUFACTURER
Spacelabs Healthcare Inc., Snoqualmie, WA on 1/17/2018. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
12 devices<p>
DISTRIBUTION
US Distribution to the states of : VA, NJ, MI, GA, and Internationally to F <p>

2/14/2018 Philips Ingenuity CT xray system Cl II
Company:Philips Medical Systems (Cleveland) Inc
Date of Enforcement Report 2/14/2018
Class II:<p>
PRODUCT
Philips Ingenuity CT computed tomography x-ray system
Recall Number Z-0521-2018<p>
REASON
Numerous issues related to software Brilliance iCT 4.1.6 software version.<p>
RECALLING FIRM/MANUFACTURER
Philips Medical Systems (Cleveland) Inc, Cleveland, OH on 10/6/2017. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE

<p>
DISTRIBUTION
26 US Govt accounts <p>

2/14/2018 Philips Ingenuity Core 128 CT xray system Cl II

Company:Philips Medical Systems (Cleveland) Inc
Date of Enforcement Report 2/14/2018
Class II:<p>
PRODUCT
Philips Ingenuity Core 128 computed tomography x-ray system
Recall Number Z-0520-2018<p>
REASON
Numerous issues related to software Brilliance iCT 4.1.6 software version.<p>
RECALLING FIRM/MANUFACTURER
Philips Medical Systems (Cleveland) Inc, Cleveland, OH on 10/6/2017. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
<p>
DISTRIBUTION
26 US Govt accounts <p>

2/14/2018 Philips Ingenuity Core CT xray, Cl II

Company:Philips Medical Systems (Cleveland) Inc
Date of Enforcement Report 2/14/2018
Class II:<p>
PRODUCT
Philips Ingenuity Core computed tomography x-ray system
Recall Number Z-0519-2018<p>
REASON
Numerous issues related to software Brilliance iCT 4.1.6 software version.<p>
RECALLING FIRM/MANUFACTURER
Philips Medical Systems (Cleveland) Inc, Cleveland, OH on 10/6/2017. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
<p>
DISTRIBUTION
26 US Govt accounts <p>

2/14/2018 Philips Brilliance 64 Ct xray system Cl II

Company:Philips Medical Systems (Cleveland) Inc
Date of Enforcement Report 2/14/2018
Class II:<p>
PRODUCT
Philips Brilliance 64 computed tomography x-ray system
Recall Number Z-0518-2018<p>
REASON
Numerous issues related to software Brilliance iCT 4.1.6 software version.<p>
RECALLING FIRM/MANUFACTURER
Philips Medical Systems (Cleveland) Inc, Cleveland, OH on 10/6/2017. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
<p>

DISTRIBUTION
26 US Govt accounts <p>

2/14/2018 Syngo.plaza systems with SW VB20A, Cl II
Company:Siemens Medical Solutions USA, Inc.
Date of Enforcement Report 2/14/2018
Class II:<p>
PRODUCT
Syngo.plaza systems with SW VB20A, Model Number - 10863171, 10863172, 10863173Product Usage:Syngo.plaza is a Picture Archiving and Communication System (PACS) intended to display, process, read, report, communicate, distribute, store and archive digital medical images. It supports the physician in diagnosis and treatment planning.
Recall Number Z-0524-2018 <p>
REASON
When a prior study is being replaced in the workflow step, in certain scenarios (based on the Display Protocol configuration) the prior study will only be replaced in the active Workflow Step and not show in all other workflow steps. The other workflow steps will continue to show the initially loaded study. .<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc., Malvern, PA on 8/23/2017. Voluntary firm initiated recall is ongoing
VOLUME OF PRODUCT IN COMMERCE
76<p>
DISTRIBUTION
Nationwide <p>

2/7/2018 Syngo.plaza PACS, Cl II
Company:Siemens Medical Solutions USA, Inc.
Date of Enforcement Report 2/7/2018
Class II:<p>
PRODUCT
Syngo.plaza Picture Archiving and Communication System (PACS) with software version VB20A; Model numbers: 10863171, 10863172, 10863173Syngo.plaza is a Picture Archiving and Communication System (PACS) software device intended to display, process, read, report, communicate, distribute, store and archive digital medical images. It supports the physician in diagnosis and treatment planning.
Recall Number Z-0495-2018 <p>
REASON
Software update to correct several issues that include (1)Potential data loss, (2) Study mix-up, (3) Incorrect measurements on multi-frame images, (4) Dearchiving issue, and (5) Unauthorized access of data due to inadequate permissions for shared folders.<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc., Malvern, PA on 8/18/2017. Voluntary firm initiated recall is ongoing
VOLUME OF PRODUCT IN COMMERCE
47<p>
DISTRIBUTION
Nationwide <p>

2/7/2018 GE HEALTHCARE CARESCAPE software, Cl II
Company:GE Medical Systems Information Technologies, Inc.
Date of Enforcement Report 27/2018
Class II:<p>
PRODUCT
GE HEALTHCARE CARESCAPE Central Station (CSCS) software version 2.0.2The CARESCAPE

Central Station is intended to collect information from a network and display this data. This data includes physiological, patient demographic and/or other non-medical information
Recall Number Z-0487-2018 <p>
REASON
CARESCAPE Central Station (CSCS) software version 2.0.2 units may experience unexpected NO COMM (No Communication) and network communication issues after boot-up or system restart.<p>
RECALLING FIRM/MANUFACTURER
GE Medical Systems Information Technologies, Inc., Milwaukee, WI on 1/11/2018. Voluntary firm initiated recall is ongoing
VOLUME OF PRODUCT IN COMMERCE
1803 units<p>
DISTRIBUTION
Nationwide and Internationally<p>

2/7/2018 Metrotom 800 (130kV CT scanner) Industrial C
Cl II
Company:Carl Zeiss Metrology Inc
Date of Enforcement Report 2/7/2018
Class II:<p>
PRODUCT
Metrotom 800 (130kV CT scanner) Industrial CT scanner for measuring and inspecting complete components made of plastic or light metal.
Recall Number Z-0379-2018 <p>
REASON
Due to a software error, it was observed that when the user closes the access door, the system will resume its scan cycle automatically, instead of the user initiating x-ray generation from the control panel..<p>
RECALLING FIRM/MANUFACTURER
Carl Zeiss Metrology Inc., Maple Grove, MN on 11/14/2017. Voluntary firm initiated recall is ongoing
VOLUME OF PRODUCT IN COMMERCE
13 US<p>
DISTRIBUTION
Nationwide and Canada<p>

2/7/2018 Roche / Hitachi MODULAR Analyzer Systems,
Cl II
Company:Roche Diagnostics Corporation
Date of Enforcement Report 2/7/2018
Class II:<p>
PRODUCT
Roche / Hitachi MODULAR Analyzer Systems-Immunoassay Analyzer-Model/Catalog/Part Number: 11568248001/11568248692 - Elecsys 2010 analyzer (disk system) and 11804014001/11804014692 - Elecsys 2010 analyzer (rack system) Medical Device Listing number: D053244 - Elecsys 2010 Elecsys analyzer is a fully automated, random access, computer controlled analytical systems for quantitative and qualitative determinations of analytes in body fluids.
Recall Number Z-04992018 <p>
REASON
A software malfunction can occur on the cobas e 411 and Elecsys 2010 analyzers in the Sample& Control data file which may lead to a potential data mismatch.<p>
RECALLING FIRM/MANUFACTURER
Roche Diagnostics Corporation, Indianapolis, IN on 7/5/2017. Voluntary firm initiated recall is ongoing
VOLUME OF PRODUCT IN COMMERCE
255 instruments<p>

DISTRIBUTION
Nationwide <p>

2/7/2018 Roche cobas e 411 Immunoassay Analyze, Cl II

Company:Roche Diagnostics Corporation
Date of Enforcement Report 2/7/2018
Class II:<p>
PRODUCT
cobas e 411 Immunoassay Analyzer-Model/Catalog/Part number: 04775279001/04775279973 - cobas e 411 analyzer (disk system) and 04775201001/04775201973 - cobas e 411 analyzer (rack system), medial device listing number: E116019 cobas e 411 Elecsys analyzer is a fully automated, random access, computer controlled analytical systems for quantitative and qualitative determinations of analytes in body fluids.
Recall Number Z-0498-2018 <p>
REASON
A software malfunction can occur on the cobas e 411 and Elecsys 2010 analyzers in the Sample& Control data file which may lead to a potential data mismatch.<p>
RECALLING FIRM/MANUFACTURER
Roche Diagnostics Corporation, Indianapolis, IN on 7/5/2017. Voluntary firm initiated recall is ongoing
VOLUME OF PRODUCT IN COMMERCE
923 instruments<p>
DISTRIBUTION
Nationwide <p>

2/7/2018 Edwards Hemosphere System, Cl II

Company:Edwards Lifesciences, LLC
Date of Enforcement Report 27/2018
Class II:<p>
PRODUCT
Hemosphere System with the following three components: HEM1 Advanced Monitor, HEMSGM10 (Swan-Ganz Module), and HEMOXSC100 (Oximetry Smart Cable). Product Usage: The HemoSphere Advanced Monitor (HEM1) is intended to be used in combination with a compatible Edwards hemodynamic monitoring technology module and/or cable and accompanying Edwards accessories and/or disposables.
Recall Number Z-0496-2018 <p>
REASON
Pre-procedural issues related to software defects.<p>
RECALLING FIRM/MANUFACTURER
Edwards Lifesciences, LLC, Irvine, CA on 10/2/2017. Voluntary firm initiated recall is ongoing
VOLUME OF PRODUCT IN COMMERCE
198 devices<p>
DISTRIBUTION
Nationwide <p>

1/31/2018 Brilliance iCT - Model 728306, Cl II

Company:Philips Medical Systems (Cleveland) Inc
Date of Enforcement Report 1/31/2018
Class II:<p>
PRODUCT
Brilliance iCT - Model 728306 Computed Tomography X-ray systems
Recall Number Z-0403-2018 <p>
REASON

Numerous software issues with Brilliance iCT 4.1.6 version. Issues affect scan start position, data acquisition, exam stop, tube overheat, memory overflow, failure to give error message, length of acquisition, image volume and other functions.<p>
RECALLING FIRM/MANUFACTURER
Philips Medical Systems (Cleveland) Inc., cleveland, OH on 7/11/2017. Voluntary firm initiated recall is ongoing
VOLUME OF PRODUCT IN COMMERCE
559 total<p>
DISTRIBUTION
Nationwide and Internationally<p>

1/31/2018 Siemens Syngo Imaging version V31 , Cl II
Company:Siemens Medical Solutions USA, Inc.
Date of Enforcement Report 1/31/2018
Class II:<p>
PRODUCT
Syngo Imaging version V31 (model # 10014063) is a Picture Archiving and Communication System (PACS) intended to display, process, read, report, communicate, distribute, store and archive digital medical images, including digital mammography images. It supports the physician in diagnosis and treatment planning.
Recall Number Z-0405-2018 <p>
REASON
Siemens is releasing a letter to inform about potential data loss relevant to diagnosis.<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc., Malvern, PA on 7/25/2017. Voluntary firm initiated recall is ongoing
VOLUME OF PRODUCT IN COMMERCE
36<p>
DISTRIBUTION
Nationwide <p>

1/31/2018 Brilliance iCT SP systems, Cl II
Company:Philips Medical Systems (Cleveland) Inc
Date of Enforcement Report 1/31/2018
Class II:<p>
PRODUCT
Brilliance iCT SP - Model 728311 Brilliance iCT - Model 728306 Computed Tomography X-ray systems
Recall Number Z-0402-2018 <p>
REASON
Numerous software issues with Brilliance iCT 4.1.6 version. Issues affect scan start position, data acquisition, exam stop, tube overheat, memory overflow, failure to give error message, length of acquisition, image volume and other functions.<p>
RECALLING FIRM/MANUFACTURER
Philips Medical Systems (Cleveland) Inc., cleveland, OH on 7/11/2017. Voluntary firm initiated recall is ongoing
VOLUME OF PRODUCT IN COMMERCE
559 total<p>
DISTRIBUTION
Nationwide and Internationally<p>

1/31/2018 MyCareLink Smart Patient Monitors, Cl II
Company:Medtronic Inc., Cardiac Rhythm and Heart Failure
Date of Enforcement Report 1/31/2018
Class II:<p>
PRODUCT
MyCareLink Smart Patient Monitors. It is intended for use with a compatible Medtronic patient implanted heart device. The reader is a portable electronic device that communicates with an implanted heart device
Recall Number Z-0400-2018 <p>
REASON
Patients monitored on two (2) or more implanted Medtronic heart devices in the Medtronic CareLink Network may have potential impact on the ability to remotely monitor the patient's heart devices. Potential impacts could lead to missed CareAlert notifications or device reports.<p>
RECALLING FIRM/MANUFACTURER
Medtronic Inc., Cardiac Rhythm and Heart Failure, Mountain View, MN on 7/14/2017. Voluntary firm initiated recall is ongoing
VOLUME OF PRODUCT IN COMMERCE
1,519,984 enrollments total<p>
DISTRIBUTION
Nationwide and Internationally<p>

1/31/2018 MyCareLink Patient Monitors, Cl II
Company:Medtronic Inc., Cardiac Rhythm and Heart Failure
Date of Enforcement Report 1/31/2018
Class II:<p>
PRODUCT
MyCareLink Patient Monitors. It is intended for used with a compatible Medtronic patient implanted heart device. The monitor is an external electronic device that interfaces with Medtronic implanted heart devices and a telecommunications connection to transmit stored implanted heart device data to the physician or clinician.
Recall Number Z-0399-2018 <p>
REASON
Patients monitored on two (2) or more implanted Medtronic heart devices in the Medtronic CareLink Network may have potential impact on the ability to remotely monitor the patient's heart devices. Potential impacts could lead to missed CareAlert notifications or device reports.<p>
RECALLING FIRM/MANUFACTURER
Medtronic Inc., Cardiac Rhythm and Heart Failure, Mountain View, MN on 7/14/2017. Voluntary firm initiated recall is ongoing
VOLUME OF PRODUCT IN COMMERCE
1,519,984 enrollments total<p>
DISTRIBUTION
Nationwide and Internationally<p>

1/24/2018 RayStation Product Usage, Cl II
Company:RAYSEARCH LABORATORIES AB
.
Date of Enforcement Report 1/24/2018
Class II:<p>
PRODUCT
RayStation Product Usage: is a software system designed for treatment planning and analysis of radiation therapy. The treatment plans provide treatment unit set-up parameters and estimates of dose distributions expected during the proposed treatment, and may be used to administer treatments after review and approval by the intended user..

Recall Number Z-0380-2018 <p>
REASON
For the proton QA preparation module in RayStation 6 (including SP1 and SP2), if the snout position or gap is modified in the QA module, the dose in the QA module may be computed for a different setup than what is used for QA measurements. This could result in an incorrect dosage being provided to a patient. <p>
RECALLING FIRM/MANUFACTURER
RAYSEARCH LABORATORIES AB, Stockholm, Sweden. on 7/17/2017. Voluntary firm initiated recall is ongoing
VOLUME OF PRODUCT IN COMMERCE
117 units<p>
DISTRIBUTION
Nationwide<p>

1/24/2018 Cobas c 6000 MODULAR Series System, Cl II
Company:Roche Diagnostics Corporation
Date of Enforcement Report 1/24/2018
Class II:<p>
PRODUCT
cobas c 6000 MODULAR Series System e 601 ¿ cobas c 8000 MODULAR Series System - e 602 ¿ Roche / Hitachi MODULAR Analytics Combination System Model/Catalog/Part Number: MODULAR Analytics E 170 ¿ 03022109001 ¿ 03023109973 ¿ 03739040001 ¿ 03739040692 ¿ 05023572001 ¿ 05023599001 cobas e 601 module ¿ 04745922001 ¿ 04745922692 ¿ 05036348001 ¿ 05036348692 ¿ 05860652001 cobas e 602 module ¿ 05990378001 The Roche/Hitachi MODULAR Analytics System (E170) is a fully automated, random-access, software- controlled system for immunoassay and photometric analysis intended for qualitative and quantitative in vitro determinations using a wide variety of tests.
Recall Number Z-0378-2018 <p>
REASON
Roche has confirmed that a possible sample mismatch issue may occur on the MODULAR ANALYTICS E 170 module, cobas e 601 analyzer, or cobas e 602 analyzer due to a software limitation.<p>
RECALLING FIRM/MANUFACTURER
Roche Diagnostics Corporation, Indianapolis IN on 6/19/2017. Voluntary firm initiated recall is ongoing
VOLUME OF PRODUCT IN COMMERCE
2517<p>
DISTRIBUTION
Nationwide<p>

1/24/2018 Phadia 1000 Instrument,, Cl II
Company:Phadia US Inc.
Date of Enforcement Report 1/24/2018
Class II:<p>
PRODUCT
Phadia 1000 Instrument, Article Number 12-3800-01..
Recall Number Z-0387-2018 <p>
REASON
The "Retry" command does not function properly which could cause a shortage of Wash and Rinse solution and affect assay performance and test results<p>
RECALLING FIRM/MANUFACTURER
Phadia US Inc, Portage, MI. on 7/5/2017. Voluntary firm initiated recall is ongoing
VOLUME OF PRODUCT IN COMMERCE
70<p>

DISTRIBUTION
Nationwide<p>

1/17/2018 Orthoscan Mobile Mini C-arm system, Cl II
Company:OrthoScan Inc
Date of Enforcement Report 1/17/2018
Class II:<p>
PRODUCT
Mobile Mini C-arm system Part # 1000-0001. Intended to provide the physician with general fluoroscopic visualization of the patient, including, but not limited to, surgical orthopedic procedures and critical and emergency care procedures..
Recall Number Z-0258-2018 to Z-0261-2018<p>
REASON
OrthoScan Inc. discovered during investigation of a non-standard work flow a non-conformity of the devices. Specifically, the system software allows a user to activate the Digital Zoom feature in the course of taking a live image exposing a larger x-ray field than can be viewed by the user.<p>
RECALLING FIRM/MANUFACTURER
OrthoScan Inc., Scottsdale, AZ on 8/31/2017. Voluntary firm initiated recall is ongoing
VOLUME OF PRODUCT IN COMMERCE
2012 total<p>
DISTRIBUTION
Nationwide and Internationally<p>

12/27/2017 Xper Flex Cardio Physiomonitoring system, Cl II
Company:Invivo Corporation
Date of Enforcement Report 12/27/2017
Class II:<p>
PRODUCT
Xper Flex Cardio Physiomonitoring system. Used to facilitate invasive investigations of heart and vascular disease when non-invasive indicators warrant such..
Recall Number Z-0263-2018<p>
REASON
Beckman Coulter has identified that due to a software nonconformity in connection with a changed service setting Remisol could display wrong results.<p>
RECALLING FIRM/MANUFACTURER
Invivo Corporation, Orlanda, FL on 8/182017. Voluntary firm initiated recall is ongoing
VOLUME OF PRODUCT IN COMMERCE
4,535<p>
DISTRIBUTION
Nationwide and Internationally<p>

12/20/2017 Radiometer ABL800 analyzer with FLEXQ module Cl II
Company:Radiometer America
Date of Enforcement Report 12/20/2017
Class II:<p>
PRODUCT
ABL800 analyzer with FLEXQ module.Device intended for in vitro testing of samples of whole blood for the parameters pCO2, cK+, cNa+, cCa2+, cCl , cGlu, cLac, cCrea, ctBil, and co-oximetry parameters (ctHb, sO2, and the hemoglobin fractions FO2Hb, FCOHb, FMetHb, FHHb and FHbF) - in vitro testing of samples
Recall Number Z-0231-2018<p>

REASON
Due to misinterpretation of the barcode by the scanner, when the registration receipt barcode is scanned by the analyzer , a result from a different patient will be printed or displayed on the analyzer.<p>
RECALLING FIRM/MANUFACTURER
Radiometer America, Brea, CA on 10/24/2017. Voluntary firm initiated recall is ongoing
VOLUME OF PRODUCT IN COMMERCE
1,749 analyze<p>
DISTRIBUTION
Nationwide and Canada<p>

12/20/2017 Remisol Advance Software, Cl II
Company:Normand Informatique
Date of Enforcement Report 12/20/2017
Class II:<p>
PRODUCT
Remisol Advance Software (Driver Architect) Catalog Number B32129 The Remisol Advance Data Manager (Stand alone Data Management Systems) collects and manages data and manages workflows for connected systems. (i.e. Beckman Coulter Instruments, Automations, LIS &). It provides data analysis capabilities such as automatic results validation, delta checking, reflex testing, quality control, results editing and data management (i.e. archiving and restoration of patient results). The Remisol Advance system also offers workstation consolidation to three Beckman Coulter instruments from a single user console.
Recall Number Z-0235-2018<p>
REASON
Beckman Coulter has identified that due to a software nonconformity in connection with a changed service setting Remisol could display wrong results.<p>
RECALLING FIRM/MANUFACTURER
Normand Informatique, France on 10/162017. Voluntary firm initiated recall is ongoing
VOLUME OF PRODUCT IN COMMERCE
34<p>
DISTRIBUTION
Nationwide and Internationally<p>

12/20/2017 enGen Track System, Cl II
Company:Ortho-Clinical Diagnostics
Date of Enforcement Report 12/20/2017
Class II:<p>
PRODUCT
enGen Track System with TCAutomation Software Version 4.2
Recall Number Z-0254-2018<p>
REASON
A software anomaly with TCA Software V4.2 may potentially cause a delay in reporting of results due to patient samples being routed to an unintended location when samples are reintroduced back onto the enGEN track<p>
RECALLING FIRM/MANUFACTURER
Ortho-Clinical Diagnostics, Rochester, NY on 4/26/2017. Voluntary firm initiated recall is ongoing
VOLUME OF PRODUCT IN COMMERCE
16<p>
DISTRIBUTION
GA, IL, MO, NC & NY and Internationally<p>

12/13/2017 ICU Mednet(TM) Medication Management Suites, Cl II
Company:ICU Medical Inc
Date of Enforcement Report 12/13/2017
Class II:<p>
PRODUCT
ICU Mednet(TM) Medication Management Suite 6.1 and 6.21, Product Code/List Numbers:(a) 16037-64-01; MedNet 6.1b) 16037-64-02; MedNet 6.1c) 16037-64-03; MedNet 6.1d) 16037-64-04; MedNet 6.21The ICU Medical MedNet Medication Management Suite (MMS) is intended to facilitate networked communication between MMS compatible computer systems and MedNet compatible infusion pumps.
Recall Number Z-0195-2018<p>
REASON
Issue 1: The MedNet Meds 6.1 and 6.21 programs, under certain conditions, can change the piggyback medication entry set settings for existing defined medication entries. <p>
RECALLING FIRM/MANUFACTURER
ICU Medical Inc, Lake Forest, IL on 10/30/2017. Voluntary firm initiated recall is ongoing
VOLUME OF PRODUCT IN COMMERCE
108 installations<p>
DISTRIBUTION
Nationwide and Internationally<p>

12/13/2017 CARESCAPE Patient Data Module , Cl II
Company:GE Medical Systems Information Technologies, Inc.
Date of Enforcement Report 12/13/2017
Class II:<p>
PRODUCT
CARESCAPE Patient Data Module (PDM) v2.6 software used with CARESCAPE Monitors B850, B650, and B450 v2.0.7 or earlier softwareThe PDM is intended to provide uninterrupted acquisition of physiologic parameter data on adult, pediatric and neonatal patients during non-transport/bedside and transport patient care episodes.
Recall Number Z-0202-2018<p>
REASON
Device does not produce a visual or audible impedance respiration APN alarm when an impedance respiration apnea event occurs.<p>
RECALLING FIRM/MANUFACTURER
GE Medical Systems Information Technologies, Inc., Milwaukee, WI on 7/132017. Voluntary firm initiated recall is ongoing
VOLUME OF PRODUCT IN COMMERCE
1,196 (1,176 US; 20 OUS)<p>
DISTRIBUTION
US including NY, WI; Foreign: Australia, France, Germany.<p>

12/13/2017 Accu-Chek Connect App, Cl II
Company:Roche Diabetes Care, Inc.
Date of Enforcement Report 12/13/2017
Class II:<p>
PRODUCT
Accu-Chek Connect diabetes management software app, Catalog number 07562462001 / GTIN number 00365702700000, Catalog number 07250452001 / GTIN number 00365702700017 The Accu-Chek Connect Diabetes Management App is indicated as an aid in the treatment of diabetes. The software provides for electronic download of blood glucose meters, manual data entry, storage, display, transfer, and self-managing of blood glucose and other related health indicators which can be shown in

report and graphical format. The Accu-Chek Bolus Advisor, as a component of the Accu-Chek Connect Diabetes Management App, is indicated for the management of diabetes by calculating an insulin dose or carbohydrate intake based on user-entered data
Recall Number Z-0197-2018<p>
REASON
Certain iOS and Android App versions contain a program error (bug) in the Bolus Advisor feature. After pairing a meter with the app for the first time, a customer may encounter the rare condition in which the countdown timer is not displayed and correction bolus advice is not available for the most recent, valid glucose reading. This same blood glucose value may become available for bolus advice calculation at a later time (countdown timer is displayed).<p>
RECALLING FIRM/MANUFACTURER
Roche Diabetes Care, Inc. Indianapolis, IN on 6/8/2017. Voluntary firm initiated recall is ongoing
VOLUME OF PRODUCT IN COMMERCE
1,134 bolus advisor features used<p>
DISTRIBUTION
Nationwide and Canada<p>

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12/6/2017 Volcano Imaging Systems, Cl II
Company:Volcano Corp.
Date of Enforcement Report 12/6/2017
Class II:<p>
PRODUCT
Volcano Imaging System s5i REF 807400001; CORE Mobile Imaging System (120V) REF 400-0100.01; CORE Mobile Imaging System Refurbished REF 400-0100.01-R; CORE Mobile Imaging System (240V) REF 400-0100.07; CORE Mobile Imaging System Refurbished REF 400-0100.07-R; CORE Mobile Imaging System (100V) REF 400-0100.08; CORE Mobile Imaging System Refurbished REF 400-0100.08-R; CORE Imaging System REF 400-0100.02 For intravascular ultrasound imaging.
Recall Number Z-0189-2018<p>
REASON
On certain Impacted Systems, an unexpected Microsoft Windows Security dialog may appear during use, and the users response to the dialog may adversely affect the subsequent operation of the device.<p>
RECALLING FIRM/MANUFACTURER
Volcano Corp., Rancho Cordova, CA on 11/3/2017. Voluntary firm initiated recall is ongoing
VOLUME OF PRODUCT IN COMMERCE
1166 Units<p>
DISTRIBUTION
Nationwide and Internationally<p>

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12/6/2017 BRAINLAB EXACTRAC VERO, Cl II
Company:BRAINLAB AG
Date of Enforcement Report 12/6/2017
Class II:<p>
PRODUCT
BRAINLAB EXACTRAC VERO, Model/Catalog Numbers: 46228 EXACTRAC VERO 3.5 46238 EXACTRAC VERO 3.5 46216 EXACTRAC VERO SW UPDATE 3.5.2 TO 3.5.3 46218 EXACTRAC VERO SW UPDATE 3.5.3 TO 3.5.4 The ExacTrac Vero system is intended to be used in conjunction with the MHI-TM2000 Radiation Therapy Linear Accelerator System manufactured by Mitsubishi Heavy Industries, Ltd.
Recall Number Z-0172-2018<p>
REASON
Brainlab has internally detected that under specific conditions ExacTrac Vero may not correctly account for this ring angle correction during the calculation of the corresponding couch shift. This may result in

the treatment couch not moving to the exact planned position resulting in a deviation between the planned and the treatment target position. This deviation may not be clearly visible to the user if no verification image of the patient position is acquired after this couch shift has been performed. .<p>
RECALLING FIRM/MANUFACTURER
BRAINLAB AG, MUnich Germanyon 11/3/2017. Voluntary firm initiated recall is ongoing
VOLUME OF PRODUCT IN COMMERCE
28<p>
DISTRIBUTION
Nationwide and Internationally<p>

12/6/2017 Rosa Spine 1.0.2 Cl II
Company:Zimmer Biomet, Inc
Date of Enforcement Report 12/6/2017
Class II:<p>
PRODUCT
Rosa Spine 1.0.2 Stereotaxic Instrument Computer-Assisted Surgical Device The device is intended for the spatial positioning and orientation of instrument holders or tool guides to be used by surgeons to guide standard neurosurgical instruments during spine surgery.
Recall Number Z-0177-2018<p>
REASON
A design change was initiated to update ROSA Spine 1.0.2 to version ROSA Spine 1.0.2.16 to resolve software bugs and improve usability and stability of the ROSA Spine device.<p>
RECALLING FIRM/MANUFACTURER
Zimmer Biomet, Inc.Warsaw, IN on 10/29/2015. Voluntary firm initiated recall is ongoing
VOLUME OF PRODUCT IN COMMERCE
2 <p>
DISTRIBUTION
France and Germany<p>

12/6/2017 ROSA Surgical Device 2.5.8. Cl II
Company:Zimmer Biomet, Inc
Date of Enforcement Report 12/6/2017
Class II:<p>
PRODUCT
ROSA Surgical Device 2.5.8 ROSA Surgical Device is a computer-controlled electromechanical arm. It is intended to be used in the operating room for the spatial positioning and orientation of an instrument holder or tool guide. Guidance is based on a pre-operative plan developed with three-dimensional imaging software, and uses fiducial markers or optical registration.
Recall Number Z-0184-2018<p>
REASON
The software issue described was corrected in the modification to the MXTTOUT controller parameter settings.<p>
RECALLING FIRM/MANUFACTURER
Zimmer Biomet, Inc.Warsaw, IN on 9/5/2014. Voluntary firm initiated recall is ongoing
VOLUME OF PRODUCT IN COMMERCE
29 (8 US and 21 OUS) <p>
DISTRIBUTION
Nationwide Distribution to AK, OH, TX, GA, and MI<p>

11/29/2017 ROSA Brain 3.0.0. Cl II
Company:Zimmer Biomet, Inc
Date of Enforcement Report 11/29/2017
Class II:<p>
PRODUCT
ROSA Brain 3.0.0Usage:The device is intended for the spatial positioning and orientation of instrument holders or tool guides to be used by neurosurgeons to guide standard neurosurgical instruments (biopsy needle, stimulation or recording electrode, endoscope).
Recall Number Z-0167-2018<p>
REASON
Communication errors between ROSANNA BRAIN software, MARIO software and the St¿ubli CS8C controller.<p>
RECALLING FIRM/MANUFACTURER
Zimmer Biomet, Inc.Warsaw, IN on 7/20/2016. Voluntary firm initiated recall is ongoing
VOLUME OF PRODUCT IN COMMERCE
18 <p>
DISTRIBUTION
Worldwide Distribution - US Nationwide in the states of OH, FL, MA, MN, DC, NC, CA, NY, PA and countries of Australia and France<p>

11/29/2017 Arkon Anesthesia Delivery System, Class I
Company:Spacelabs Healthcare, Ltd.
Date of Enforcement Report 11/29/2017
Class I:<p>
PRODUCT
Arkon Anesthesia Delivery System, Model 99999, and software version 2.61 and upgrade kit 050-9043-00 Rev G. The Spacelabs Arkon Anesthesia Workstation is intended for use in the hospital environment and operating room. It may be used for the delivery of oxygen, air and nitrous oxide in a controlled manner to various patient breathing circuits with or without the use of mechanical ventilator, and may be used for the delivery of anesthetic vapor by use of a dismountable vaporizer.
Recall Number Z-0072-2018<p>
REASON
Arkon Anesthesia Workstation, with software version 2.61, experienced failure in mechanical ventilation, oxygen and anesthetic gas delivery, with concurrent failure of the display unit that resulted in a blank screen without audible or visible alarms<p>
RECALLING FIRM/MANUFACTURER
Spacelabs Healthcare, Ltd., Hertford UK on 10/11/2017. Voluntary firm initiated recall is ongoing.
VOLUME OF PRODUCT IN COMMERCE
110 units<p>
DISTRIBUTION
Nationwide Distribution to the states of NM, WY, FL, NC, MS, CO, CT, ME, and AL.<p>

11/29/2017 3M Bair Hugger(TM) Normothermia System, Cl II
Company:3M Company - Health Care Business
Date of Enforcement Report 11/29/2017
Class II:<p>
PRODUCT
3M Bair Hugger(TM) Normothermia System, Temperature Monitoring System Sensors Model 360 (Part Number 36000)
Recall Number Z-0114-2018<p>
REASON
During a recent investigation, 3M confirmed that a programming translation error could occur in a small

amount of the sensors that could lead to a temperature readout that is lower than the patient's actual temperature.<p>
RECALLING FIRM/MANUFACTURER
3M Company - Health Care Business, Saint Paul, MN on 10/17/2017. Voluntary firm initiated recall is ongoing.
VOLUME OF PRODUCT IN COMMERCE
153 cases (3825 sensors)<p>
DISTRIBUTION
CA, MI, IL, MO, MN, GA, and Canada, Switzerland<p>

11/29/2017 ROSA Surgical Device 2.5.8., CI II
Company:Zimmer Biomet, Inc
Date of Enforcement Report 11/29/2017
Class II:<p>
PRODUCT
ROSA Surgical Device 2.5.8.
Recall Number Z-0115-2018<p>
REASON
Potential for software to change the final tool orientation for the command position without command.<p>
RECALLING FIRM/MANUFACTURER
Zimmer Biomet, Inc.Warsaw, IN on 4/8/2016. Voluntary firm initiated recall is complete.
VOLUME OF PRODUCT IN COMMERCE
64 units<p>
DISTRIBUTION
AL, AR, CA, CO, CT, FL, GA, KY, MA, MI, MO, NY, OH, PA, TX, and WA Canada, China, France, Germany, India, Israel, Italy, Russia, Saudi Arabia, Spain, and United Kingdom<p>

11/29/2017 Siemens Syngo.plaza PACS CI II
CompanySiemens Medical Solutions USA, Inc
Date of Enforcement Report 11/29/2017
Class II:<p>
PRODUCT
Syngo.plaza, Picture Archiving and Communications System(PACS), Model 10863171 Syngo.plaza is a Picture Archiving and Communication System (PACS) intended to display, process, read, report, communicate, distribute, store and archive digital medical images.
Recall Number Z-0168-2018<p>
REASON
Siemens is releasing a non-medical software application LTA Incomplete Archive Check Tool V1.0. It is intended to eliminate an issue that occurs during syngo.plaza de-archiving from Dicom LTA. It has been defined that the number of de-archived images is less than the count of the archived images for the series. <p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc., Malvern, PA on 6/22/2017. Voluntary firm initiated recall is ongoing
VOLUME OF PRODUCT IN COMMERCE
2 units<p>
DISTRIBUTION
MN<p>

11/22/2017 ROSA Surgical Device 2.5.8. Cl II
Company:Zimmer Biomet, Inc
Date of Enforcement Report 11/22/2017
Class II:<p>
PRODUCT
ROSA Surgical Device 2.5.8. It is intended to be used in the operating room for the spatial positioning and orientation of an instrument holder or tool guide.
Recall Number Z-0102-2018<p>
REASON
An undetected shift between the information displayed in the navigation software and the actual patient anatomy<p>
RECALLING FIRM/MANUFACTURER
Zimmer Biomet, Inc.Warsaw, IN on 2/14/2014. Voluntary firm initiated recall is ongoing
VOLUME OF PRODUCT IN COMMERCE
<p>
DISTRIBUTION
OH, MI and TX<p>

11/22/2017 Plum 360 Infusion System, Cl II
Company:ICU Medical Inc
Date of Enforcement Report 11/22/2017
Class II:<p>
PRODUCT
Plum 360 Infusion System, List number 30010.
Recall Number Z-0101-2018<p>
REASON
(1) Under certain conditions, if a malfunction alarm occurs while the pump is in the "Paused" state waiting for the distal pressure to decrease, the pump cannot be turned off and delivery cannot be restarted until the battery is discharged or is disconnected; and (2) when the user accesses the Preventive Maintenance Screen in Service/Biomed Mode with a Total Delivery Time >1,500 hours, the user will not be able to interact with the device and the device must be power cycled.<p>
RECALLING FIRM/MANUFACTURER
ICU Medical Inc., Lake Forest, IL on 10/30/2017. Voluntary firm initiated recall is ongoing
VOLUME OF PRODUCT IN COMMERCE
21,461 devices<p>
DISTRIBUTION
Distribution was nationwide to medical facilities. Foreign distribution was made to Canada and Australia. Government and military distribution was also made.<p>

11/22/2017 Symbia Intevo 16, SPECT/CT System Cl II
Company:Siemens Medical Solutions USA, Inc..
Date of Enforcement Report 11/22/2017
Class II:<p>
PRODUCT
Symbia Intevo 6, SPECT/CT System, Emission Computed Tomography System To detect or image the distribution of radionuclides in the body or organ, using the following techniques: planar imaging, whole body imaging, tomographic imaging for isotopes with energies up to 588keV. Serial Number: 2141, 2144
Recall Number Z-0094-2018<p>
REASON
The Broad Quantification option of the Symbia product software version VB20A may not allow modification of two data input values. The failure occurs when the system with the Broad Quantification option is calibrated with phantoms that do not have a volume of 6500ml and/or when residual dose

needs to be entered.<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc.,Hoffman Estates, IL on 11/7/2017. Firm initiated recall is ongoing
VOLUME OF PRODUCT IN COMMERCE
2 units<p>
DISTRIBUTION
Worldwide Distribution to Malaysia, France, Japan, Reunion Island<p>

11/22/2017 Symbia Intevo 16, SPECT/CT, Cl II
Company:Siemens Medical Solutions USA, Inc..
Date of Enforcement Report 11/22/2017
Class II:<p>
PRODUCT
Symbia Intevo 16, SPECT/CT System, Emission Computed Tomography System To detect or image the distribution of radionuclides in the body or organ, using the following techniques: planar imaging, whole body imaging, tomographic imaging for isotopes with energies up to 588keV. Serial Number: 2136, 2142
Recall Number Z-0093-2018<p>
REASON
The Broad Quantification option of the Symbia product software version VB20A may not allow modification of two data input values. The failure occurs when the system with the Broad Quantification option is calibrated with phantoms that do not have a volume of 6500ml and/or when residual dose needs to be entered.<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc.,Hoffman Estates, IL on 11/7/2017. Firm initiated recall is ongoing
VOLUME OF PRODUCT IN COMMERCE
2 units<p>
DISTRIBUTION
Worldwide Distribution to Malaysia, France, Japan, Reunion Island<p>

11/15/2017 RESONATE EL ICD VR, Cl II
Company:Boston Scientific Corporation.
Date of Enforcement Report 11/15/2017
Class II:<p>
PRODUCT
RESONATE EL ICD VR, Model D432, Sterile.
Recall Number Z-0077-2018<p>
REASON
The devices have an incorrect firmware configuration.<p>
RECALLING FIRM/MANUFACTURER
Boston Scientific Corporation, Saint Paul, MN. on 10/4/2017. Voluntary:
Firm Initiated recall is complete. <p>
VOLUME OF PRODUCT IN COMMERCE
5 devices<p>
DISTRIBUTION
The devices were distributed to medical facilities located in MN and OH. There was no foreign/government/military distribution<p>

11/8/2017 THERMOCOOL SF NAV Catheters Cl II
Company:Biosense Webster, Inc.
Date of Enforcement Report 11/8/2017
Class II:<p>
PRODUCT

THERMOCOOL SF NAV Catheters Model Numbers - BNI35FJCT, BNI35DFCT, D-131503-S, D-131504-S
Recall Number Z-0058-2018<p>
REASON
Biosense Webster, Inc. has recently received an increased number of complaints related to the display of Alert 402 on the CARTO 3 System for certain lots of THERMOCOOL brand catheters. Alert 402 implies a "Map: magnetic distortion" when connected to CARTO 3 System. This issue may subsequently lead the physician to ablate in an unintended area when delivering RF energy..<p>
RECALLING FIRM/MANUFACTURER
Biosense Webster, Inc., Irwindale CA. on 9/16/2017. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
329 units<p>
DISTRIBUTION
Nationwide and Internationally <p>

11/8/2017 THERMOCOOL SMARTTOUCH Uni-Directional Cath Cl II

Company:Biosense Webster, Inc.
Date of Enforcement Report 11/8/2017
Class II:<p>
PRODUCT
HERMOCOOL SMARTTOUCH Uni-Directional Navigation Catheter
Recall Number Z-0057-2018<p>
REASON
Biosense Webster, Inc. has recently received an increased number of complaints related to the display of Alert 402 on the CARTO 3 System for certain lots of THERMOCOOL brand catheters. Alert 402 implies a "Map: magnetic distortion" when connected to CARTO 3 System. This issue may subsequently lead the physician to ablate in an unintended area when delivering RF energy..<p>
RECALLING FIRM/MANUFACTURER
Biosense Webster, Inc., Irwindale CA. on 9/16/2017. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
19 units<p>
DISTRIBUTION
Nationwide and Internationally <p>

11/8/2017 THERMOCOOL SMARTTOUCH Catheter Cl II

Company:Biosense Webster, Inc.
Date of Enforcement Report 11/8/2017
Class II:<p>
PRODUCT
THERMOCOOL SMARTTOUCH Bi-Directional Navigation Catheter (D-132704-S, D-132705-S)
Recall Number Z-0056-2018<p>
REASON
Biosense Webster, Inc. has recently received an increased number of complaints related to the display of Alert 402 on the CARTO 3 System for certain lots of THERMOCOOL brand catheters. Alert 402 implies a "Map: magnetic distortion" when connected to CARTO 3 System. This issue may subsequently lead the physician to ablate in an unintended area when delivering RF energy..<p>
RECALLING FIRM/MANUFACTURER
Biosense Webster, Inc., Irwindale CA. on 9/16/2017. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
64 units<p>
DISTRIBUTION
Nationwide and Internationally <p>

11/8/2017 THERMOCOOL SMARTTOUCH Bi-Directional, CI II

Company:Biosense Webster, Inc.
Date of Enforcement Report 11/8/2017
Class II:<p>
PRODUCT
THERMOCOOL SMARTTOUCH SF Bi-Directional Product Codes D-1348-01-S, D-1348-04-S, D-1348-05-S
Recall Number Z-0055-2018<p>
REASON
Biosense Webster, Inc. has recently received an increased number of complaints related to the display of Alert 402 on the CARTO 3 System for certain lots of THERMOCOOL brand catheters. Alert 402 implies a "Map: magnetic distortion" when connected to CARTO 3 System. This issue may subsequently lead the physician to ablate in an unintended area when delivering RF energy..<p>
RECALLING FIRM/MANUFACTURER
Biosense Webster, Inc., Irwindale CA. on 9/16/2017. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
1962 units<p>
DISTRIBUTION
Nationwide and Internationally <p>

11/8/2017 THERMOCOOL SMARTTOUCH SF, CI II

Company:Biosense Webster, Inc.
Date of Enforcement Report 11/8/2017
Class II:<p>
PRODUCT
THERMOCOOL SMARTTOUCH SF Uni-Directional Product Codes D-1347-01-S, D-1347-02-S, D-1347-03-S
Recall Number Z-0054-2018<p>
REASON
Biosense Webster, Inc. has recently received an increased number of complaints related to the display of Alert 402 on the CARTO 3 System for certain lots of THERMOCOOL brand catheters. Alert 402 implies a "Map: magnetic distortion" when connected to CARTO 3 System. This issue may subsequently lead the physician to ablate in an unintended area when delivering RF energy..<p>
RECALLING FIRM/MANUFACTURER
Biosense Webster, Inc., Irwindale CA. on 9/16/2017. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
357 units<p>
DISTRIBUTION
Nationwide and Internationally <p>

11/1/2017 Ablatherm(R) Integrated Imaging CI II

Company:Edap Technomed Inc.
Date of Enforcement Report 11/1/2017
Class II:<p>
PRODUCT
Ablatherm(R) Integrated Imaging, High Intensity Ultrasound System For Prostate Tissue Ablation Transrectal high intensity focused ultrasound (HIFU) ablation of prostate tissue
Recall Number Z-0049-2018<p>
REASON
The US FDA has requested the optional energy treatment settings, "medium" and "low" (Software Protocols 02-Medium and 03-Low) be removed from all Ablatherm Integrated Imagining devices in the

U.S. until supporting clinical data can be submitted and evaluated by FDA.<p>
RECALLING FIRM/MANUFACTURER
Edap Technomed Inc., Austin, TX on 8/14/2017. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
12<p>
DISTRIBUTION
US Distribution to states of: NY, FL CA, NC, TX and NJ. <p>

11/1/2017 Oncentra Brachy 4.5 radiation therapy SW Cl II

Company:Nucletron BV
Date of Enforcement Report 11/1/2017
Class II:<p>
PRODUCT
Oncentra Brachy 4.5 radiation therapy software The firm name on the label is Nucletron B.V. Oncentra is a radiation therapy planning software designed to analyze and plan radiation treatments in three dimensions for the purpose of treating patients with cancer.
Recall Number Z-0050-2018<p>
REASON
Incorrect source step size may occur in the software plans.<p>
RECALLING FIRM/MANUFACTURER
Nucletron BV, Veenendaal, Netherlands on 8/10/2017. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
89 customer sites have the affected software<p>
DISTRIBUTION
Nationwide and Internationally<p>

11/1/2017 Power Processor 1K Stockyard Cl II

Company:Beckman Coulter Inc..
Date of Enforcement Report 11/1/2017
Class II:<p>
PRODUCT
Power Processor 1K Stockyard. The Power Processor performs all pre-analytical sample tube preparation.
Recall Number Z-0046-2018<p>
REASON
Beckman Coulter has identified that due to a PLC software nonconformity the 1K Stockyard can initiate a retrieval of a sample tube during the rack loading process, which should not occur. This issue and associated complaint were discovered and filed internally.<p>
RECALLING FIRM/MANUFACTURER
Bedkman Coulter, Brea, CA on 8/3/2017. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
27<p>
DISTRIBUTION
Nationwide China France Italy Kuwait Spain Turkey <p>

10/25/2017 Toshiba Medical Kalare Fluoroscopic X-Ray Cl II

Company:oshiba American Medical Systems Inc
Date of Enforcement Report 10/25/2017
Class II:<p>
PRODUCT
Toshiba Medical Kalare Fluoroscopic X-Ray System (DREX-KL80) Kalare is intended to be used as a

universal diagnostic imaging system for radiographic and fluoroscopic examinations, including general R&F and pediatric examinations. It is intended for use by qualified/trained doctors or technologists on both adult and pediatric subjects
Recall Number Z-0012-2018<p>
REASON
During an examination images were displayed on the live monitor,but the images were not displayed on the system monitor nor were they saved to the hard disk.<p>
RECALLING FIRM/MANUFACTURER
oshiba American Medical Systems Inc, Tustin, CAon 9/12/2017. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
96<p>
DISTRIBUTION
Nationwide <p>

10/25/2017 Philips Healthcare Brilliance iCT XP Cl II
Company:Philips Electronics North America Corporation
Date of Enforcement Report 10/25/2017
Class II:<p>
PRODUCT
Philips Healthcare Brilliance iCT SP Xray Tomography, Computed These computed tomography x-ray systems are intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data taken at different angles and planes.
Recall Number Z-0020-2018<p>
REASON
During a bolus tracking procedure, no images were generated when the scan was completed, and the raw data file was not available for offline reconstruction. There is a discrepancy between the calculated reconstruction length and the actual scan length that results in the inability to reconstruct raw data<p>
RECALLING FIRM/MANUFACTURER
Philips Electronics North America Corporation, Andover, MA on 1/18/2017. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
606<p>
DISTRIBUTION
Nationwide <p>

10/25/2017 Philips Healthcare Brilliance iCT Cl II
Company:Philips Electronics North America Corporation
Date of Enforcement Report 10/25/2017
Class II:<p>
PRODUCT
Philips Healthcare Brilliance iCT Xray Tomography, Computed These computed tomography x-ray systems are intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data taken at different angles and planes.
Recall Number Z-0019-2018<p>
REASON
During a bolus tracking procedure, no images were generated when the scan was completed, and the raw data file was not available for offline reconstruction. There is a discrepancy between the calculated reconstruction length and the actual scan length that results in the inability to reconstruct raw data<p>
RECALLING FIRM/MANUFACTURER
Philips Electronics North America Corporation, Andover, MA on 1/18/2017. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE

606<p>
DISTRIBUTION
Nationwide <p>

10/25/2017 Philips Healthcare Ingenuity Core128 Cl II
Company:Philips Electronics North America Corporation
Date of Enforcement Report 10/25/2017
Class II:<p>
PRODUCT
Philips Healthcare Ingenuity Core128 Xray Tomography, Computed These computed tomography x-ray systems are intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data taken at different angles and planes.
Recall Number Z-0018-2018<p>
REASON
During a bolus tracking procedure, no images were generated when the scan was completed, and the raw data file was not available for offline reconstruction. There is a discrepancy between the calculated reconstruction length and the actual scan length that results in the inability to reconstruct raw data<p>
RECALLING FIRM/MANUFACTURER
Philips Electronics North America Corporation, Andover, MA on 1/18/2017. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
606<p>
DISTRIBUTION
Nationwide <p>

10/25/2017 Philips Healthcare Ingenuity CT X-RayCl II
Company:Philips Electronics North America Corporation
Date of Enforcement Report 10/25/2017
Class II:<p>
PRODUCT
Philips Healthcare Ingenuity CT X-Ray, Tomography, Computed These computed tomography x-ray systems are intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data taken at different angles and planes.
Recall Number Z-0017-2018<p>
REASON
During a bolus tracking procedure, no images were generated when the scan was completed, and the raw data file was not available for offline reconstruction. There is a discrepancy between the calculated reconstruction length and the actual scan length that results in the inability to reconstruct raw data<p>
RECALLING FIRM/MANUFACTURER
Philips Electronics North America Corporation, Andover, MA on 1/18/2017. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
606<p>
DISTRIBUTION
Nationwide <p>

10/25/2017 Philips Healthcare Ingenuity Core X-Ray Cl II
Company:Philips Electronics North America Corporation
Date of Enforcement Report 10/25/2017
Class II:<p>
PRODUCT
Philips Healthcare Ingenuity Core X-Ray, Tomography, Computed These computed tomography x-ray systems are intended to produce cross-sectional images of the body by computer reconstruction of

x-ray transmission data taken at different angles and planes.
Recall Number Z-0016-2018<p>
REASON
During a bolus tracking procedure, no images were generated when the scan was completed, and the raw data file was not available for offline reconstruction. There is a discrepancy between the calculated reconstruction length and the actual scan length that results in the inability to reconstruct raw data<p>
RECALLING FIRM/MANUFACTURER
Philips Electronics North America Corporation, Andover, MA on 1/18/2017. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
606<p>
DISTRIBUTION
Nationwide <p>

10/25/2017 Philips Healthcare Brilliance 64 System Cl II
Company:Philips Electronics North America Corporation
Date of Enforcement Report 10/25/2017
Class II:<p>
PRODUCT
Philips Healthcare Brilliance 64 System, X-Ray, Tomography, Computed These computed tomography x-ray systems are intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data taken at different angles and planes.
Recall Number Z-0015-2018<p>
REASON
During a bolus tracking procedure, no images were generated when the scan was completed, and the raw data file was not available for offline reconstruction. There is a discrepancy between the calculated reconstruction length and the actual scan length that results in the inability to reconstruct raw data<p>
RECALLING FIRM/MANUFACTURER
Philips Electronics North America Corporation, Andover, MA on 1/18/2017. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
606<p>
DISTRIBUTION
Nationwide <p>

10/25/2017 Alaris Pump Module model 8100 Cl II
Company:Beckman Coulter Inc..
Date of Enforcement Report 10/25/2017
Class II:<p>
PRODUCT
Alaris Pump Module model 8100 manufactured between November 2011 and March 2012; Alaris Pump Module serviced with LVP Mechanism Sub Assembly (P/N) 10942012 between November 2011 and March 2012; Alaris Pump module Bezel Kit Assembly (P/N) 10964559) shipped between November 2011 and March 2012. The Alaris Pump module is a large volume infusion pump offered under the Alaris System. The Alaris Pump module will deliver medication and fluids using the IV administration sets for continuous or intermittent delivery through clinically acceptable routes of administration such as intravenous or epidural
Recall Number Z-0026-2018<p>
REASON
The recalling firm has received reports of increased or decreased flows that have occurred in certain pumps<p>
RECALLING FIRM/MANUFACTURER
CareFusion 303, Inc, San Diego CA on 8/9/2017. Voluntary: Firm Initiated recall is ongoing. <p>

VOLUME OF PRODUCT IN COMMERCE
31,622 units (28,224 in US)<p>
DISTRIBUTION
Nationwide and Internationally<p>

9/20/2017 Baxter Amia Automated Peritoneal Dialysis Cl II

Company:Baxter Healthcare Corp
Date of Enforcement Report 9/20/2017
ClassII:<p>
PRODUCT
Baxter Amia Automated Peritoneal Dialysis Set with Cassette, REF 5C5479
Recall Number Z-3133-2017<p>
REASON
The firm received increased customer complaints for Missing Red Line, Patient Slow Flow, Solution Slow Flow, and Inadequate Drain alerts on certain lots of the AMIA Automated Peritoneal Dialysis Set with Cassette.<p>
RECALLING FIRM/MANUFACTURER
Baxter Healthcare Corp., Mountain Home, AR on 9/1/2017. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
164,700 units<p>
DISTRIBUTION
Nationwide and Canada<p>

9/20/2017 Mako Total Hip Application, Cl II

Company:Mako Surgical Corporation.
Date of Enforcement Report 9/20/2017
ClassII:<p>
PRODUCT
Total Hip Application (THA) Product Usage: The Robotic Arm Interactive Orthopedic System (RIO) is intended to assist the surgeon in providing software define spatial boundaries for orientation and reference information to anatomical structures during orthopedic procedures.
Recall Number Z-3131-2017<p>
REASON
Software discrepancy of not showing all the EE constants, when the screen is filled.<p>
RECALLING FIRM/MANUFACTURER
Mako Surgical Corporation, Davie, FL on 8/7/2017. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
291 (US) and 66 (OUS)<p>
DISTRIBUTION
Nationwide and Internationally<p>

9/20/2017 Makoplasty Partial Knee Application, Cl II

Company:Mako Surgical Corporation.
Date of Enforcement Report 9/20/2017
ClassII:<p>
PRODUCT
Makoplasty Partial Knee Application (PKA) Product Usage: The Robotic Arm Interactive Orthopedic System (RIO) is intended to assist the surgeon in providing software define spatial boundaries for orientation and reference information to anatomical structures during orthopedic procedures.
Recall Number Z-3130-2017<p>
REASON

Software discrepancy of not showing all the EE constants, when the screen is filled.<p>
RECALLING FIRM/MANUFACTURER
Mako Surgical Corporation, Davie, FL on 8/7/2017. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
349 (US) and 78 (OUS)<p>
DISTRIBUTION
Nationwide and Internationally<p>

9/20/2017 Toshiba Medical Radrex, Cl II
Company: Toshiba American Medical Systems
Date of Enforcement Report 9/20/2017
Class II:<p>
PRODUCT
Toshiba Medical Radrex - i Digital Radiography X-ray systemRadrex-i is intended for use in conjunction with the ceiling suspended tube support, high voltage generator, and bucky stand or bucky table incorporating a fixed or detachable (portable) flat panel detector for radiography of the head, chest, abdomen, spine, neck, and limbs.
Recall Number Z-3111-2017<p>
REASON
It was discovered during a procedure that when the operator made an exposure on the wireless x-ray detector and the image data was sent to the digital radiography system, and error message was displayed " System Error (2063)" which required a reboot and loss of the image.<p>
RECALLING FIRM/MANUFACTURER
Toshiba American Medical Systems, Tustin, CA on 3/23/2017. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
140<p>
DISTRIBUTION
Nationwide<p>

9/20/2017 FFR Link-FFR Signal Processing Module, Cl II
Company:Boston Scientific Corporation.
Date of Enforcement Report 9/20/2017
ClassII:<p>
PRODUCT
FFR Link-FFR Signal Processing Module, Material Number H7495551000 It is intended to condition physiological signals from measuring devices (BSC Pressure Guidewire or an external pressure transducer), transmit and receive via radiofrequency, and recondition the signals so they can be displayed on and/or recorded in a receiving device (iLab POLARIS Multi-Modality Guidance System or other monitoring device). The physiological signals can also be distributed by cable
Recall Number Z-3132-2017<p>
REASON
The device history record (DHR) was missing its test documentation for final HIPOT (high potential) electrical testing.<p>
RECALLING FIRM/MANUFACTURER
Boston Scientific Corporation,MJarlborough, MA on 5/15/2017. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
3<p>
DISTRIBUTION
Missouri<p>

9/13/2017 Merge Unity software, Cl II
Company: Merge Healthcare, Inc.
Date of Enforcement Report 9/13/2017
Class II:<p>
PRODUCT
Merge Unity software, formerly known as DR Systems Unity PACS software. The firm name on the label is Merge Healthcare, Hartland, WI.Merge Unity is a medical image and information management system that allows viewing, selection, processing, printing, telecommunications, and media interchange of medical images from a variety of diagnostic imaging
Recall Number Z-3105-2017<p>
REASON
The software is not identifying the patient as having atypical hyperplasia, resulting in an incorrect Gail Risk calculation.<p>
RECALLING FIRM/MANUFACTURER
Merge Healthcare, Inc., Hartland, WI on 8/14/2017. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
98 sites <p>
DISTRIBUTION
Nationwide<p>

9/6/2017 Biomerieux VITEK 2 Compact 30, Cl II
Company:Biomerieux Inc.
Date of Enforcement Report 9/6/2017
ClassII:<p>
PRODUCT
VITEK¿ 2 Compact 30, REF numbers: 27530 and 27530R (clinical), and 27630 and 17630R (industry) software and reagent cards designed for the identification (ID) and antimicrobial susceptibility testing (AST) of bacteria and yeast.
Recall Number Z-3076-2017<p>
REASON
Customers have reported that some VITEK¿ 2 cards are staying in preliminary status, not finalizing after ejection from the instrument, and not allowing cards in subsequent carousel slots to be processed. The issue was reported to occur on VITEK¿ 2 Compact 15 and Compact 30 systems following a system software update to version 8.01. <p>
RECALLING FIRM/MANUFACTURER
Biomerieux Inc., Hazelwood, MO on 7/12/2017. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
9234 units <p>
DISTRIBUTION
Worldwide<p>

9/6/2017 Biomerieux VITEK 2 Compact 15, Cl II
Company:Biomerieux Inc.
Date of Enforcement Report 9/6/2017
ClassII:<p>
PRODUCT
VITEK¿ 2 Compact 15, REF numbers: 27415 and 27415R software and reagent cards designed for the identification (ID) and antimicrobial susceptibility testing (AST) of bacteria and yeast.
Recall Number Z-3075-2017<p>
REASON
Customers have reported that some VITEK¿ 2 cards are staying in preliminary status, not finalizing after ejection from the instrument, and not allowing cards in subsequent carousel slots to be processed. The issue was reported to occur on VITEK¿ 2 Compact 15 and Compact 30 systems following a

system software update to version 8.01.<p>
RECALLING FIRM/MANUFACTURER
Biomerieux Inc., Hazelwood, MO on 7/12/2017. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
1866 units <p>
DISTRIBUTION
Worldwide<p>

9/6/2017 Neusoft NeuViz 128 Multi-slice CT Scanner ,
Cl II
Company:Neusoft Medical Systems Co., Ltd.
Date of Enforcement Report 9/6/2017
ClassII:<p>
PRODUCT
Neusoft NeuViz 128 Multi-slice CT Scanner System Product Usage: The Multi-Slice CT Scanner System can be used as a whole body computed tomography X-ray system featuring a continuously rotating X-ray tube and detector array. The acquired X-RAY transmission data is reconstructed by computer into cross-sectional images of the body from either the same axial plane taken at different angles or spiral planes taken at different angles.
Recall Number Z-3045-2017<p>
REASON
Software defect.<p>
RECALLING FIRM/MANUFACTURER
Neusoft Medical Systems Co., Ltd. Shenyang, China on 5/19/2017. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
154 <p>
DISTRIBUTION
Nationwide<p>

9/6/2017 Neusoft Medical NeuViz 64 , Cl II
Company:Neusoft Medical Systems Co., Ltd.
Date of Enforcement Report 9/6/2017
ClassII:<p>
PRODUCT
Neusoft Medical NeuViz 64 Multi-slice CT Scanner System, including: NeuViz 64e, NeuViz 64i with software version 1.0.6.3258 +P11 or previous version, NeuViz 64En, NeuViz 641n with software version 1.0.7.4021+P11 or previous version Product Usage: The Multi-Slice CT Scanner System can be used as a whole body computed tomography X-ray system featuring a continuously rotating X-ray tube and detector array. The acquired X-RAY transmission data is reconstructed by computer into cross-sectional images of the body from either the same axial plane taken at different angles or spiral planes taken at different angles.
Recall Number Z-3044-2017<p>
REASON
Software defect.<p>
RECALLING FIRM/MANUFACTURER
Neusoft Medical Systems Co., Ltd. Shenyang, China on 5/19/2017. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
234 <p>
DISTRIBUTION
Nationwide<p>

9/6/2017 Datascope/Maquet Intra-Aortic Balloon Pump
Class I
Company:Datascope Corp./MAQUET.
Date of Enforcement Report 9/6/2017
ClassII:<p>
PRODUCT
Datascope Corp./MAQUET Recalls Intra-Aortic Balloon Pumps Due to False Blood Detection Alarm and Ingress of Fluid into the Intra-Aortic Balloon Pump.
The devices addressed in this communication are the following St. Jude Medical pacemaker and CRT-P devices: Accent, Anthem, Accent MRI, Accent ST, Assurity, Allure
This communication does NOT apply to any implantable cardiac defibrillators (ICDs) or to cardiac resynchronization ICDs (CRT-Ds).
Datascope Corp./MAQUET's CS100i, CS100, and CS300 Intra-Aortic Balloon Pumps (IABP) are cardiac assist devices used to assist patients undergoing cardiac and non-cardiac surgery, and to treat patients with acute coronary syndrome or complications from heart failure.<p>
REASON
Datascope Corp./MAQUET is recalling its CS100i, CS100, and CS300 Intra-Aortic Balloon Pumps manufactured July 1, 2003 to June 16, 2017 due to False Blood Detection Alarm and Ingress of Fluid into the Intra-Aortic Balloon Pump. If a patient requires circulatory support with an IABP and the device does not work, or if therapy is stopped during use without a replacement IABP available, device failure may result in immediate and serious adverse health consequences, including death.<p>
RECALLING FIRM/MANUFACTURER
On July 17, 2017, Datascope Corp./MAQUET sent affected customers an "Urgent Product Recall Medical Device Field Correction" notice informing them of the device's risks, and listing actions that should be taken to minimize the risk of patient harm until affected IABP units can be serviced. <p>
VOLUME OF PRODUCT IN COMMERCE
5,049 <p>
DISTRIBUTION
Nationside<p>

8/30/2017 ORA System with VerifEye, Cl II
Company:Alcon Research, Ltd..
Date of Enforcement Report 8/30/2017
ClassII:<p>
PRODUCT
ORA System with VerifEye, Catalog Number 8065998300 For use during intraocular lens surgery Recall Number Z-3050-2017<p>
REASON
Some ORA Carts have the potential to return an incorrect IOL power measurement during cataract surgery. This issue appears to have been caused by a software coding error that results in the lens coefficients for an IOL model being downloaded from the Alcon server in an incorrect order..<p>
RECALLING FIRM/MANUFACTURER
Alcon Research, Ltd., Fort Worth TX on 6/30/2017. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
367 units <p>
DISTRIBUTION
Nationwide and Internationally<p>

8/30/2017 ORA System with VerifEye+ Cart, Cl II
Company:Alcon Research, Ltd..
Date of Enforcement Report 8/30/2017
ClassII:<p>
PRODUCT

ORA System with VerifEye+ Cart, Catalog Number 8065998307 For use during intraocular lens surgery.
Recall Number Z-3049-2017<p>
REASON
Some ORA Carts have the potential to return an incorrect IOL power measurement during cataract surgery. This issue appears to have been caused by a software coding error that results in the lens coefficients for an IOL model being downloaded from the Alcon server in an incorrect order..<p>
RECALLING FIRM/MANUFACTURER
Alcon Research, Ltd., Fort Worth TX on 6/30/2017. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
429 units <p>
DISTRIBUTION
Nationwide and Internationally<p>

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8/29/2017 Abbott Implantable Cardiac Pacemakers,
Class I
Company:Abbott.
Date of Enforcement Report 8/29/2017
ClassII:<p>
PRODUCT
Abbott's (formerly St. Jude Medical's) implantable cardiac pacemakers, including cardiac resynchronization therapy pacemaker (CRT-P) devices, provide pacing for slow or irregular heart rhythms. These devices are implanted under the skin in the upper chest area and have connecting insulated wires called "leads" that go into the heart. A patient may need an implantable cardiac pacemaker if their heartbeat is too slow (bradycardia) or needs resynchronization to treat heart failure.
The devices addressed in this communication are the following St. Jude Medical pacemaker and CRT-P devices: Accent, Anthem, Accent MRI, Accent ST, Assurity, Allure
This communication does NOT apply to any implantable cardiac defibrillators (ICDs) or to cardiac resynchronization ICDs (CRT-Ds).<p>
REASON
On August 23, 2017, the FDA approved a firmware update that is now available and is intended as a recall, specifically a corrective action, to reduce the risk of patient harm due to potential exploitation of cybersecurity vulnerabilities for certain Abbott (formerly St. Jude Medical) pacemakers. "Firmware" is a specific type of software embedded in the hardware of a medical device (e.g. a component in the pacemaker).
For the purposes of this safety communication, cybersecurity focuses on protecting patients' medical devices and their associated computers, networks, programs, and data from unintended or unauthorized access, change, or destruction.
The FDA recommends that patients and their health care providers discuss the risks and benefits of the cybersecurity vulnerabilities and the associated firmware update designed to address such vulnerabilities at their next regularly scheduled visit.
Summary of Problem and Scope
Many medical devices - including St. Jude Medical's implantable cardiac pacemakers - contain configurable embedded computer systems that can be vulnerable to cybersecurity intrusions and exploits. As medical devices become increasingly interconnected via the Internet, hospital networks, other medical devices, and smartphones, there is an increased risk of exploitation of cybersecurity vulnerabilities, some of which could affect how a medical device operates.
The FDA has reviewed information concerning potential cybersecurity vulnerabilities associated with St. Jude Medical's RF-enabled implantable cardiac pacemakers and has confirmed that these vulnerabilities, if exploited, could allow an unauthorized user (i.e. someone other than the patient's physician) to access a patient's device using commercially available equipment. This access could be used to modify programming commands to the implanted pacemaker, which could result in patient harm from rapid battery depletion or administration of inappropriate pacing.
There are no known reports of patient harm related to the cybersecurity vulnerabilities in the 465,000 (US) implanted devices impacted.

To address these cybersecurity vulnerabilities and improve patient safety, St. Jude Medical has developed and validated this firmware update as a corrective action (recall) for all of their RF-enabled pacemaker devices, including cardiac resynchronization pacemakers. The FDA has approved St. Jude Medical's firmware update to ensure that it addresses these cybersecurity vulnerabilities, and reduces the risk of exploitation and subsequent patient harm.
After installing this update, any device attempting to communicate with the implanted pacemaker must provide authorization to do so. The Merlin Programmer and Merlin@home Transmitter will provide such authorization.
The firmware update will be available beginning August 29, 2017. Pacemakers manufactured beginning August 28, 2017 will have this update pre-loaded in the device and will not need the update.
Firmware Update Details
The firmware update requires an in-person patient visit with a health care provider – it cannot be done from home via Merlin.net. The update process will take approximately 3 minutes to complete. During this time, the device will operate in backup mode (pacing at 67 beats per minute), and essential, life-sustaining features will remain available. At the completion of the update, the device will return to its pre-update settings.
As with any firmware update, there is a very low risk of an update malfunction. Based on St. Jude Medical's previous firmware update experience, installing the updated firmware could potentially result in the following malfunctions (including the rate of occurrence previously observed):
reloading of previous firmware version due to incomplete update (0.161 percent),
loss of currently programmed device settings (0.023 percent),
loss of diagnostic data (none reported), or
complete loss of device functionality (0.003 percent).
.<p>
RECALLING FIRM/MANUFACTURER
<p>
VOLUME OF PRODUCT IN COMMERCE
<p>
DISTRIBUTION
<p>

8/23/2017 SQ-RX 1010 Pulse Generator, Cl II
Company:Boston Scientific Corporation.
Date of Enforcement Report 8/23/2017
ClassII:<p>
PRODUCT
EMBLEM S-ICD, Model A209, Subcutaneous Implantable Cardioverter Defibrillator, RX. Product Usage: The S-ICD system is intended to provide defibrillation therapy for the treatment of life-threatening ventricular tachyarrhythmias in patients who do not have symptomatic bradycardia, incessant ventricular tachycardia, or spontaneous, frequently recurring ventricular tachycardia that is reliably terminated with anti-tachycardia pacing.
Recall Number Z-3039-2017<p>
REASON
The device can deliver an atypical amount of energy due to memory corruption inside the device.<p>
RECALLING FIRM/MANUFACTURER
Boston Scientific Corporation, Saint Paul, MN on 6/29/2017. Voluntary: Firm Initiated recall is ongoing.
<p>
VOLUME OF PRODUCT IN COMMERCE
Approximately 12,450 devices <p>
DISTRIBUTION
Nationwide and Internationally<p>

8/23/2017 EMBLEM MRI S- Implantable Cardioverter
Defib Cl II
Company:Boston Scientific Corporation.
Date of Enforcement Report 8/23/2017
ClassII:<p>
PRODUCT
EMBLEM S-ICD, Model A209, Subcutaneous Implantable Cardioverter Defibrillator, RX. Product Usage: The S-ICD system is intended to provide defibrillation therapy for the treatment of life-threatening ventricular tachyarrhythmias in patients who do not have symptomatic bradycardia, incessant ventricular tachycardia, or spontaneous, frequently recurring ventricular tachycardia that is reliably terminated with anti-tachycardia pacing.
Recall Number Z-3038-2017<p>
REASON
The device can deliver an atypical amount of energy due to memory corruption inside the device.<p>
RECALLING FIRM/MANUFACTURER
Boston Scientific Corporation, Saint Paul, MN on 6/29/2017. Voluntary: Firm Initiated recall is ongoing.
<p>
VOLUME OF PRODUCT IN COMMERCE
Approximately 9200 devices <p>
DISTRIBUTION
Nationwide and Internationally<p>

8/23/2017 EMBLEM S-ICD Implantable Cardioverter
Defib Cl II
Company:Boston Scientific Corporation.
Date of Enforcement Report 8/23/2017
ClassII:<p>
PRODUCT
EMBLEM S-ICD, Model A209, Subcutaneous Implantable Cardioverter Defibrillator, RX. Product Usage: The S-ICD system is intended to provide defibrillation therapy for the treatment of life-threatening ventricular tachyarrhythmias in patients who do not have symptomatic bradycardia, incessant ventricular tachycardia, or spontaneous, frequently recurring ventricular tachycardia that is reliably terminated with anti-tachycardia pacing.
Recall Number Z-3037-2017<p>
REASON
The device can deliver an atypical amount of energy due to memory corruption inside the device.<p>
RECALLING FIRM/MANUFACTURER
Boston Scientific Corporation, Saint Paul, MN on 6/29/2017. Voluntary: Firm Initiated recall is ongoing.
<p>
VOLUME OF PRODUCT IN COMMERCE
Approximately 16,750 devices <p>
DISTRIBUTION
Nationwide and Internationally<p>

8/9/2017 SoftLab Software Lab information system Cl II
Company:Soft Computer Consultants, Inc.
Date of Enforcement Report 8/9/2017
ClassII:<p>
PRODUCT
SoftLab Software Laboratory information system to be used in a medical research or clinical laboratory by knowledgeable, trained,
Recall Number Z-2865-2017<p>
REASON

Display of lab results based on incorrect LOINC code/test descriptions for tests that were performed at a reference lab, saved incorrectly, and sent to systems that display the EMR.<p>
RECALLING FIRM/MANUFACTURER
Soft Computer Consultants, Inc., clearwater, FL on 5/31/2017. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
18 units <p>
DISTRIBUTION
US Distribution to states of: CA, IL, LA, MA, MD, MI, MN, NJ, NY, PA, and TX.<p>

8/2/2017 CS 300 Intra-Aortic Balloon Pump Class I
Company:Maquet Datascope Corp - Cardiac Assist Division
Date of Enforcement Report 8/2/2017
ClassII:<p>
PRODUCT
CS 300 Intra-Aortic Balloon Pump
Recall Number Z-2738-2017<p>
REASON
The device failed to pump due to an electrical test failure code #58 (power up vent test fail), maintenance code #3, and an autofill failure which has been associated to a patient death due to the failure of the device to initiate therapy.<p>
RECALLING FIRM/MANUFACTURER
Maquet Datascope Corp - Cardiac Assist Division Mahwah, NJ on 6/16/2017. Voluntary: Firm Initiated recall is ongling. <p>
VOLUME OF PRODUCT IN COMMERCE
12,319 units total<p>
DISTRIBUTION
Nationwide and Internationally<p>

8/2/2017 CS 100i Intra-Aortic Balloon Pump Classi
Company:Maquet Datascope Corp - Cardiac Assist Division
Date of Enforcement Report 8/2/2017
Class II:<p>
PRODUCT
CS 100i Intra-Aortic Balloon Pump.
Recall Number Z-2736-2017<p>
REASON
The device failed to pump due to an electrical test failure code #58 (power up vent test fail), maintenance code #3, and an autofill failure which has been associated to a patient death due to the failure of the device to initiate therapy.<p>
RECALLING FIRM/MANUFACTURER
Maquet Datascope Corp - Cardiac Assist Division Mahwah, NJ on 6/16/2017. Voluntary: Firm Initiated recall is ongling. <p>
VOLUME OF PRODUCT IN COMMERCE
12,319 units total<p>
DISTRIBUTION
Nationwide and Internationally<p>

8/2/2017 Beckman Coulter PK7300(R) Cl III
Company:Beckman Coulter Inc..
Date of Enforcement Report 8/2/2017
Class III:<p>
PRODUCT

Beckman Coulter PK7300(R) Automated Microplate System, Catalogue Numbers: N3209000 and N2007600y Acute Care System (M540) Catalog Numbers: MK31501/MK31701/MK31722.
Recall Number B-0741-2017<p>
REASON
Beckman Coulter's PK7300, associated with a defect or glitch with the dispensing monitoring board, was distributed..<p>
RECALLING FIRM/MANUFACTURER
Bedkman Coulter, Brea, CA on 6/19/2017. Voluntary: Firm Initiated recall is ongling. <p>
VOLUME OF PRODUCT IN COMMERCE
342 units<p>
DISTRIBUTION
Nationwide and Internationally<p>

7/26/2017 Agfa Healthcare NX 3.0.8950 Software Cl II
Company:AGFA Healthcare Corp.
Date of Enforcement Report 7/26/2017
Class II:<p>
PRODUCT
Agfa Healthcare NX 3.0.8950 Imaging Processing Software
Recall Number Z-2735-2017<p>
REASON
A customer reported that when using an NX workstation with software version NX 3.0.8950 software and selecting the affected patient/exam from closed exams, initially the wrong image was linked to the exam and appeared. After a short time the wrong image was replaced by the correct image, however the wrong image was used for transmitting to PACS.<p>
RECALLING FIRM/MANUFACTURER
AGFA Healthcare Corp., Greenville, SC on 12/21/2016. Voluntary: Firm Initiated recall is ongling. <p>
VOLUME OF PRODUCT IN COMMERCE
221 units<p>
DISTRIBUTION
Nationwide Distribution.<p>

7/26/2017 Merge Eye Care PACS Viewer 5.2Cl II
Company: Merge Healthcare, Inc.
Date of Enforcement Report 7/26/2017
Class II:<p>
PRODUCT
Merge Eye Care PACS Viewer 5.2 Merge Eye Care PACS is a software solution for the display, management, archive, interface and integration of ophthalmic device reports, images and data. Merge Eye Care PACS is a software solution using databases for patient demographics, server and other systems of intercommunication with hospital systems via HL7 and DICOM to provide to clinicians a single image viewing and management solution of images imported from various contributing devices throughout the clinical environment. Merge Eye Care PACS provides the ability to review data from any network-connected computer, and is protected by appropriate security login which permits only authorized user access. Symphony uses 256 bit or greater encryption via secure socket layer (SSL) to assure a network environment which is secure.
Recall Number Z-2754-2017<p>
REASON
When the user has not set up any user preference on the sorting order to render the study images (OS/OD/etc.) and reports, the ECP may get an incorrect study index. If the user attempts to delete an image, ECP may then read that image as OS when it is, in fact, OD.<p>
RECALLING FIRM/MANUFACTURER
Merge Healthcare, Inc., Hartland, WI on 6/13/2017. Voluntary: Firm Initiated recall is ongling. <p>

VOLUME OF PRODUCT IN COMMERCE
18 units<p>
DISTRIBUTION
FL, IL, CO, MI, CA, NY, ND, OH, CT<p>

7/26/2017 Draeger Infinity Acute Care System Cl II
Company:Draegar Medical Systems, Inc.
Date of Enforcement Report 7/26/2017
Class II:<p>
PRODUCT
Draeger Medical Systems Infinity Acute Care System (M540) Catalog Numbers: MK31501/MK31701/MK31722.
Recall Number Z-2734-2017<p>
REASON
Cockpits with revision index 06 or higher that contain 4GB RAM modules may not annunciate audio or visual alarms on the Cockpit and Central Station..<p>
RECALLING FIRM/MANUFACTURER
Draegar Medical Systems, Inc., Andover, MA on 6/6/2017. Voluntary: Firm Initiated recall is ongling. <p>
VOLUME OF PRODUCT IN COMMERCE
37 US and 682 OUS<p>
DISTRIBUTION
Nationwide and Internationally<p>

7/26/2017 Medtronic Navigation Install CD, Spine tools Cl II
Company:Medtronic Navigation Inc.
Date of Enforcement Report 7/26/2017
Class II:<p>
PRODUCT
Install CD, Spine tools, Plus and S7, Version 25. Model Number 9731958.
Recall Number Z-2746-2017<p>
REASON
Software issue related to the StealthStation S7 system and the Synergy Spine application Version 2.1 configured with Spine Tool Install CD version 25. Issue may result in user being unable to navigate the Navigated Elevate Inserter with the StealthAiR Spine Frame during spine surgical procedures..<p>
RECALLING FIRM/MANUFACTURER
Medtronic Navigation Inc, Louisville, COon 5/10/2017. Voluntary: Firm Initiated recall is ongling. <p>
VOLUME OF PRODUCT IN COMMERCE
108<p>
DISTRIBUTION
Worldwide Distribution - USA (nationwide) Distribution and to the countries of : Brazil, Germany, Switzerland and Great Britain.<p>

7/12/2017 Ion Beam Proteus 235 Cl II
Company: Ion Beam Applications S.A..
Date of Enforcement Report 7/12/2017
Class II:<p>
PRODUCT
Proteus 235, Proton Therapy System Product Usage: The Proton Therapy System - Proteus 235 is a medical device designed to produce and deliver a proton beam for the treatment of patients with localized tumors and other conditions susceptible to treatment by radiation.
Recall Number Z-2684-2017<p>

REASON
Software issue.<p>
RECALLING FIRM/MANUFACTURER
Ion Beam Applications S.A., Louvain La Neuve, Belgium on 12/13/2016. Voluntary: Firm Initiated recall is ongling. <p>
VOLUME OF PRODUCT IN COMMERCE
6 worldwide and 5 in the U.S.<p>
DISTRIBUTION
Distributed to FL, VA, IL, NJ, WA and South Korea<p>

7/12/2017 Siemens Sensis Vibe Systems, Cl II
Company: Siemens Medical Solutions USA, Inc
Date of Enforcement Report 7/12/2017
Class II:<p>
PRODUCT
Sensis Vibe Systems with Software Version VD10B, Model Numbers 10765502, 10910620, 11007641, 6648161 --- Programmable diagnostic computer,
Recall Number Z-2688-2017<p>
REASON
Software error. In Sensis Vibe systems with software version VD10B, a software error can result in: problems generating a report and/ or- information from different examinations of the same patient being combined into one report. --- The error causes information from two examinations to be combined into one report.<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc., Malvern, PA on 5/16/2017. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
US: 13 units<p>
DISTRIBUTION
US Distribution to the states of : IN, MI, IA <p>

7/12/2017 Alaris PC Unit, Model 8015 Cl II
Company:CareFusion 303, Inc.
Date of Enforcement Report 7/12/2017
Class II:<p>
PRODUCT
Alaris PC Unit, Model 8015
Recall Number Z-2671-2017<p>
REASON
BD initiated the recall of Alaris PC unit model 8015 after the firm identified five scenarios which can result in the occurrence of Systems Error Code 255-16-275 and can potentially result in interrupted infusions.<p>
RECALLING FIRM/MANUFACTURER
CareFusion 303, Inc., San Diego, CA on 6/12/2017. Voluntary: Firm Initiated recall is ongling. <p>
VOLUME OF PRODUCT IN COMMERCE
568,283 units<p>
DISTRIBUTION
Worldwide Distribution - USA (nationwide) and to the countries of : Europe, Australia, New Zealand, South Africa, Greater Asia, Middle East, and Canada.<p>

7/12/2017 CardioTek EP-TRACER Software Cl II
Company: CardioTek BV.
Date of Enforcement Report 7/12/2017
Class II:<p>
PRODUCT
CardioTek EP-TRACER Software V1.x and V2.0 The EP-TRACER System is an electrophysiology measurement system used to acquire, filter, digitize, amplify, display, and record signals obtained during electrophysiological studies and related procedures.
Recall Number Z-2657-2017<p>
REASON
Software bug which allows parameters to be changed unintentionally during use.<p>
RECALLING FIRM/MANUFACTURER
CardioTek BV, Netherlands on 4/13/2017. Voluntary: Firm Initiated recall is ongling. <p>
VOLUME OF PRODUCT IN COMMERCE
8 units in US<p>
DISTRIBUTION
Nationwide and internationally<p>

7/5/2017 IMPAX CV Reporting module Cl II
Company: AGFA Healthcare Corp..
Date of Enforcement Report 7/5/2017
Class II:<p>
PRODUCT
IMPAX Cardiovascular The IMPAX CV Reporting module consists of a database and graphical user interface (GUI) that allows users to document procedure and clinical findings as structured data, with representation in printed or electronic formats
Recall Number Z-2652-2017<p>
REASON
A customer experienced when using IMPAX CV Reporting software, specifically, when building a NIV report, the NIV Cardio report was showing incorrect findings for Aneurysm..<p>
RECALLING FIRM/MANUFACTURER
AGFA Healthcare Corp., Greenville, SC on 12/22/2016. Voluntary: Firm Initiated recall is ongling. <p>
VOLUME OF PRODUCT IN COMMERCE
10<p>
DISTRIBUTION
Nationwide Distribution to NJ, NC, OH, PA, SC, TN, TX, and WI<p>

7/5/2017 Merge LIS software Cl II
Company: Merge Healthcare, Inc.
Date of Enforcement Report 7/5/2017
Class II:<p>
PRODUCT
Merge LIS software. The firm name on the label is Merge Healthcare. Merge LIS system is a complete system for ordering, managing and reporting a patient s laboratory work, from the time of order entry to the time the laboratory test results are reported.
Recall Number Z-2628-2017<p>
REASON
There are potential issues with results reporting for certain run-based tests. Under certain conditions, the wrong results could inadvertently be verified.<p>
RECALLING FIRM/MANUFACTURER
Merge Healthcare, Inc., Hartland, WI on 4/15/2016. Voluntary: Firm Initiated recall is ongling. <p>
VOLUME OF PRODUCT IN COMMERCE
638 sites potentially have the affected versions<p>

DISTRIBUTION
US and internationally<p>

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6/21/2017 Merge: Merge PACS software Cl II
Company: Merge Healthcare, Inc.
Date of Enforcement Report 6/21/2017
Class II:<p>
PRODUCT
Merge PACS software. Merge PACS (Picture Archiving Communication System) is designed and marketed for soft copy reading, communication, and storage of studies produced by digital modalities, including digital mammography
Recall Number Z-2591-2017<p>
REASON
Merge PACS did not show unviewed images when the last view was skipped. There is a potential risk to health of a physician misdiagnosis because not all images are available for viewing.<p>
RECALLING FIRM/MANUFACTURER
Merge Healthcare, Inc., Hartland, WI on 5/8/2017. Voluntary: Firm Initiated recall is ongling. <p>
VOLUME OF PRODUCT IN COMMERCE
47 sites potentially have the affected versions<p>
DISTRIBUTION
Nationwide<p>

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6/21/2017 Merge: Merge PACS software Cl II
Company: Merge Healthcare, Inc.
Date of Enforcement Report 6/21/2017
Class II:<p>
PRODUCT
Merge PACS software. The firm name on the label is Merge Healthcare, Hartland, WI.
Recall Number Z-2590-2017<p>
REASON
Merge PACS did not show unviewed images when the last view was skipped. There is a potential risk to health of a physician misdiagnosis because not all images are available for viewing.<p>
RECALLING FIRM/MANUFACTURER
Merge Healthcare, Inc., Hartland, WI on 5/8/2017. Voluntary: Firm Initiated recall is ongling. <p>
VOLUME OF PRODUCT IN COMMERCE
47 sites potentially have the affected versions<p>
DISTRIBUTION
Nationwide<p>

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6/14/2017 Nexstim NBS System 4 and 5 Cl II
Company: Nexstim PLC
Date of Enforcement Report 6/14/2017
Class II:<p>
PRODUCT
NBS System 4 (sw version 4.0 or higher), Software update to 4.3.3 and NBS System 5 (sw version 5.0 or higher), Software update to 5.1.1. The Nexstim Navigated Brain Stimulation System (NBS System) is indicated for noninvasive mapping of the primary motor cortex of the brain to its cortical gyrus.
Recall Number Z-2320-2017<p>
REASON
Software defect: the NBS software may accidentally generate duplicate copies of one or several files..<p>
RECALLING FIRM/MANUFACTURER
Nexstim PLC, Helsinki, Finland on 3/14/2017. Voluntary: Firm Initiated recall is ongling. <p>

VOLUME OF PRODUCT IN COMMERCE
21<p>
DISTRIBUTION
Worldwide Distribution - US to GA only, Foreign: Europe.<p>

6/14/2017 Nexstim eXima NBS System Software Cl II
Company: Nexstim PLC
Date of Enforcement Report 6/14/2017
Class II:<p>
PRODUCT
Nexstim eXima NBS System Software version 2.2 or higher. The Nexstim Navigated Brain Stimulation System (NBS System) is indicated for noninvasive mapping of the primary motor cortex of the brain to its cortical gyrus.
Recall Number Z-2319-2017<p>
REASON
Software defect: the NBS software may accidentally generate duplicate copies of one or several files.<p>
RECALLING FIRM/MANUFACTURER
Nexstim PLC, Helsinki, Finland on 3/14/2017. Voluntary: Firm Initiated recall is ongling. <p>
VOLUME OF PRODUCT IN COMMERCE
11 units<p>
DISTRIBUTION
Worldwide Distribution - US to GA only, Foreign: Europe.<p>

6/14/2017 Circadiance SmartMonitor 2 PS/PSL Cl II
Company: Circadiance LLC
Date of Enforcement Report 6/14/2017
Class II:<p>
PRODUCT
SmartMonitor 2 PS/PSL, Monitor, Apnea, Facility USE. Intended for use in the continuous monitoring of respiration, heart rate, and SP02 of infant, pediatric and adult patients
Recall Number Z-2250-2017<p>
REASON
Circadiance has determined that it is possible for certain Smart Monitor 2PS/PSL monitors to exhibit intermittent operation of the nurse call feature. The firm has updated the device to increase the "Nurse Call" feature to ensure monitor alarms are transmitted to compatible nurse call systems<p>
RECALLING FIRM/MANUFACTURER
Circadiance LLC, Export, PA on 5/1/2017. Voluntary: Firm Initiated recall is ongling. <p>
VOLUME OF PRODUCT IN COMMERCE
1242<p>
DISTRIBUTION
Nationwide.<p>

6/7/2017 Toshiba Angio WorkStation Cl II
Company: Toshiba American Medical Systems Inc
Date of Enforcement Report 6/7/2017
Class II:<p>
PRODUCT
Angio WorkStation (XIDF-AWS801) used in conjunction with your Infinix System (INFX-8000V;INFX-8000C;INFX-8000F
Recall Number Z-2109-2017<p>
REASON
It was found that during a procedure the Peak Skin Dose (PSD) value displayed by the Dose Tracking

System (DTS) was larger than the DTS expected value. This issue occurs when the power for the Angio Workstation is turned on after the power for the Infinix system is turned on.<p>
RECALLING FIRM/MANUFACTURER
Toshiba American Medical Systems Inc, Tustin, CA on 2/1/2017. Voluntary: Firm Initiated recall is ongling. <p>
VOLUME OF PRODUCT IN COMMERCE
70 systems<p>
DISTRIBUTION
Nationwide.<p>

5/31/2017 Merge: Merge Cardio software Cl II
Company: Merge Healthcare, Inc.
Date of Enforcement Report 5/31/2017
Class II:<p>
PRODUCT
Merge Cardio software
Recall Number Z-2123-2017<p>
REASON
Fetal patient report was automatically pulling prior measurement data for a prior fetus since the fetal study is based on the mother's MRN, resulting in the wrong fetal measurements getting referenced.<p>
RECALLING FIRM/MANUFACTURER
Merge Healthcare, Inc., Hartland, WI on 4/13/2016. Voluntary: Firm Initiated recall is ongling. <p>
VOLUME OF PRODUCT IN COMMERCE
30 sites potentially have the affected versions<p>
DISTRIBUTION
Distributed to the states of AZ, CT, FL, GA, IL, IN, LA, MI, NY, NC, OH, OK, TX, and VT.<p>

5/31/2017 Siemens AXIOM Sensis, Cl II
Company: Siemens Medical Solutions USA, Inc
Date of Enforcement Report 5/31/2017
Class II:<p>
PRODUCT
AXIOM Sensis, Computer, Diagnostic, Programmable. Intended to be used as a diagnostic and administrative tool supporting hemodynamic cardiac catheterizations and/or intracardiac electrophysiology studies..
Recall Number Z-2156-2017<p>
REASON
An extremely dusty computer can cause problems at system start, or rarely, cause system fail. Perform a system check prior to performing exams. If the Sensis system fails, its functions can not be used. Clinical treatment may need to be terminated, restarted, or transferred to a functioning system<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc., Malvern, PA on 4/12/2017. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
4,095<p>
DISTRIBUTION
Nationwide Distribution <p>

5/31/2017 HeartMate II LVAS with Pocket Controller, Cl II
Company: Thoratec Corporation
Date of Enforcement Report 5/31/2017
Class II:<p>

PRODUCT
HeartMate¿ II LVAS with Pocket Controller; 107801 - HMII PUMP & POCKET CTRL ONLY UDI:00813024011286 Intended to provide hemodynamic support in patients with end-stage, refractory left ventricular heart failure; intended for use inside or outside the hospital.
Recall Number Z-2051-2017<p>
REASON
St. Jude Medical is providing all users of their HeartMate II LVAS with Pocket Controller with new software and updates to hardware to make the exchange to a backup controller easier. This is related to recall Z-1227/1230-2014.<p>
RECALLING FIRM/MANUFACTURER
Thoratec Corporation , Pleasanton, CA on 3/20/2017. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
24,077 active units in US<p>
DISTRIBUTION
Nationwide and Internationally.<p>

5/24/2017 MagellaLeadCare Plu& Ultra Testing Systems
Class I
Company: Magellan Diagnostics Inc.
Date of Enforcement Report 5/24/2017
Class I:<p>
PRODUCT
Magellan Diagnostics Inc. Recalls LeadCare Plus and Ultra Testing Systems Due to Inaccurate Test Results.
The LeadCare Plus and the LeadCare Ultra Testing Systems detect the amount of lead in a blood sample obtained from finger or heel prick (capillary) or from a vein (venous).
Recall Number <p>
REASON
Magellan Diagnostics is recalling the LeadCare Plus and the LeadCare Ultra Testing Systems because they may underestimate the blood lead levels (BLL) and give inaccurate results when processing venous blood samples. Falsely lower test results may lead to improper patient management and treatment for lead exposure or poisoning. The use of affected product may cause serious adverse health consequences.
This recall accompanies FDA's safety communication from May 17, 2017. Magellan's LeadCare Plus and Ultra Testing Systems are two of four blood lead testing systems affected by the recommendations in FDA's safety communication.
The FDA is unable to identify the root cause for the inaccurate results, based on data provided by Magellan. We are conducting studies with the Center for Disease Control and Prevention (CDC) to identify the cause and better characterize the extent of the problem.
Abbott-Thoratec has received a total of 70 reports of incidents in which the controller has malfunctioned after an exchange, including 19 injuries and 26 deaths. All of the deaths occurred when patients attempted to exchange controllers while away from the hospital. <p>
RECALLING FIRM/MANUFACTURER
Abbott-Thoratec on 4/12/2017. Voluntary: Firm Initiated recall is ongling. <p>
VOLUME OF PRODUCT IN COMMERCE
<p>
DISTRIBUTION
<p>

5/24/2017 Mobius3D , Cl II
Company: Mobius Medical Systems, LP
Date of Enforcement Report 5/24/2017
Class II:<p>
PRODUCT
Mobius3D Product Usage: Mobius3D software is used for quality assurance and treatment plan verification in radiation therapy. It calculates radiation dose three-dimensionally in a representation of a patient or a phantom. The calculation is based on read-in treatment plans that are initially calculated by a treatment planning system, and may additionally be based on external measurements of radiation fields from other sources such as linac delivery log data. Mobius3D is not a treatment planning system. It is only to be used by trained radiation oncology personnel as a quality assurance tool.
Recall Number Z-2100-2017<p>
REASON
Mobius3D version 1.5.0 contained a defect in software code which affects users who perform beam customization, and may lead to a discrepancy in dose calculation between this version of Mobius3D (1.5.0) and the prior version (1.4.2), where none should have been expected..<p>
RECALLING FIRM/MANUFACTURER
Mobius Medical Systems, LP, Houston, TX on 2/23/2015. Voluntary: Firm Initiated recall is ongling. <p>
VOLUME OF PRODUCT IN COMMERCE
270<p>
DISTRIBUTION
Nationwide and Internationally.<p>

5/24/2017 Ion Beam Applications-Proteus 235 Cl II
Company: Ion Beam Applications S.A .
Date of Enforcement Report 5/24/2017
Class II:<p>
PRODUCT
Proton therapy system -Proteus 235 aka Proteus Plus. A medical device designed to produce and deliver a proton beam for the treatment of patients with localized tumors and other conditions susceptible to treatment by radiation.
Recall Number Z-2097-2017<p>
REASON
A PBS (Pencil Beam Scanning) irradiation may pause for different reasons. After a pause, irradiation may restart from the beginning instead of recalculating the field based on the already delivered dose<p>
RECALLING FIRM/MANUFACTURER
Ion Beam Applications S.A., Louvain La Neuve, Belgium on 4/10/2017. Voluntary: Firm Initiated recall is ongling. <p>
VOLUME OF PRODUCT IN COMMERCE
2<p>
DISTRIBUTION
FL<p>

5/24/2017 enGen (TM) Laboratory Automation Systems ,
Cl II
Company: Ortho-Clinical Diagnostics.
Date of Enforcement Report 5/24/2017
Class II:<p>
PRODUCT
enGen (TM) Laboratory Automation Systems using all TCAutomation(TM) Software Versions with the InOut Communication Interface, IVD
Recall Number Z-2077-2017<p>
REASON

Software anomaly; Thermo-Fisher Scientific initially discovered and Ortho-Clinical Diagnostics, subsequently, confirmed a software anomaly that may potentially result in miss-associated sample IDs involving the communication between enGen TCAutomation (TCA) Bypass modules (manufactured by Thermo-Fisher Scientific) and the VITROS Analyzers. To date, no occurrences of this issue have been observed on Ortho□s enGen(TM) Systems.<p>
RECALLING FIRM/MANUFACTURER
Ortho-Clinical Diagnostics, Rochester, NY on 3/8/2017. Voluntary: Firm Initiated recall is ongling. <p>
VOLUME OF PRODUCT IN COMMERCE
US: 33 units; OUS: 43 units<p>
DISTRIBUTION
Nationwide and Internationally.<p>

5/23/2017 HeartMate II LVS Controller Class I
Company: Abbott-Thoratec
Date of Enforcement Report 5/23/2017
Class I:<p>
PRODUCT
HeartMate II Left Ventricular Assist (LVAS) Pocket System Controller
The Pocket System Controller is a power supply that connects to the implanted HeartMate II LVAS pump through a lead (driveline) under the skin. The controller helps power the LVAS system, a mechanical device that circulates blood throughout the body when the heart is too weak to pump blood adequately on its own. The controller is powered by batteries or connected to a main power supply.
The HeartMate II LVAS Pocket System Controller is intended for use inside or outside of the hospital. A back-up system controller is provided to each patient for use in case of a device alarm or malfunction. Instructions and training are provided on how to switch from one system controller to the other.
Recall Number <p>
REASON
Patients may sometimes need to change to their backup back-up system controller during the course of ventricular assist therapy. The change should be done quickly and in the hospital, because it can present a significant challenge to patients that are elderly and/or untrained. For these patients, a slow or improper driveline changeover places them at risk of serious injury or death.
Abbott-Thoratec has received a total of 70 reports of incidents in which the controller has malfunctioned after an exchange, including 19 injuries and 26 deaths. All of the deaths occurred when patients attempted to exchange controllers while away from the hospital.
To address this issue, Abbott-Thoratec is providing all HeartMate II LVAS with Pocket Controller users with new software and hardware updates to assist patients in successfully changing their pocket controller in emergency situations. <p>
RECALLING FIRM/MANUFACTURER
Abbott-Thoratec on 3/30/2017. Voluntary: Firm Initiated recall is ongling. <p>
VOLUME OF PRODUCT IN COMMERCE
<p>
DISTRIBUTION
<p>

5/10/2017 AQUIOS CL Flow Cytometer, Cl II
Company: Beckman Coulter Inc.
Date of Enforcement Report 5/10/2017
Class II:<p>
PRODUCT
AQUIOS CL Flow Cytometer, Ref no. B30166, Software Versions 2.0 and 2.0.1 Product Usage: The AQUIOS CL Flow Cytometer is intended for use with in vitro diagnostic flow cytometric applications using up to four fluorescent detection channels using a blue (488 nm) laser, two light scatter detection channels and electronic volume (EV)

Recall Number Z-2035-2017<p>
REASON
Beckman Coulter has confirmed that the Export feature located in the Results area of the AQUIOS System software is not correctly exporting Tetra Combo CRD files.<p>
RECALLING FIRM/MANUFACTURER
Beckman Coulter Inc., Brea, CA on 4/3/2017. Voluntary: Firm Initiated recall is ongling. <p>
VOLUME OF PRODUCT IN COMMERCE
188 units total (24 units in US)<p>
DISTRIBUTION
Nationwide and Internationally.<p>

5/10/2017 Accu-Chek Connect Diabetes Management App Cl II

Company: Roche Diabetes Care, Inc.
Date of Enforcement Report 5/10/2017
Class II:<p>
PRODUCT
Accu-Chek Connect Diabetes Management App versions 2.0.0, 2.0.1 and 2.1.0 for iOS and Android Product Usage: This is a digital product available for download direct to customers from the Apple App Store and the Google Play Store. The total number of downloads is not available. The number of unique users for each affected version from the date of initial distribution through 03/23/2017 is noted in 7a. However, some users will have used all three affected versions as they upgraded from version to version when the versions became available and many others will have tried the app and discontinued use. In the last 30 days, 02/22/2017 03/23/2017, there have been 16,781 unique users in the US with 264 of those seeking bolus advice and 19,268 unique users in the rest of world (excluding Canada) with 415 of those users seeking bolus advice
Recall Number Z-1899-2017<p>
REASON
A program error (bug) in the Bolus Advisor feature, which could result in incorrect bolus advice and a potential insulin over-delivery..<p>
RECALLING FIRM/MANUFACTURER
Roche Diabetes Care, Inc., Indianapolis, IN on 3/14/2017. Voluntary: Firm Initiated recall is ongling. <p>
VOLUME OF PRODUCT IN COMMERCE
64,324<p>
DISTRIBUTION
Nationwide <p>

5/3/2017 Orthosoft Navitrack System Cl II

Company: Orthosoft, Inc. dba Zimmer CAS.
Date of Enforcement Report 5/3/2017
Class II:<p>
PRODUCT
Navitrack System - OS Knee Universal, Orthopedic Stereotaxic Instrument CAS Software application intended to assist in the placement of total knee replacement components
Recall Number Z-1881-2017<p>
REASON
Zimmer CAS voluntarily conducted a retrospective recall of the Navitrack System - OS Knee Universal software ORTHOsoft-UniTkr-2.3.2.6, due to a calibration sequence crash.<p>
RECALLING FIRM/MANUFACTURER
Orthosoft, Inc. dba Zimmer CAS, Montreal Canada on 10/6/2011. Voluntary: Firm Initiated recall is ongling. <p>
VOLUME OF PRODUCT IN COMMERCE
105<p>

DISTRIBUTION
Nationwide and Internationally.<p>

5/3/2017 18L6 HD transducer on the ACUSON S, Cl II
Company: Siemens Medical Solutions USA, Inc
Date of Enforcement Report 5/3/2017
Class II:<p>
PRODUCT
18L6 HD transducer on the ACUSON S Family ultrasound systems with software versions VD10A or VD10C;Model numbers:18L6 HD transducer 10041227 & 10789400S1000 10441701S2000 10041461S2000 (Refurb) - 10440017S3000 10441730Radiology
Recall Number Z-1875-2017<p>
REASON
When scanning with the 18L6 HD transducer on the ACUSON HELX" Evolution with Touch Control, the ultrasound system may display a triple image or an image with a dark band. For the triple image issue, the system repeats one-third of the aperture, but does not display the full field of view.<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc., Mountain View CA on 3/30/2017. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
2,045 systems<p>
DISTRIBUTION
Nationwide and Intenrationally <p>

5/2/2017 Newport HT70 & Newport HT70 Plus Ventilators Cl I
Company: Medtronic Inc.
Date of Enforcement Report 5/2/2017
Class I:<p>
PRODUCT
The Newport™ HT70 and HT70 Plus ventilators are intended to provide breathing support for individuals who require mechanical ventilation. These devices can be used with infant, pediatric or adult patients greater than or equal to 5kg (11lbs). These devices are used in hospitals, other health care facilities, and home care environments and may be used for transport and emergency response situations.
Recall Number Z-1874-2017<p>
REASON
Newport Medical Instruments Inc. now a part of Medtronic, is recalling the Newport™ HT70 and Newport™ HT70 Plus ventilators because a software problem may cause the ventilator to shut down unexpectedly without sounding an alarm. If the ventilator shuts down, the patient may not receive enough oxygen and could suffer serious adverse health consequences such as brain damage, or even death. <p>
RECALLING FIRM/MANUFACTURER
Newport Medical Instruments Inc., , Costa Mesa, CA on 3/30/2017. Voluntary: Firm Initiated recall is ongling. <p>
VOLUME OF PRODUCT IN COMMERCE
12,966<p>
DISTRIBUTION
Nationwide and Internationally<p>

4/26/2017 Merge Eye Station and Merge Eye Care PACS
Cl II
Company: Merge Healthcare, Inc.
Date of Enforcement Report 4/26/2017
Class II:<p>
PRODUCT
Merge Eye Station and Merge Eye Care PACS
Recall Number Z-1828-2017<p>
REASON
During an antivirus program scan of the Eye Station or Eye Care PACS, the antivirus program may detect a newly captured image to be an unwanted file and delete the image permanently.<p>
RECALLING FIRM/MANUFACTURER
Merge Healthcare, Inc., Hartland, WI on 4/4/2016. Voluntary: Firm Initiated recall is ongling. <p>
VOLUME OF PRODUCT IN COMMERCE
1627 sites potentially have the affected versions<p>
DISTRIBUTION
Distribution was nationwide to medical facilities. Foreign distribution was made to Canada, as well as to other countries. There was also government distribution.<p>

4/19/2017 da Vinci Xi EndoWrist Suction Irrigator, Cl II
Company: Intuitive Surgical, Inc.
Date of Enforcement Report 4/19/2017
Class II:<p>
PRODUCT
da Vinci Xi EndoWrist Suction Irrigator, 8 mm instrument; PN 480299-03; and SOFTWARE, EMBEDDED RLS, IS4000, A70_P6_B440; PN 610092-440. General and Plastic Surgery: The EndoWrist¿ Suction Irrigator is designed to be used in conjunction with an Intuitive Surgical da Vinci Surgical System and compatible suction and irrigation sources and tubing sets for delivering fluid to the surgical site and for evacuation and aspiration of fluids. The instrument may also be used for retraction and blunt dissection of tissue. The instrument tip is blunt and intended to contact tissue.
Recall Number Z-1819-2017<p>
REASON
Intuitive Surgical has become aware that in specific scenarios with system software P6 and the da Vinci Xi Suction Irrigator (PN 480299-03), users can experience unexpected motion of a system arm.<p>
RECALLING FIRM/MANUFACTURER
Intuitive Surgical, Inc., Sunnyvale, CA on 3/31/2017. Voluntary: Firm Initiated recall is ongling. <p>
VOLUME OF PRODUCT IN COMMERCE
15 x 6 packs (90 units)<p>
DISTRIBUTION
US Only - one location each in AL, CO, KS, NV, NY, and 2 in TX<p>

4/19/2017 iConnect Enterprise Archive (ICEA) software
Cl II
Company: Merge Healthcare, Inc.
Date of Enforcement Report 4/19/2017
Class II:<p>
PRODUCT
iConnect Enterprise Archive (ICEA) software. The firm name on the labeling is Merge Healthcare, Hartland, WI.
Recall Number Z-1762-2017<p>
REASON
Use of the software may show an incorrect value to the user when viewing the Fractional Flow Reserve (FFR) results during recording.<p>

RECALLING FIRM/MANUFACTURER
Merge Healthcare, Inc., Hartland, WI on 4/4/2016. Voluntary: Firm Initiated recall is ongling. <p>
VOLUME OF PRODUCT IN COMMERCE
333 sites potentially have the affected accessory<p>
DISTRIBUTION
Distribution was made nationwide to medical facilities. Foreign distribution was made to Canada, as well as other countries. Government/military distribution was also made.<p>

4/19/2017 Draegar Medical Delta XL Cl II
Company: Draegar Medical Systems, Inc.
Date of Enforcement Report 4/19/2017
Class II:<p>
PRODUCT
Delta XL, Catalog Number: MS18596 in combination with Scio, Scio Four, Scio Four Oxi plus, Scio Four Oxi, Scio Four plus.
Recall Number Z-1773-2017<p>
REASON
It was reported that a set low O2 alarm does not go off although the measured O2 level is below the alarm limit.<p>
RECALLING FIRM/MANUFACTURER
Draegar Medical Systems, Inc., Andover, MA on 3/28/2017. Voluntary: Firm Initiated recall is ongling. <p>
VOLUME OF PRODUCT IN COMMERCE
2156<p>
DISTRIBUTION
Nationwide and Internationally<p>

4/19/2017 Draegar Medical Delta Cl II
Company: Draegar Medical Systems, Inc.
Date of Enforcement Report 4/19/2017
Class II:<p>
PRODUCT
Delta, Catalog Number: MS18597 in combination with Scio, Scio Four, Scio Four Oxi plus, Scio Four Oxi, Scio Four plus.
Recall Number Z-1772-2017<p>
REASON
It was reported that a set low O2 alarm does not go off although the measured O2 level is below the alarm limit.<p>
RECALLING FIRM/MANUFACTURER
Draegar Medical Systems, Inc., Andover, MA on 3/28/2017. Voluntary: Firm Initiated recall is ongling. <p>
VOLUME OF PRODUCT IN COMMERCE
2156<p>
DISTRIBUTION
Nationwide and Internationally<p>

4/19/2017 Merge Hemo software Cl II
Company: Merge Healthcare, Inc.
Date of Enforcement Report 4/19/2017
Class II:<p>
PRODUCT
Merge Hemo software. The firm name on the labeling is Merge Healthcare, Hartland, WI. Merge Hemo monitors, measures, and records physiologic data from a human patient undergoing a cardiac

catheterization procedure
Recall Number Z-1778-2017<p>
REASON
Use of the software may show an incorrect value to the user when viewing the Fractional Flow Reserve (FFR) results during recording.<p>
RECALLING FIRM/MANUFACTURER
Merge Healthcare, Inc., Hartland, WI on 4/4/2016. Voluntary: Firm Initiated recall is ongling. <p>
VOLUME OF PRODUCT IN COMMERCE
24 sites potentially have the affected accessory<p>
DISTRIBUTION
Nationwide and Internationally<p>

4/19/2017 GE Vivid CI II
Company:GE Healthcare, LLC
Date of Enforcement Report 4/192017
Class II:<p>
PRODUCT
1. Vivid E95/E90/E80, H45581DC, H45581LB and H45581DA.
Recall Number Z-1779-2017
2. Vivid S60/S70/S60N/S70N, H45041SU, H45041SW, H45581MS, H45581PD.
Recall Number Z-1779-2017<p>
REASON
GE Healthcare has become aware of an issue where a patient other than the intended is incorrectly selected by the operator in situations where DICOM Worklist search response time is slow. This issue is limited to certain Vivid Ultrasound systems and can result in the incorrect patient information showing on the screen during the exam. If not detected by the operator, images from the actual (intended) patient will be stored under the incorrect patient after the exam. This issue could lead to misdiagnosis. There have been no injuries reported because of this issue.<p>
RECALLING FIRM/MANUFACTURER
GE Healthcare, LLC, Waukesha, WI on 3/10/2017. Voluntary: Firm Initiated recall is ongling. <p>
VOLUME OF PRODUCT IN COMMERCE
1. 971(412 US; 559 OUS)
2. 396 (67 US; 329 OUS)<p>
DISTRIBUTION
Nationwide and Internationally <p>

4/19/2017 Nihon Kohden America Bedside monitor CI II
Company:Nihon Kohden America, Inc
Date of Enforcement Report 4/192017
Class II:<p>
PRODUCT
Bedside monitor CSM-1901(Life Scope G9) with main unit CU-192RA. The Problem only affects CSM-1901(Life Scope G9) communicating with CNS-6201A (PU-621RA) and CNS-9701A (MU-971RA).
Recall Number Z-1768-2017<p>
REASON
The Pause function on central monitors will not automatically resume when connected to a Life Scope G9 patient monitor. <p>
RECALLING FIRM/MANUFACTURER
Nihon Kohden America, Inc., Irvine, CA on 3/13/2017. Voluntary: Firm Initiated recall is ongling. <p>
VOLUME OF PRODUCT IN COMMERCE
654 units total (230 units in US) <p>
DISTRIBUTION
Nationwide and Internationally <p>

4/19/2017 VITROS Immunodiagnostic Products, Cl II
Company:ORTHO-CLINICAL DIAGNOSTICS
Date of Enforcement Report 4/192017
Class II:<p>
PRODUCT
VITROS Immunodiagnostic Products NT-pro BNP Reagent Pack, REF/Catalog 680 2156, IVD --- Ortho-Clinical Diagnostics Pencoed, Bridgend CF35 5PZ, UK
Recall Number Z-1765-2017<p>
REASON
Increased frequency of calibration failures for VITROS Immunodiagnostic Products NT-proBNP Reagent Lots 1568, 1570, 1580 and 1590, due to background signals for these affected NT-proBNP lots that have been increasing with time since release testing, resulting in higher than expected VITROS Immunodiagnostic Products NT-proBNP level 1 calibrator signals produced, leading to calibration failures.<p>
RECALLING FIRM/MANUFACTURER
ORTHO-CLINICAL DIAGNOSTICS, FELINDRE MEADOWS ,Bridgend, United Kingdom on 3/7/2017. Voluntary: Firm Initiated recall is ongling. <p>
VOLUME OF PRODUCT IN COMMERCE
US: 6324; Foreign: 1868<p>
DISTRIBUTION
Nationwide and Internationally <p>

4/19/2017 PerkinElmer Specimen Gate Laboratory, Cl II
Company:PerkinElmer Life and Analytical Sciences, Wallac, OY
Date of Enforcement Report 4/192017
Class II:<p>
PRODUCT
Specimen Gate Laboratory; Product Number: 5002-0180 Specimen Gate Laboratory is intended for use as a data processing software used in the storage, retrieving, and processing of laboratory data.
Recall Number Z-1761-2017<p>
REASON
"Roche Diagnostics Corp. initiated a voluntary correction because a rack crash may occur on the Cobas 8100 bi-directional reformatter (BRF) and uni-directional reformatter (URF) modules with software version 02-xx, only when rack buffering is activated and the rack buffer is completely full. This issue can lead to sample spillage, posing a potential risk to operators / laboratory staff due to exposure to potentially infectious material, cross-contamination of samples in the affected racks and erroneous results due to sample carry-over." <p>
RECALLING FIRM/MANUFACTURER
PerkinElmer Life and Analytical Sciences, Wallac, OY, Turku, Finland on 3/7/2017. Voluntary: Firm Initiated recall is ongling. <p>
VOLUME OF PRODUCT IN COMMERCE
29<p>
DISTRIBUTION
US including AL, AZ, AR, CA, CO, CT, FL, GA, IL, IN, KS, KY, LA, MD, MI, MO, NV, OH, OK, OR, TN, TX, VA; and Internationally to Canada and Brazil <p>

4/19/2017 Roche Cobas 8100 uni-directional reformatter
Cl II
Company:Roche Diagnostics Corporation
Date of Enforcement Report 4/192017
Class II:<p>
PRODUCT

Cobas 8100 uni-directional reformatter (BRF) module with Software Version 02-xx
Recall Number Z-1764-2017<p>
REASON
"Roche Diagnostics Corp. initiated a voluntary correction because a rack crash may occur on the Cobas 8100 bi-directional reformatter (BRF) and uni-directional reformatter (URF) modules with software version 02-xx, only when rack buffering is activated and the rack buffer is completely full. This issue can lead to sample spillage, posing a potential risk to operators / laboratory staff due to exposure to potentially infectious material, cross-contamination of samples in the affected racks and erroneous results due to sample carry-over." <p>
RECALLING FIRM/MANUFACTURER
Roche Diagnostics Corporation, Indianapolis, IN on 3/1/2017. Voluntary: Firm Initiated recall is ongling. <p>
VOLUME OF PRODUCT IN COMMERCE
45 <p>
DISTRIBUTION
Domestic: MA, IN, AL, OH, MO, NE, LA, CA, IA, NJ, AR, PA, SC, IL, TX, and MI. Foreign: None <p>

4/19/2017 Roche Cobas 8100 bi-directional reformatter, Cl II

Company:Roche Diagnostics Corporation
Date of Enforcement Report 4/192017
Class II:<p>
PRODUCT
Cobas 8100 bi-directional reformatter (BRF) module with Software Version 02-xx
Recall Number Z-1763-2017<p>
REASON
"Roche Diagnostics Corp. initiated a voluntary correction because a rack crash may occur on the Cobas 8100 bi-directional reformatter (BRF) and uni-directional reformatter (URF) modules with software version 02-xx, only when rack buffering is activated and the rack buffer is completely full. This issue can lead to sample spillage, posing a potential risk to operators / laboratory staff due to exposure to potentially infectious material, cross-contamination of samples in the affected racks and erroneous results due to sample carry-over." <p>
RECALLING FIRM/MANUFACTURER
Roche Diagnostics Corporation, Indianapolis, IN on 3/1/2017. Voluntary: Firm Initiated recall is ongling. <p>
VOLUME OF PRODUCT IN COMMERCE
45 units<p>
DISTRIBUTION
Domestic: MA, IN, AL, OH, MO, NE, LA, CA, IA, NJ, AR, PA, SC, IL, TX, and MI. Foreign: None <p>

4/19/2017 RayStation Radiation Therapy Treatment Plan Cl II

Company:RAYSEARCH LABORATORIES AB
Date of Enforcement Report 4/19/2017
Class II:<p>
PRODUCT
Radiation Therapy Treatment Planning System, Model 4.5, 4.7, 5.0 RayStation is a software system designed for treatment planning and analysis of radiation therapy. The treatment plans provide treatment unit set-up parameters and estimates of dose distributions expected during the proposed treatment, and may be used to administer treatments after review and approval by the intended user. The system functionality can be configured based on user need
Recall Number Z-1815-2017<p>
REASON

An error in NVIDIA GPU (Graphics Processing Unit) card drivers can occur for certain software programs. In a non-standard Citrix environment where the GPU settings are configured with a virtual Citrix graphics board (graphics card) an erroneous calculation may be allowed.<p>
RECALLING FIRM/MANUFACTURER
RAYSEARCH LABORATORIES AB, Stockholm, Sweden on 1/18/2017 Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
741 units<p>
DISTRIBUTION
Nationwide <p>

4/12/2017 eCare Coordinator, Cl II
Company:Philips Visicu
Date of Enforcement Report 4/12/2017
Class II:<p>
PRODUCT
eCare Coordinator Product Usage: is software intended for use in data aggregation, patient interaction facilitation, storage and clinical information management with independent physiological devices and ancillary systems that are connected either directly or through networks. The software is intended to provide patient information from the patient location through networking technology to a remote care team. eCare Coordinator does not send any real time alarms and is not intended to provide automated treatment decisions. This software is an informational tool only and is not to be used as a substitute for professional judgment of healthcare providers in diagnosing and treating patients.
Recall Number Z-1708-2017<p>
REASON
eCareCoordinator (eCC) is intended for use in data aggregation, patient interaction facilitation, storage and clinical information management with independent physiological devices and ancillary systems that are connected either directly or through networks. The software is intended to provide patient information from the patient location through networking technology to a remote care team. A software defect was discovered in the Philips eCareCoordinator (eCC) Clinical User Interface that can at times cause missing or redundant data to be saved without notification to the user. <p>
RECALLING FIRM/MANUFACTURER
Philips Visicu, Baltimore, MD on 3/2/2017. Voluntary: Firm Initiated recall is ongling. <p>
VOLUME OF PRODUCT IN COMMERCE
26<p>
DISTRIBUTION
Nationwide <p>

4/12/2017 Philips IntelliVue Patient Wearable Monitor, Cl II
Company:Philips Electronics North America Corporation
Date of Enforcement Report 4/12/2017
Class II:<p>
PRODUCT
Philips IntelliVue MX4O WLAN Patient Wearable MonitorProduct: 865352Exchange part (service numbers):453564615311 TELE PWM,802.lla/b/g,ECG only, US only453564615331 TELE PWM,802.1 1 a/b/g,ECG&Sp02, US onlyProduct Usage:Indicated for use by health care professionals whenever there is a need for monitoring the physiological parameters of patients.
Recall Number Z-1707-2017<p>
REASON
Philips IntelliVue MX4O WLAN Patient Wearable Monitor may not automatically switch to Monitor Mode with audible alarms when association with central monitoring system is unsuccessful [incomplete]<p>
RECALLING FIRM/MANUFACTURER

Philips Electronics North America Corporation, Andover, MA on 3/6/2017. Voluntary: Firm Initiated recall is ongling. <p>
VOLUME OF PRODUCT IN COMMERCE
2648<p>
DISTRIBUTION
Nationwide and Internationally<p>

4/5/2017 MergeiConnect Enterprise Archive (ICEA) sw
Cl II
Company: Merge Healthcare, Inc.
Date of Enforcement Report 4/5/2017
Class II:<p>
PRODUCT
iConnect Enterprise Archive (ICEA) software. iConnect Enterprise Archive is intended for use as a vendor neutral archive for storage and communications of medical images and data
Recall Number Z-1697-2017<p>
REASON
The study is archived but cannot be opened in iConnect Access and cannot send to PACS resulting in comparison studies not being available for physician review to determine the progression of disease.<p>
RECALLING FIRM/MANUFACTURER
Merge Healthcare, Inc., Hartland, WI on 4/4/2016. Voluntary: Firm Initiated recall is ongling. <p>
VOLUME OF PRODUCT IN COMMERCE
289 sites potentially have the affected accessory<p>
DISTRIBUTION
Nationwide and Internationally<p>

4/5/2017 Merge iConnect Enterprise Archive software,
Cl II
Company: Merge Healthcare, Inc.
Date of Enforcement Report 4/5/2017
Class II:<p>
PRODUCT
iConnect Enterprise Archive software
Recall Number Z-1700-2017<p>
REASON
The versions allow images to be stored without pixel data, resulting in the system not being able to present all the prior studies, which could cause a delay in treatment in determining the progression of disease.<p>
RECALLING FIRM/MANUFACTURER
Merge Healthcare, Inc., Hartland, WI on 4/4/2016. Voluntary: Firm Initiated recall is ongling. <p>
VOLUME OF PRODUCT IN COMMERCE
371 sites potentially have the affected accessory<p>
DISTRIBUTION
Distribution was nationwide to medical facilities. Foreign distribution was made to Canada, as well as other countries. Government and military distribution was also made.<p>

4/5/2017 Siemens Syngo.via, Cl II
Company: Siemens Medical Solutions USA, Inc
Date of Enforcement Report 4/5/2017
Class II:<p>
PRODUCT
Syngo.via Picture archiving and communication system Syngo via is a software solution intended to be

used for viewing, manipulation, communication, and storage of medical images.
Recall Number Z-1689-2017<p>
REASON
Software changes now available to address several issues<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc., Malvern, PA on 3/6/2017. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
104 systems<p>
DISTRIBUTION
Nationwide Distribution <p>

4/5/2017 Siemens Syngo.x, Cl II
Company: Siemens Medical Solutions USA, Inc
Date of Enforcement Report 4/5/2017
Class II:<p>
PRODUCT
Syngo.x, Picture archiving and communication system Syngo via is a software solution intended to be used for viewing, manipulation, communication, and storage of medical images.
Recall Number Z-1688-2017<p>
REASON
Software changes now available to address several issues<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc., Malvern, PA on 3/6/2017. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
104 systems<p>
DISTRIBUTION
Nationwide Distribution <p>

4/5/2017 SynchroMed II implantable drug infusion pump Cl II
Company: Medtronic Neuromodulation
Date of Enforcement Report 4/5/2017
Class II:<p>
PRODUCT
SynchroMed II implantable drug infusion pump, Model 8637-40,
Recall Number Z-1694-2017<p>
REASON
Medtronic received a complaint that there was an error code displayed on the programmer when the physician attempted to interrogate an implanted SynchroMed II pump. The error code prevented the physician from updating the pump; however the pump was providing therapy.<p>
RECALLING FIRM/MANUFACTURER
Medtronic Neuromodulation, Minneapolis, MN on 2/9/2017. Voluntary: Firm Initiated recall is ongling. <p>
VOLUME OF PRODUCT IN COMMERCE
1 unit<p>
DISTRIBUTION
IL<p>

4/5/2017 Philips V60 Ventilator, Cl II
Company:Respironics California Inc, Inc.
Date of Enforcement Report 4/5/2017
Class II:<p>
PRODUCT
Philips V60 Ventilator with Version 2.20 Software, Description: V 60 Ventilator,Intl Opt: CFLEX,AVAPS,PPV V60 Ventilator,Intl Opt: CFLEX,AVAPS V60 Ventilator,Intl Opt: None V60 Ventilator,English Opt: None V60 Ventilator,Engl Opt: CFLEX,AVAPS V60 Us Demo Unit V60 USED ENGL OPT:CFLEX, AVAPS,PPV,AT+cl V60 VENT, JAPAN OPT: CFLEX, AVAPS, AT+ V60 VENT, JAPAN OPT: CFLEX, AVAPS, AT+ Catalog/REF No. 1053613, 1053614, 1053615, 1053616, 1053617, DU1053617, U1053617, 1076709, R107670
Recall Number Z-1687-2017<p>
REASON
The V60 Ventilator with Version 2.20 software installed may falsely detect that the blower motor has stalled. If this condition occurs, the software will cause the ventilator to shut down (Vent Inop) and display Error Code 100E. Ventilatory support will cease.<p>
RECALLING FIRM/MANUFACTURER
Respironics California Inc., Carlsbad, CA on 2/1/2017. Voluntary: Firm Initiated recall is ongling. <p>
VOLUME OF PRODUCT IN COMMERCE
2512 units<p>
DISTRIBUTION
Nationwide and Internationally<p>

4/5/2017 Hospira Plum 360 Infusion Pump, Cl II
Company: Hospira, Inc.
Date of Enforcement Report 4/5/2017
Class II:<p>
PRODUCT
Plum 360 Infusion Pump, Software Version 15.02. The infusion pump is capable of delivering fluids for a variety of therapies such as parenteral, enteral, or epidural infusions
Recall Number Z-1682-2017<p>
REASON
Depleted Battery alarm shows instead of Replace Battery. On battery power, ongoing therapy stops, alarms show and sound, pump shuts down after 3 minutes. On AC power, the pump reboots (takes about 25 seconds). Therapy can resume. AC power interruption of 3-7 seconds prompts an incorrect E323 alarm, ongoing therapy stop, and pump reboot. Longer power loss results in battery power operation.<p>
RECALLING FIRM/MANUFACTURER
Hospira, Inc., Lake Forest, IL on 12/30/2016. Voluntary: Firm Initiated recall is ongling. <p>
VOLUME OF PRODUCT IN COMMERCE
862,847 units<p>
DISTRIBUTION
Nationwide and Internationally<p>

3/29/2017 Merge Cardio software., Cl II
Company: Merge Healthcare, Inc.
Date of Enforcement Report 3/29/2017
Class II:<p>
PRODUCT
Merge Cardio software. Product Usage: Merge Cardio is a system intended to be used to acquire, store, print, transfer, and archive clinical information including images, Hemodynamic studies and reports, measurements (via import from DICOM Structured Reporting, text files or optical character recognition of measurements captured on images) and cardiology signal (waveform) data..

Recall Number Z-1517-2017<p>
REASON
Users can merge a device import file with an image study that already has a confirmed report, which may result in including information not present at the time of physician interpretation.<p>
RECALLING FIRM/MANUFACTURER
Merge Healthcare, Inc., Hartland, WI on 9/22/2015. Voluntary: Firm Initiated recall is ongling. <p>
VOLUME OF PRODUCT IN COMMERCE
89 sites potentially have the affected accessory<p>
DISTRIBUTION
Nationwide sites.. Military distribution was also made. There was no foreign/government distribution.<p>

3/29/2017 Merge Cardio software with PID Cl II
Company: Merge Healthcare, Inc.
Date of Enforcement Report 3/29/2017
Class II:<p>
PRODUCT
Merge Cardio software with Issuer of Patient ID (IPID). The firm name on the label is Merge Healthcare, Hartland, WI.
Recall Number Z-1496-2017<p>
REASON
For sites using the Issuer of Patient ID (IPID), the system will display the study list and images from different patients with different IPIDs as though they are for the same patient if they all have the first name, last name, and medical record number in common.<p>
RECALLING FIRM/MANUFACTURER
Merge Healthcare, Inc., Hartland, WI on 9/22/2015. Voluntary: Firm Initiated recall is ongling. <p>
VOLUME OF PRODUCT IN COMMERCE
11 sites potentially have the affected accessory<p>
DISTRIBUTION
US Distribution was made to medical facilities located in GA, IL, MD, MI, MO, OH, TN, and VT. There was no foreign/government/military distribution.<p>

3/29/2017 ONCOR" Expression,Impression,Impression Plus Cl II
Company: Siemens Medical Solutions USA, Inc
Date of Enforcement Report 3/29/2017
Class II:<p>
PRODUCT
ONCOR" Expression ONCOR" Impression ONCOR" Impression plus
Recall Number Z-1491-2017<p>
REASON
Software updates<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc., Malvern, PA on 2/14/2017. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
80 systems<p>
DISTRIBUTION
Nationwide Distribution <p>

3/29/2017 Siemens ONCOR" Avant-garde, Cl II
Company: Siemens Medical Solutions USA, Inc
Date of Enforcement Report 3/29/2017
Class II:<p>
PRODUCT
ONCOR" Avant-garde
Recall Number Z-1490-2017<p>
REASON
Software updates<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc., Malvern, PA on 2/14/2017. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
80 systems<p>
DISTRIBUTION
Nationwide Distribution <p>

3/29/2017 Siemens ARTISTE" MV System, Cl II
Company: Siemens Medical Solutions USA, Inc
Date of Enforcement Report 3/29/2017
Class II:<p>
PRODUCT
ARTISTE" MV System
Recall Number Z-1488-2017<p>
REASON
Software updates<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc., Malvern, PA on 2/14/2017. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
80 systems<p>
DISTRIBUTION
Nationwide Distribution <p>

3/29/2017 Siemens Syngo.plaza., Cl II
Company: Siemens Medical Solutions USA, Inc
Date of Enforcement Report 3/29/2017
Class II:<p>
PRODUCT
Syngo.plaza, Picture Archiving and Communications System (PACS)Syngo.plaza is a Picture Archiving and Communication System (PACS) intended to display, process, read, report, communicate, distribute, store and archive digital medical images. It supports the physician in diagnosis and treatment planning.
Recall Number Z-1533-2017<p>
REASON
Software updates<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc., Malvern, PA on 2/20/2017. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
13<p>
DISTRIBUTION
ationwide Distribution to MO,TX, FL, MA, WI, PA, IN, and CA<p>

3/29/2017 Siemens ADVIA Centaur XPT System, Cl II
Company: Siemens Healthcare Diagnostics, Inc
Date of Enforcement Report 3/29/2017
Class II:<p>
PRODUCT
The ADVIA Centaur XPT System is a stand-alone, continuous operation, immunochemistry analyzer that performs the following functions: aspirates and dispenses samples; Performs dilutions; Adds reagents; Incubates reaction vessels; Separates solid and liquid wastes; Measures photon emissions; Performs data reduction; Collects and maintains patient demographics and results. Siemens has identified multiple software issues affecting multiple versions of the software used by this analyzer system.
Recall Number Z-1537-2017<p>
REASON
Siemens Healthcare Diagnostics has identified multiple software issues for all the ADVIA Centaur XPT System Software Versions V1.0.1, V1.0.2, V1.0.3, V1.1 and V1.2. These issues may affect the operation and workflow of the system. The potential exists for an apparent delay to testing when these issues occur. The software issues affecting the analyzer may potentially impact all analytes available on the ADVIA Centaur XPT System test menu.<p>
RECALLING FIRM/MANUFACTURER
Siemens Healthcare Diagnostics, Inc., Tarrytown, NY on 2/2/2017. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
US: 17 units; Foreign: 712 units<p>
DISTRIBUTION
Nationwide and Internationally<p>

3/29/2017 Zimmer Biomet Orthosize Templating, Cl II
Company: Zimmer Biomet, Inc.
Date of Enforcement Report 3/29/2017
Class II:<p>
PRODUCT
Orthosize Templating Version 1.2.6 Echo Bi-Metric Hip Stem Digital Templates. For preoperative planning of orthopedic surgery.
Recall Number Z-1495-2017<p>
REASON
Digital templates were created with the incorrect files.<p>
RECALLING FIRM/MANUFACTURER
Zimmer Biomet, Inc., Warsaw, IN on 2/14/2017. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
3232<p>
DISTRIBUTION
Nationwide and Internationally<p>

3/29/2017 Merge Cardio software., Cl II
Company: Merge Healthcare, Inc.
Date of Enforcement Report 3/29/2017
Class II:<p>
PRODUCT
Merge Cardio software..
Recall Number Z-1486-2017<p>
REASON
Cardio study list does not show STAT studies without refreshing.<p>

RECALLING FIRM/MANUFACTURER
Merge Healthcare, Inc., Hartland, WI on 4/4/2016. Voluntary: Firm Initiated recall is ongling. <p>
VOLUME OF PRODUCT IN COMMERCE
217 sites potentially have the affected accessory<p>
DISTRIBUTION
USA (nationwide) Distribution to medical facilities. Military distribution was also made. There was no foreign/government distribution.<p>

3/29/2017 EyeSuite i.8.2.1.0 Software, Cl II
Company: Haag-Streit USA Inc
Date of Enforcement Report 3/29/2017
Class II:<p>
PRODUCT
EyeSuite i.8.2.1.0 Software for ophthalmic use including selection of Intra Ocular Lenses (IOLs).
Recall Number Z-1500-2017<p>
REASON
There is a possibility for data to be stored under the wrong patient on the DICOM Server following a non-standard workflow.<p>
RECALLING FIRM/MANUFACTURER
Haag-Streit USA Inc., Mason OH on 1/5/2017. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
163<p>
DISTRIBUTION
Nationwide <p>

3/29/2017 Nidek Final Fit Software, Cl II
Company: Nidek Inc
Date of Enforcement Report 3/29/2017
Class II:<p>
PRODUCT
Final Fit Software Version 1.11 and 1.12; PC Based software installed outside Nidek EC-5000 Excimer Laser System. Ophthalmic laser system use for correction of corneal refraction and ablation of the corneal surface. The system is composed of a laser generator which produces an excimer laser radiation of wavelength 193nm, a beam delivery unit, an optical system for observation, a gas system and a computer for system control
Recall Number Z-1594-2017<p>
REASON
During treatment planning, the procedure was programmed with an unintended (wrong) correction.<p>
RECALLING FIRM/MANUFACTURER
Nidek Inc, Fremont, CA on 2/1/2017. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
29<p>
DISTRIBUTION
Nationwide Distribution to MN, NV, OH, NC, CA, CO, CA, GA, VA, MI, AZ, PA, TN, WA, TX, NY.<p>

3/29/2017 Hitachi Echelon MRI System, Cl II
Company: Hitachi Medical Systems America Inc
Date of Enforcement Report 3/29/2017
Class II:<p>
PRODUCT
Hitachi Oasis MRI System
Recall Number Z-1542-2017<p>
REASON

Image data transferred from the MRI system to a workstation showed errors on the slice position reference image.<p>
RECALLING FIRM/MANUFACTURER
Hitachi Medical Systems America Inc., Twinsburg, OH on 4/16/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
68 units<p>
DISTRIBUTION
Nationwide and Internationally<p>

3/29/2017 Hitachi Oasis MRI System, Cl II
Company: Hitachi Medical Systems America Inc
Date of Enforcement Report 3/29/2017
Class II:<p>
PRODUCT
Hitachi Oasis MRI System
Recall Number Z-1540-2017<p>
REASON
Image data transferred from the MRI system to a workstation showed errors on the slice position reference image.<p>
RECALLING FIRM/MANUFACTURER
Hitachi Medical Systems America Inc., Twinsburg, OH on 4/16/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
210 units<p>
DISTRIBUTION
Nationwide and Internationally<p>

3/29/2017 Merge Eye Station Import Utility Cl II
Company: Merge Healthcare, Inc.
Date of Enforcement Report 3/29/2017
Class II:<p>
PRODUCT
Merge Eye Station Import Utility (ESIU). The firm name on the labeling is Merge Healthcare.
Recall Number Z-1498-2017<p>
REASON
System locks up which may result in potential patient injury or delay in diagnosis or treatment.<p>
RECALLING FIRM/MANUFACTURER
Merge Healthcare, Inc., Hartland, WI on 4/4/2016. Voluntary: Firm Initiated recall is ongling. <p>
VOLUME OF PRODUCT IN COMMERCE
78 sites potentially have the affected accessory<p>
DISTRIBUTION
USA (nationwide) Distribution to medical facilities. Government distribution was also made. Foreign distribution was made to Canada. There was no military distribution.<p>

3/29/2017 Arial Wireless Water-Resistant Call Pendant,
Cl II
Company: Stanley Security Solutions Inc.
Date of Enforcement Report 3/29/2017
Class II:<p>
PRODUCT
Arial Wireless Water-Resistant Call Pendant The Arial Pendant tag is part of the Arial wireless emergency call management system. It enables residents in assisted living, skilled nursing or

independent living to call staff with the press of a button.
Recall Number Z-1499-2017<p>
REASON
Devices were incorrectly programmed during manufacturing therefore depressing the pendant button may result in an alarm not sounding as intended.<p>
RECALLING FIRM/MANUFACTURER
Stanley Security Solutions Inc., Lincoln, NE on 6/22/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
500 individual pendants<p>
DISTRIBUTION
Nationwide <p>

3/29/2017 Alaris System PC unit, CI II
Company: CareFusion 303, Inc.
Date of Enforcement Report 3/29/2017
Class II:<p>
PRODUCT
Alaris System PC unit, model no. 8000 and 8015. The central programming, monitoring and power supply component for the Alaris infusion pump System.
Recall Number Z-1520-2017<p>
REASON
Reports where the Low Battery alarm and/or the Very Low Battery alarm are not being triggered before the battery is discharged and all infusion channels are stopped<p>
RECALLING FIRM/MANUFACTURER
CareFusion 303, Inc., San Diego, CA on 11/1/2016. Voluntary: Firm Initiated recall is ongling. <p>
VOLUME OF PRODUCT IN COMMERCE
613,800 total units (575,221 units in US)<p>
DISTRIBUTION
Nationwide and Internationally.<p>

3/22/2017 Merge iConnect Enterprise Archive CI II
Company: Merge Healthcare, Inc.
Date of Enforcement Report 3/22/2017
Class II:<p>
PRODUCT
iConnect Enterprise Archive when used with RadSuite. The firm name on the label is Merge Healthcare
Recall Number Z-1470-2017<p>
REASON
The software produced a number of "do not route" exceptions, which may result in potential patient injury or delay in diagnosis or treatment..<p>
RECALLING FIRM/MANUFACTURER
Merge Healthcare, Inc., Hartland, WI on 4/4/2016. Voluntary: Firm Initiated recall is ongling. <p>
VOLUME OF PRODUCT IN COMMERCE
187 sites potentially have the affected versions<p>
DISTRIBUTION
USA (nationwide) Distribution to medical facilities. Government distribution was also made. There was no foreign or military distribution.<p>

3/22/2017 Philips BrightView X Cl II
Company: Philips Medical Systems, Inc.
Date of Enforcement Report 3/22/2017
Class II:<p>
PRODUCT
BrightView Xdesigned for single or dual detector nuclear imaging accommodating a range of ECT studies. In addition it can be used to perform planar static, dynamic, gated, total body, circular-orbit and noncircular orbit SPECT, gated SPECT (circular and noncircular)studies, computer-programmed protocol strings, and reference scans (dual detectors). .
Recall Number Z-1481-2017<p>
REASON
Four issues: 1. Motion controller problem stops scan and no data image produced. 2. Door interlock switch problem disables CT scan. 3. Detector contacts head holder when performing Patient Unload. 4. JETStream freezes during gated planar scan<p>
RECALLING FIRM/MANUFACTURER
Philips Medical Systems, Inc., Cleveland, OH on 1/31/2017. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
1218 total<p>
DISTRIBUTION
Nationwide and Internationally<p>

3/22/2017 PhilipsBrightView Cl II
Company: Philips Medical Systems, Inc.
Date of Enforcement Report 3/22/2017
Class II:<p>
PRODUCT
882480: BrightView designed for single or dual detector nuclear imaging accommodating a range of ECT studies. In addition it can be used to perform planar static, dynamic, gated, total body, circular-orbit and noncircular orbit SPECT, gated SPECT (circular and noncircular)studies, computer-programmed protocol strings, and reference scans (dual detectors). .
Recall Number Z-1480-2017<p>
REASON
Four issues: 1. Motion controller problem stops scan and no data image produced. 2. Door interlock switch problem disables CT scan. 3. Detector contacts head holder when performing Patient Unload. 4. JETStream freezes during gated planar scan<p>
RECALLING FIRM/MANUFACTURER
Philips Medical Systems, Inc., Cleveland, OH on 1/31/2017. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
1218 total<p>
DISTRIBUTION
Nationwide and Internationally<p>

3/22/2017 Philips BrightView XCT 882454 Cl II
Company: Philips Medical Systems, Inc.
Date of Enforcement Report 3/22/2017
Class II:<p>
PRODUCT
BrightView XCT 882454 BrightView X upgrade to XCT, designed for single or dual detector nuclear imaging accommodating a range of ECT studies. In addition it can be used to perform planar static, dynamic, gated, total body, circular-orbit and noncircular orbit SPECT, gated SPECT (circular and noncircular)studies, computer-programmed protocol strings, and reference scans (dual detectors). .

Recall Number Z-1479-2017<p>
REASON
Four issues: 1. Motion controller problem stops scan and no data image produced. 2. Door interlock switch problem disables CT scan. 3. Detector contacts head holder when performing Patient Unload. 4. JETStream freezes during gated planar scan<p>
RECALLING FIRM/MANUFACTURER
Philips Medical Systems, Inc., Cleveland, OH on 1/31/2017. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
1218 total<p>
DISTRIBUTION
Nationwide and Internationally<p>

3/22/2017 Merge Hemo software Cl II
Company: Merge Healthcare, Inc.
Date of Enforcement Report 3/22/2017
Class II:<p>
PRODUCT
Merge Hemo software. Product Usage: Merge Hemo is a hemodynamic monitoring system that records and displays physiological data.
Recall Number Z-1457-2017<p>
REASON
In some instances, the system will lock tabs within a study, even when a second user does not have the study open on a different workstation..<p>
RECALLING FIRM/MANUFACTURER
Merge Healthcare, Inc., Hartland, WI on 4/4/2016. Voluntary: Firm Initiated recall is ongling. <p>
VOLUME OF PRODUCT IN COMMERCE
361 sites potentially have the affected versions<p>
DISTRIBUTION
Nationwide<p>

3/22/2017 CADD Solis VIP Ambulatory Infusion Pump
Cl II
Company: Smiths Medical ASD, Inc.
Date of Enforcement Report 3/22/2017
Class II:<p>
PRODUCT
CADD Solis VIP Ambulatory Infusion Pump, Model 21-21210, Reorder 21-2120-0102-15,
Recall Number Z-1439-2017<p>
REASON
I20 Pumps sold to the Finnish market contain a message in which one word in the message is mistranslated. When the user follows a specific set of key presses the pump will display the incorrect message. The message indicates that a Patient Controlled Analgesia (PCA) dose is unavailable because the pump is running. It should indicate that the PCA dose is not available because the pump is stopped. The function of the pump is unchanged and no patient injury can occur since no drug is being delivered.<p>
RECALLING FIRM/MANUFACTURER
Smiths Medical ASD, Inc., St Paul, MN on 10/31/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
20<p>
DISTRIBUTION
Internationally to Finland<p>

3/15/2017 Merge Cardio software Cl II
Company: Merge Healthcare, Inc.
Date of Enforcement Report 3/15/2017
Class II:<p>
PRODUCT
Merge Cardio software
Recall Number Z-1403-2017<p>
REASON
When taking measurements from images on the Cardio workstation or from the US cart, numbers are not crossing to the report in the correct unit of measure.<p>
RECALLING FIRM/MANUFACTURER
Merge Healthcare, Inc., Hartland, WI on 4/4/2016. Voluntary: Firm Initiated recall is ongling. <p>
VOLUME OF PRODUCT IN COMMERCE
110 sites potentially have the affected versions<p>
DISTRIBUTION
US Distribution was made to medical facilities in CA, FL, IL, MD, MO, OH, OK, TX, VT, and WI. Military distribution was also made.<p>

3/15/2017 Merge Cardio software using EchoIMS Cl II
Company: Merge Healthcare, Inc.
Date of Enforcement Report 3/15/2017
Class II:<p>
PRODUCT
Merge Cardio software using EchoIMS
Recall Number Z-1415-2017<p>
REASON
A situation can occur allowing two physicians to access the same study report in EchoIMS when launched from the Cardio Study List without receiving the read-only notification prompt.<p>
RECALLING FIRM/MANUFACTURER
Merge Healthcare, Inc., Hartland, WI on 4/4/2016. Voluntary: Firm Initiated recall is complete. <p>
VOLUME OF PRODUCT IN COMMERCE
17
sites potentially have the affected versions<p>
DISTRIBUTION
US Distribution was made to medical facilities in CA, FL, IL, MD, MO, OH, OK, TX, VT, and WI. Military distribution was also made.<p>

3/15/2017 LIFEPAK 1000 defibrillator Class I
Company:Physio-Control, Inc.
Date of Enforcement Report 3/15/2017
Class I<p>
PRODUCT
The LIFEPAK 1000 defibrillator is intended for use by personnel who are authorized by a physician/medical director and are trained in CPR and the use of the LIFEPAK 1000 defibrillator.
Recall Number Z-1257-2017<p>
REASON
The firm has received complaints that the LIFEPAK 1000 Defibrillator is unexpectedly powering off during device usage.<p>
RECALLING FIRM/MANUFACTURER
Physio-Control, Inc. REdmond, WA on 1/13/2017. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
total 133,330 units (50,046 units in the US)<p>
DISTRIBUTION

Nationwide and Internationally<p>

3/8/2017 McKesson Radiology 12.2 - PACS Cl II
Company: Mckesson Medical Imaging
Date of Enforcement Report 3/8/2017
Class II:<p>
PRODUCT
McKesson Radiology 12.2 - Picture Archive Communication System (PACS).
Recall Number Z-1245-2017<p>
REASON
Issue for customers that use an EMR login or legacy web URL login or legacy web URL login for McKesson Radiology PACS that may result in missing images in a newly imported study, and/or study imports that remain in an "in-progress" status.<p>
RECALLING FIRM/MANUFACTURER
Mckesson Medical Imaging, Richmond, Canada on 12/2/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
17<p>
DISTRIBUTION
AK, CA, FL, HI, KY, MD, MI, MS, NH, OH, PA, TN, TX, VT<p>

3/8/2017 Medtronic SynchroMed Infusion System Class I
Company:Medtronic Neuromodulation
Date of Enforcement Report 3/8/2017
Class I<p>
PRODUCT
Medtronic SynchroMed II Implantable Drug Infusion System. This system includes: Model 8870 Software Application Card, Model 8840 N'Vision Clinician Programmer, and Model 8637 SynchroMed II Implantable Drug Infusion Pump (supplied in 20 ml or 40 ml reservoir size.)
Recall Number Z-0788-2017<p>
REASON
Medtronic is following up to a May 2013 communication regarding the Priming Bolus function for the SynchroMed Infusion System. Medtronic is updating the Model 8870 software application card (to version AAU01) and the Synchro<p>
RECALLING FIRM/MANUFACTURER
Medtronic Neuromodulation, Minneapolis, MN on 10/3/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
22,298 software cards<p>
DISTRIBUTION
Nationwide and Internationally<p>

3/1/2017 Philips Efficia CMS200 Cl II
Company: Philips Electronics North America Corporation
Date of Enforcement Report 3/1/2017
Class II:<p>
PRODUCT
Philips Efficia CMS200 Central Monitoring System; 863352 The Efficia CMS200 central monitoring system is intended for use by healthcare professionals for central viewing of physiologic waves, parameters, and trends from other networked medical devices (patient monitors and vital signs monitors) for multiple patients. It provides secondary operator notification of alarms from other networked medical devices. It provides for the retrospective review of alarm conditions, physiologic

waves and parameters from multiple patients. The intended use of the printer, when present, is to provide hardcopy text, graphics, and wave data. The Efficia CMS200 may provide for connection and information exchange to external systems. The Efficia CMS200 is intended for use in hospitals and out of hospital patient care settings (such as clinics, outpatient surgery facilities, long-term care facilities and physician offices) in which care is administered by healthcare professionals
Recall Number Z-1229-2017<p>
REASON
The monitor may not alarm appropriately for a pediatric or neonatal patient.<p>
RECALLING FIRM/MANUFACTURER
Philips Electronics North America Corporation, Andover, MA on 1/17/2017. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
158<p>
DISTRIBUTION
Internationally<p>

3/1/2017 Keyspan High-High Speed USB to Serial Adap
Cl II
Company: Tosoh Smd Inc
Date of Enforcement Report 3/1/2017
Class II:<p>
PRODUCT
Keyspan High-High Speed USB to Serial Adapter Product Usage: The Reporting Software is an application which serves as middle ware between the Tosoh Automated HPLC G8 analyzer and an LIS or as a stand alone data repository for the analyzer.
Recall Number Z-1245-2017<p>
REASON
Power outages causes reporting software to shutdown.<p>
RECALLING FIRM/MANUFACTURER
Tosoh Smd Inc., Grove City, OH on 12/22/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
34<p>
DISTRIBUTION
Nationwide <p>

3/1/2017 Merge Eye Station Import Utility (ESIU) Cl II
Company: Merge Healthcare, Inc.
Date of Enforcement Report 3/1/2017
Class II:<p>
PRODUCT
Merge Eye Station Import Utility (ESIU) when used with Merge Eye Station and Merge Eye Care PACS. The firm name on the labeling is Merge Healthcare, Hartland, WI.
Recall Number Z-1246-2017<p>
REASON
Eye Station images were not importing properly and were imported under "unknown" due to an issue when validating patients using only an Medical Record Number (MRN)<p>
RECALLING FIRM/MANUFACTURER
Merge Healthcare, Inc., Hartland, WI on 3/28/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
1,627 sites potentially have the affected versions<p>
DISTRIBUTION
Nationwide and Internationally<p>

2/22/2017 VIDAS 3 software v. 1.1.4 CI II
Company: BioMerieux SA
Date of Enforcement Report 2/22/2017
Class II:<p>
PRODUCT
VIDAS 3 software v. 1.1.4
Recall Number Z-1200-2017<p>
REASON
During development of the VIDAS 3 software version 1.2, some anomalies have been identified and observed to be already present in the current software version VIDAS 3 version 1.1.4. available in the field.<p>
RECALLING FIRM/MANUFACTURER
BioMerieux SA Chemin De L'Orme, France on 1/11/2017. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
1161 units<p>
DISTRIBUTION
Nationwide <p>

2/22/2017 Siemens CentraLink Data Management System SW CI II
Company: Siemens Healthcare Diagnostics, Inc.
Date of Enforcement Report 2/22/2017
Class II:<p>
PRODUCT
CentraLink¿ Data Management System Software Versions: v13x,v14x,v15xThe CentraLink system software is a network solution provider and multi-system data manager for the instruments and lab automation systems (LAS) within the lab. The CentraLink software consolidates data from all connected instruments so that an operator can review and edit patient and quality
Recall Number Z-1204-2017<p>
REASON
There is a remote possibility CentraLink may download an order to the ADVIA Automation System without specifying the sample type. This can occur when an order is received from the LIS without a sample type, requiring that the sample type be set in CentraLink based on the sample type of the test in the order.<p>
RECALLING FIRM/MANUFACTURER
Siemens Healthcare Diagnostics, Inc., Tarrytown, NY on 11/29/2016 Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
3,893 units<p>
DISTRIBUTION
Nationwide and Internationally <p>

2/15/2017 Boston Scientific, EMBLEM S-ICD Programmer CI II
Company: Boston Scientific Corporation
Date of Enforcement Report 2/152017
Class II:<p>
PRODUCT
Merge Eye Station. f/k/a: DFC-1024 & DFC-512 Digital Imaging System, WinStation, and WinStation Retinal Imager distributed by Ophthalmic Imaging Systems (OIS). Model number 136 T1700 Capture Stations & 46 T5810 Capture Station
Recall Number Z-1178-2017<p>

REASON
There is a potential for radio frequency (RF) interference to alter wireless communication from a programmer, which in rare instances may cause an S-ICD to perform an unintended command. This behavior can only occur during an active, in-clinic interrogation/programming session with the Model 3200 S-ICD programmer. There is no risk of this behavior occurring when the LATITUDE Patient Management System communicates with an S-ICD in an ambulatory setting.<p>
RECALLING FIRM/MANUFACTURER
Boston Scientific Corporation, Saint Paul, MN 55112-5700 on 1/12/2017. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
4500<p>
DISTRIBUTION
Nationwide and Internationally<p>

2/15/2017 Merge PACS software. CI II
Company: Merge Healthcare, Inc.
Date of Enforcement Report 2/152017
Class II:<p>
PRODUCT
Merge PACS software. The firm name on the label is Merge Healthcare, Hartland, WI.
Recall Number Z-1176-2017<p>
REASON
Potential exists for an incorrect patient image being displayed which could result in the delay in diagnosis or treatment.<p>
RECALLING FIRM/MANUFACTURER
Merge Healthcare, Inc., Hartland, WI on 4/4//2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
29 sites have the potentially affected software<p>
DISTRIBUTION
Distribution was made to medical facilities in AZ, CA, CO, FL, HI, IL, MA, MD, MI, MO, NY, OH, PA, SC, TN, UT, and WI. There was no foreign/government/military distribution.<p>

2/15/2017 Merge RadSuite software CI II
Company: Merge Healthcare, Inc.
Date of Enforcement Report 2/152017
Class II:<p>
PRODUCT
Merge RadSuite software. The firm name on the label is Merge Healthcare, Hartland, WI.
Recall Number Z-1180-2017<p>
REASON
The values provided from the Pixel Value tool do not appear to be correct, which may result in potential patient injury or delay in diagnosis or treatment..<p>
RECALLING FIRM/MANUFACTURER
Merge Healthcare, Inc., Hartland, WI on 11/17/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
8 sites have the potentially affected version<p>
DISTRIBUTION
US Distribution was made to medical facilities in AL, IN, MI, PA and WI.<p>

2/15/2017 LIFEPAK 15 Monitor/Defibrillator Cl II
Company: Physio-Control, Inc.
Date of Enforcement Report 2/15/2017
Class II:<p>
PRODUCT
LIFEPAK 15 Monitor/Defibrillator with End-Tidal CO2 option. Intended for use by trained medical personnel in out-of-doors and indoor emergency care settings within the environmental conditions specified in the Operating Instructions.
Recall Number Z-1144-2017<p>
REASON
The End-Tidal CO2 (EtCO2) reading can intermittently show a value of XXX after start-up or during device operation.<p>
RECALLING FIRM/MANUFACTURER
Physio-Control, Inc., Redmond, WA on 1/16/2017. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
2584 units total (1501 units in the US; 1034 units international; and 49 units owned by Physio). 50 modules total<p>
DISTRIBUTION
Nationwide and Internationally<p>

2/15/2017 LIFEPAK 12 Defibrillator/Monitor Cl II
Company: Physio-Control, Inc.
Date of Enforcement Report 2/15/2017
Class II:<p>
PRODUCT
LIFEPAK 12 Defibrillator/Monitor with End-Tidal CO2 option. The device is used in various areas of the hospital such as critical areas (emergency departments, critical care, operating room, etc.) and general duty floors (e.g. medical/surgical). The device is also used for in and out of hospital transport (air and ground ambulance, in hospital transport, etc.) l
Recall Number Z-1143-2017<p>
REASON
The End-Tidal CO2 (EtCO2) reading can intermittently show a value of XXX after start-up or during device operation.<p>
RECALLING FIRM/MANUFACTURER
Physio-Control, Inc., Redmond, WA on 1/16/2017. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
7 units in the US and 13 modules worldwide<p>
DISTRIBUTION
Nationwide and Internationally<p>

2/15/2017 Merge Eye Station Cl II
Company: Merge Healthcare, Inc.
Date of Enforcement Report 2/15/2017
Class II:<p>
PRODUCT
Merge Eye Station. f/k/a: DFC-1024 & DFC-512 Digital Imaging System, WinStation, and WinStation Retinal Imager distributed by Ophthalmic Imaging Systems (OIS). Model number 136 T1700 Capture Stations & 46 T5810 Capture Station
Recall Number Z-1142-2017<p>
REASON
Merge received reports of Merge Eye Station being unable to capture images of the eye as expected per the intended use of the product. Merge is recalling product from the field to reduce the risk to patient health.<p>

RECALLING FIRM/MANUFACTURER
Merge Healthcare, Inc., Hartland, WI on 12/9/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
182 capture stations<p>
DISTRIBUTION
Nationwide and Internationally<p>

2/8/2017 SiemensSyngo.plaza, Cl II
Company: Siemens Medical Solutions USA, Inc
Date of Enforcement Report 2/8/2017
Class II:<p>
PRODUCT
Syngo.plaza, picture archiving and communications system.
Recall Number Z-1116-2017<p>
REASON
Software update for improvements and to resolve several issues<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc., Malvern, PA on 1/11/2017 Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
62 systems<p>
DISTRIBUTION
Nationwide <p>

2/8/2017 MEVION S250-Proton Radiation Therapy, Cl II
Company: Mevion Medical Systems, Inc..
Date of Enforcement Report 2/8/2017
Class II:<p>
PRODUCT
MEVION S250-Proton Radiation Therapy Product Usage: Proton Radiation Therapy
Recall Number Z-1122-2017<p>
REASON
An error can occur causing Delta corrections to be lost when one setup field is closed and another is opened<p>
RECALLING FIRM/MANUFACTURER
Mevion Medical Systems, Inc., Littleton, MA on 12/16/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
2 units<p>
DISTRIBUTION
US Nationwide in the states of OK, NJ<p>

2/8/2017 FDA Safety Alert - Alaris Pump Alarm
Company: Carefusion Date of Enforcement Report 2/8/2017 Class I Recall
Alaris Syringe Pump Module (Large Volume Pump), Model 8100 and AIL Sensor Kits by CareFusion: Class I Recall - Alarm Error AUDIENCE: Risk Manager, Nursing.
The full safety alert is at the link provided and the recall report is posted on our recalls webpage.
ISSUE: CareFusion is recalling the Alaris Syringe Pump because of a faulty Air-In-Line (AIL) sensor which may generate a false alarm, and cause the syringe pump to stop supplying the infusion to the patient. If the AIL sensor is faulty, the false alarm may be repeated and require the health care provider to clear the alarm to restart the infusion. Interruption of infusion could lead to serious adverse health consequences or death.

2/8/2017 Siemens Mammomat Inspiration, Cl II
Company: Siemens Medical Solutions USA, Inc
Date of Enforcement Report 2/8/2017
Class II:<p>
PRODUCT
Mammomat Inspiration full, field digital,system,x-ray,mammographic Product Usage: The Mammomat Inspiration system is intended for mammography exams, screening, diagnosis, and stereotactic biopsies under the supervision of medical professionals. Mammographic images can be interpreted by either hard copy film or soft copy workstation.
Recall Number Z-1118-2017<p>
REASON
Software error<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc., Malvern, PA on 1/11/2017 Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
55 units<p>
DISTRIBUTION
Nationwide <p>

2/1/2017 Merge Hemo software Cl II
Company: Merge Healthcare, Inc.
Date of Enforcement Report 2/1/2017
Class II:<p>
PRODUCT
Merge Hemo software. Merge Hemo monitors, measures, and records physiologic data from a human patient undergoing a cardiac catheterization procedure
Recall Number Z-1091-2017<p>
REASON
There is a potential connection issue when powering up the Merge Hemo Record Station and the Hemo Monitor does not communicate with the Client PC.<p>
RECALLING FIRM/MANUFACTURER
Merge Healthcare, Inc., Hartland, WI on 3/28/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
242 sites<p>
DISTRIBUTION
Nationwide <p>

2/1/2017 Roche Accu-Chek App, Cl II
Company: Roche Diabetes Care, Inc.
Date of Enforcement Report 2/1/2017
Class II:<p>
PRODUCT
Accu-Chek Connect Diabetes Management App
Recall Number Z-1099-2017<p>
REASON
iOS and Android: Under certain conditions the affected app versions may disregard historical bolus data potentially leading to an incorrect bolus insulin recommendation being provided to the user. iOS only: Pairing and using multiple meters with the Accu-Chek Connect app can under rare circumstances cause the bolus advisor to fail to offer a correction bolus recommendation within the eligible time window following a blood glucose measurement (10 15 minutes). Depending on the individual metabolic situation potentially incorrect bolus advice could lead to serious health consequences such as hypoglycemia. Both software issues may also cause the amount of active insulin displayed during the

bolus calculation process to be incorrect and should not be used to manually calculate a bolus.<p>
RECALLING FIRM/MANUFACTURER
Roche Diabetes Care, Inc., Indianapolis, IN on 12/30/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
27243<p>
DISTRIBUTION
Nationwide <p>

2/1/2017 SCC Soft Computer Softbank software, Cl II
Company: Soft Computer Consultants, Inc.
Date of Enforcement Report 2/1/2017
Class II:<p>
PRODUCT
Softbank software Product Usage: Decision support software for transfusion service. It keeps track of inventory from outside sources, multi-site inventory control, records of testing of units, and allows for record keeping for transfusion preparation..
Recall Number Z-1098-2017<p>
REASON
Software error. Potential for incorrect results<p>
RECALLING FIRM/MANUFACTURER
Soft Computer Consultants, Inc., Clearwater, FL on 10/6/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
189<p>
DISTRIBUTION
Nationwide and Internationally<p>

2/1/2017 SCC Soft Computer Softbank II software, Cl II
Company: Soft Computer Consultants, Inc.
Date of Enforcement Report 2/1/2017
Class II:<p>
PRODUCT
SCC Soft Computer Softbank II software Product Usage: Supports single and multi-site transfusion services in healthcare facilities. Used by healthcare personal to document, query, and view the integrated information regarding patients and products. Quality control testing, test and transfusion history, transfusion management, inventory management, product distribution, and final disposition are all monitored using the software.
Recall Number Z-1097-2017<p>
REASON
Software error. Potential for incorrect results<p>
RECALLING FIRM/MANUFACTURER
Soft Computer Consultants, Inc., Clearwater, FL on 10/6/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
189<p>
DISTRIBUTION
Nationwide and Internationally<p>

2/1/2017 Roche Cobas b 123 POC system, Cl II
Company: Roche Diagnostics Operations, Inc.
Date of Enforcement Report 2/1/2017
Class II:<p>
PRODUCT
Cobas b 123 POC systemThe cobas b 123 POC system is a fully automated POC system for whole blood in vitro measurement of pH, blood gases (B3G), electrolytes Nat, K+, iCaWt (ISE), hematocrit (THct), metabolites (Glu, Lac), total hemoglobin (tHb), hemoglobin derivatives (O2Hb, HHb, COT~b, MetHb), and oxygen saturation (SO2).
Recall Number Z-1077-2017<p>
REASON
under specific settings, an issue may occur during simultaneous Sensor Cartridge and Fluid Pack change on the cobas b 123 <2> POC system and cobas b 123 <4> POC system. The issue occurs when the software function [AutoQC as follow-up] is configured to run all three levels of AutoQC only after a Fluid Pack change, but not after a Sensor Cartridge change. When both are changed simultaneously, starting with the Sensor Cartridge and followed by the Fluid Pack, the analyzer carries out only the follow-up actions associated with the Sensor Cartridge change after completing the change workflow. As a result, no follow-up AutoQC is performed and the three expected AutoQC measurements for the Fluid Pack change are not carried out. Without running quality control, there is a remote possibility that system issues would not be detected and wrong results would not be excluded on all parameters: pH, PO2, PCO2, Na+, K+, Ca++, Cl-, Glu, Lac, Hct, SO2, O2Hb, COHb, MetHb, HHb, and Bili.<p>
RECALLING FIRM/MANUFACTURER
Roche Diagnostics Operations, Inc., Indianapolis, INon 9/3/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
30<p>
DISTRIBUTION
Nationwide <p>

1/25/2017 Blood Bank Control System (BBCS) Cl II
Company: Blood Bank Computer Systems, Inc
Date of Enforcement Report 1/25/2017
Class II:<p>
PRODUCT
Blood Bank Control System (BBCS) Primary Application, V 5.4.3, 5.5 is intended to address all phases of donor and transfusion services. The software is also capable of operating with or without ABO QuickPass (BK14130) to allow donors to complete Computer Assisted Self Interviews (CASI) and computer assisted blood donor registrations..
Recall Number B-0257-2017<p>
REASON
Blood Bank Control System (BBCS) with Primary Application (software version BBCS Primary Application 5.4.3, 5.5; ABO Express 1.0.0, 1.1.0, 1.2.0), with a defect or glitch, was distributed.<p>
RECALLING FIRM/MANUFACTURER
Blood Bank Computer Systems, Inc., Auburn, WA on 10/282016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
40 units<p>
DISTRIBUTION
Nationwide <p>

1/25/2017 Carestream Touch Prime, Cl II
Company: Carestream Health Inc
Date of Enforcement Report 1/25/2017
Class II:<p>
PRODUCT
Carestream Touch Prime, Catalog # 1738830, and Touch Prime XE, Catalog # 1738822, Ultrasound System Diagnostic ultrasound imaging or fluid flow analysis of the human body
Recall Number Z-1052-2017<p>
REASON
Software error; Carestream Health Inc, received a complaint stating that when a user accidentally obtains a measurement value of 0 and corrects the value in the report, the resulting measurement unit is not displayed, i.e., centimeters or millimeters. As such, the user expects that the measurement is taken calculated in centimeters, consistent with other values in the report. In actuality, the measurement is taken in millimeters. When this updated measurement is used in an average calculation, the result appears incorrect as two measurements are interpreted as centimeters while the user corrected value is interpreted as millimeters. If the user selects a Calc Result display as Min or Max, the values are also interpreted as millimeters when centimeters were expected.<p>
RECALLING FIRM/MANUFACTURER
Carestream Health Inc., Rochester, NY on 11/21/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
US: 14 units; Foreign: 16 units<p>
DISTRIBUTION
Nationwide and Internationally<p>

1/25/2017 Elekta Monaco RTP System, Cl II
Company:Elekta, Inc.
Date of Enforcement Report 1/25/2017
Class II:<p>
PRODUCT
Monaco RTP System. Used to make treatment plans for patients with prescriptions for external beam radiation therapy.
Recall Number Z-1044-2017<p>
REASON
Incorrect dose after editing beam number an wedge angle.<p>
RECALLING FIRM/MANUFACTURER
Elekta Inc., Atlanta, GA, on 1/10/2017. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
1999<p>
DISTRIBUTION
Nationwide and Internationally<p>

1/25/2017 Ambra PACS UDI, Cl II
Company: DICOM GRID INC
Date of Enforcement Report 1/25/2017
Class II:<p>
PRODUCT
Ambra PACS UDI: +AMBRHEALTHSOLUTIONS0/$$+7_V3.16.13.0R Software Version Number: V3.16.13.0 Intended for use as a primary diagnostic and analysis tool for diagnostic images.
Recall Number Z-1045-2017<p>
REASON
A software error caused the window/level to become the same in one series regardless if the image had different levels; image results have a washed-out grey appearance.<p>
RECALLING FIRM/MANUFACTURER

DICOM GRID INC, Phoenix, AZ on 12/16/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
209<p>
DISTRIBUTION
Nationwide and Internationally<p>

1/25/2017 AutoMate System Series Cl III
Company: Beckman Coulter Inc.
Date of Enforcement Report 1/25/2017
Class III:<p>
PRODUCT
AutoMate 2500 Family Catalog No. ODL25120 AutoMate 1200, ODL25125, AutoMate 1250, ODL25250 AutoMate 2500, ODL25255 Automate 2550. AutoMate 1200/1250/2500/2550 System Series is a semi-open, pre- and post-analytical sample processing and sorting system. The base system automates the sample sorting, decapping, and archiving process. Handling and sorting of samples includes automatic detection of the tube type and cap type (color). Optional features include an Aliquot Module for creation of labeled secondary tubes (including detection of the presence of adequate volume for the requested aliquots) and a Recapper Module to re-seal previously decapped tubes prior to archiving.
Recall Number Z-1040-2017<p>
REASON
Beckman Coulter initiated a design change to update the Automate PC image to accommodate the operating system change to Windows 10.<p>
RECALLING FIRM/MANUFACTURER
Beckman Coulter Inc., Brea, CA on 12/21/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
4 units <p>
DISTRIBUTION
US Distribution to MD only.<p>

1/25/2017 Digital RID Plate Reader Cl II
Company: The Binding Site Group, Ltd.
Date of Enforcement Report 1/25/2017
Class II:<p>
PRODUCT
Digital RID Plate Reader and Software Product Code: AD400
Recall Number Z-1055-2017<p>
REASON
If a control ring is marked after reading, the software will not flag results that are out of the specified QC range.<p>
RECALLING FIRM/MANUFACTURER
The Binding Site Group, Ltd.Birmingham UK on 10/9/2012. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
<p>
DISTRIBUTION
Nationwide and Internationally<p>

1/25/2017 Fresenius 2008 Series Hemodialysis Systems Cl II
Company: Fresenius Medical Care Renal Therapies Group, LLC
Date of Enforcement Report 1/25/2017
Class II:<p>

PRODUCT
Fresenius 2008T Series Hemodialysis System
Recall Number Z-1026-2017 through Z-1029-2017<p>
REASON
When the UF Rate, Goal or Time is adjusted using the up and down arrow keys, and the change is cancelled by using the esc key, the cancelled UF Rate is actually being executed rather than rate displayed on the machine<p>
RECALLING FIRM/MANUFACTURER
Fresenius Medical Care Renal Therapies Group, LLC, Waltham, MA on 12/21/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
<p>
DISTRIBUTION
Nationwide and Internationally<p>

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1/25/2017 Merge Cardio software Cl II
Company: Merge Healthcare, Inc.
Date of Enforcement Report 1/25/2017
Class II:<p>
PRODUCT
Merge Cardio software. Product Usage: Merge Cardio is a system intended to be used to acquire, store, print, transfer, and archive clinical information including images, Hemodynamic studies and reports, measurements (via import from DICOM Structured Reporting, text files or optical character recognition of measurements captured on images) and cardiology signal (waveform) data.
Recall Number Z-1046-2017<p>
REASON
If a reader selects Multi-study review prior to the original study completing its loading process and then immediately returns to image review of the original study, it is possible that not all current images will be present for review, which could result in incorrect treatment/diagnosis.<p>
RECALLING FIRM/MANUFACTURER
Merge Healthcare, Inc., Hartland, WI on 3/28/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
188 sites<p>
DISTRIBUTION
Nationwide <p>

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1/25/2017 Alaris Syringe Pump Module Class I
Company: Carefusion
Date of Enforcement Report 1/25/2017
Class I:<p>
PRODUCT
Product Description: Alaris Syringe Pump Module (Large Volume Pump), Model No. 8100 and AIL sensor kits
Recall number Z-0950-2017<p>
REASON
CareFusion is recalling the Alaris Syringe Pump because of a faulty Air-In-Line (AIL) sensor which may generate a false alarm, and cause the syringe pump to stop supplying the infusion to the patient. If the AIL sensor is faulty, the false alarm may be repeated and require the health care provider to clear the alarm to restart the infusion. Interruption of infusion could lead to serious adverse health consequences or death.<p>
RECALLING FIRM/MANUFACTURER
CareFusion San Diego, CA12/2/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE

382,635 units<p>
DISTRIBUTION
Nationwide <p>

1/18/2017 Elekta Oncentra External Beam, Cl II
Company: Elekta, Inc.
Date of Enforcement Report 1/18/2017
Class II:<p>
PRODUCT
Oncentra External Beam Oncentra Brachy Product Usage: Oncentra is radiation therapy planning software designed to analyze and plan radiation treatment is three dimensions for the purpose of treating patients with cancer.
Recall Number Z-0987-2017<p>
REASON
Cross profile for Varian 60 degree wedge shows "horns."<p>
RECALLING FIRM/MANUFACTURER
Elekta inc., Atlanta, GA on 12/23/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
433<p>
DISTRIBUTION
Nationwide and Internationally<p>

1/18/2017 Toshiba Ultimax DREX-ULT80,0, Cl II
Company: Toshiba American Medical Systems Inc
Date of Enforcement Report 1/18/2017
Class II:<p>
PRODUCT
Ultimax DREX-ULT80, Model No. KXO-80XM Multipurpose digital x-ray system for gastrointestinal studies, vascular studies, general radiography, and fluoroscopy
Recall Number Z-1022-2017<p>
REASON
It has been found that the generator of the system could possibly terminate the exposure prematurely during an examination. This issue was identified due to a software problem residing in the generator firmware.<p>
RECALLING FIRM/MANUFACTURER
Toshiba American Medical Systems Inc, Tustin, CA on 12/21/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
254 systems<p>
DISTRIBUTION
Nationwide <p>

1/18/2017 Toshiba Kalare DREX-KL80, Cl II
Company: Toshiba American Medical Systems Inc
Date of Enforcement Report 1/18/2017
Class II:<p>
PRODUCT
Kalare DREX-KL80, Model No. KXO-80XD Diagnostic imaging system for radiographic and fluoroscopic examinations, including general R&F and pediatric examinations
Recall Number Z-1021-2017<p>
REASON
It has been found that the generator of the system could possibly terminate the exposure prematurely during an examination. This issue was identified due to a software problem residing in the generator

firmware.<p>
RECALLING FIRM/MANUFACTURER
Toshiba American Medical Systems Inc, Tustin, CA on 12/21/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
254 systems<p>
DISTRIBUTION
Nationwide <p>

1/18/2017 Elekta Monaco RTP System, Cl II
Company: Elekta, Inc.
Date of Enforcement Report 1/18/2017
Class II:<p>
PRODUCT
Monaco RTP System Product Usage: Used to make treatment plans for patients with prescriptions for external beam radiation therapy.
Recall Number Z-1009-2017<p>
REASON
Incorrect Enhanced Dynamic Wedge (EDW) or Virtual Wedge (VW) Calculations.<p>
RECALLING FIRM/MANUFACTURER
Elekta inc., Atlanta, GA on 12/21/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
279<p>
DISTRIBUTION
Nationwide and Internationally<p>

1/18/2017 Philips IQon Spectral CT Cl II
Company: Philips Medical Systems, Inc.
Date of Enforcement Report 1/18/20176
Class II:<p>
PRODUCT
IQon Spectral CT with software version 4.7.0Product Usage:The IQon Spectral CT is a Computed Tomography X-Ray System intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data taken at different angles and planes.
Recall Number Z-1006-2017<p>
REASON
Multiple issues have caused the device to result in CT rescans or incorrect scan location or misrepresentation of image results.<p>
RECALLING FIRM/MANUFACTURER
Philips Medical Systems, Inc., Cleveland, OH on 12/162016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
35<p>
DISTRIBUTION
Nationwide and Internationally<p>

1/18/2017 Eclipse Treatment Planning System Cl II
Company:Varian Medical Systems, Inc.
Date of Enforcement Report 1/18/2017
Class II:<p>
PRODUCT
Eclipse Treatment Planning System version 13.MR2 [13.06.31 with Smart Segmentation Knowledge Based Contouring version 2.3 [2.3.12] Radiology: The Eclipse Treatment Planning System (Eclipse

TPS) is used to plan radiotherapy treatments for patients with malignant or benign diseases. Eclipse TPS is used to plan external beam irradiation with photon, electron and proton beams, as well as for internal irradiation (brachytherapy) treatments.
Recall Number Z-0990-2017<p>
REASON
Modifications in version 13.6MR2 for Contouring, SmartAdapt, and SmartSegmentation workspaces resulted in contours not being saved consistently in Eclipse. Treatment Planning System. The issue only occurs if certain conditions are fulfilled.<p>
RECALLING FIRM/MANUFACTURER
Varian Medical Systems, Inc., Palo Alto, CA on 11/2/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
42 devices are affected<p>
DISTRIBUTION
US Distribution to the states of : NJ, TN. OR and FL.<p>

1/18/2017 Siemens Artis zee/zeego Cl II
Company: Siemens Medical Solutions USA, Inc
Date of Enforcement Report 1/18/2017
Class II:<p>
PRODUCT
Artis zee/zeego, Angiographic x-ray system Stand alone system The Artis systems are a family of dedicated angiography systems developed for single and biplane diagnostic imaging and interventional procedures including, but not limited to, pediatric and obese patients. Procedures that can be performed with the Artis zee/ zeego and Q/ Q.zen include cardiac angiography, neuro angiography, general angiography, rotational angiography, operating room angiography, multipurpose angiography and whole body radiographic/fluoroscopic procedures.
Recall Number Z-0971-2017<p>
REASON
Siemens initiated a corrective action to address two possible, mutually independent causes of a system defect related to the following: - In Artis Systems with A100 Plus or A100G generators, an attempt to resume operation following detection of a fault can result in the failure of a module in the high-voltage generator. <p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc., Malvern, PA on 12/8/2016 Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
1,500 distributed Worldwide<p>
DISTRIBUTION
Nationwide <p>

1/11/2017 Merge Eye Station Cl II
Company: Merge Healthcare, Inc.
Date of Enforcement Report 1/11/2017
Class II:<p>
PRODUCT
Merge Eye Station f/k/a: DFC-1024 & DFC-512 Digital Imaging System, WinStation, and WinStation Retinal Imager distributed by Ophthalmic Imaging Systems (OIS). Versions: 11.6.0 and prior
Recall Number Z-1017-2017<p>
REASON
This recall has been initiated due to an issue related to the potential accidental deletion of record(s) by an Eye Station user.<p>
RECALLING FIRM/MANUFACTURER

Merge Healthcare, Inc., Hartland, WI on 12/9/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
1597 (1451 US; 146 OUS)<p>
DISTRIBUTION
Nationwide and Internationally <p>

1/11/2017 Merge DR Systems Unity Cl II
Company: Merge Healthcare, Inc.
Date of Enforcement Report 1/11/2017
Class II:<p>
PRODUCT
DR Systems Unity PACS software, now known as Merge Unity PACS software.
Recall Number Z-0939-2017<p>
REASON
The software fails to associate to the correct MG image if there are two images for the same view.<p>
RECALLING FIRM/MANUFACTURER
Merge Healthcare, Inc., Hartland, WI on 10/15/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
9 sites potentially have the effected versions<p>
DISTRIBUTION
Distribution was made to medical facilities located in MT, CA, PA, and TX.<p>

1/10/2017 Implantable Device FDA Cybersecurity Notice
FDA issued a safety notice: Cybersecurity Vulnerabilities Identified in St. Jude Medical's Implantable Cardiac Devices and Merlin@home Transmitter. The full safety notice is at the link provided.

12/28/2016 Merge OrthoCase software Cl II
Company: Merge Healthcare, Inc.
Date of Enforcement Report 12/28/2016
Class II:<p>
PRODUCT
Merge OrthoCase software. The firm name on the label is Merge Healthcare, Hartland, WI..
Recall Number Z-0878-2017<p>
REASON
Measurements in the software are changing after saving a plan with a measurement result, which may result in potential patient injury or delay in diagnosis or treatment.<p>
RECALLING FIRM/MANUFACTURER
Merge Healthcare, Inc., Hartland, WI on 10/8/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
30 sites potentially have the effected versions<p>
DISTRIBUTION
Distribution was made to medical facilities in CA, CO, CT, MA, MD, MN, MT, NE, NV, NY NJ, PA, SC, WA, and WI. Foreign distribution was made to Canada, as well as other countries. <p>

12/28/2016 AQURE System Software Version 2.2 Cl II
Company: Radiometer America Inc.
Date of Enforcement Report 12/28/2016
Class II:<p>
PRODUCT
AQURE System Software Version 2.2.0Model #: 933-599UDI: (01)05700699335999(10)2.2.0 Catalog number: 933-599The AQURE system manages Radiometer blood gas and immunoassay analyzers and results from 3rd party devices for point of care testing placed throughout the hospital. It enables the user to track connected devices, monitor performance and availability
Recall Number Z-0899-2017<p>

REASON
Design error when displaying additional information in the patient view window; error may result in misreading a parameter and its value.<p>
RECALLING FIRM/MANUFACTURER
Radiometer America Inc, Brea, CA.on 11/23/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
7<p>
DISTRIBUTION
Nationwide and Internationally<p>

12/28/2016 Medtronic SynchroMed II Cl II
Company: Medtronic Neuromodulation
Date of Enforcement Report 12/28/2016
Class II:<p>
PRODUCT
Medtronic SynchroMed II Implantable Drug Infusion System. This system includes: Model 8870 Software Application Card, Model 8840 N'Vision Clinician Programmer, and Model 8637 SynchroMed II Implantable Drug Infusion Pump (supplied in 20 ml or 40 ml reservoir size.) Product Usage: The SynchroMed II Programmable Pump is indicated when patient therapy requires the chronic infusion of the following drugs or fluids: Chronic intraspinal (epidural and intrathecal) infusion of preservative-free morphine sulfate sterile solution in the treatment of chronic intractable pain, Chronic intrathecal infusion of preservative-free ziconotide sterile solution for the management of severe chronic pain, Chronic intrathecal infusion of Lioresal Intrathecal (baclofen Injection) in the management of serve spasticity, Chronic Intravascular Infusion of Floxuridine (FUDR) or methotrexate for the treatment of primary or metastatic cancer
Recall Number Z-0788-2017<p>
REASON
Medtronic is following up to a May 2013 communication regarding the Priming Bolus function for the SynchroMed Infusion System. Medtronic is updating the Model 8870 software application card (to version AAU01) and the SynchroMed pump labeling to address the priming bolus issue.<p>
RECALLING FIRM/MANUFACTURER
Medtronic Neuromodulation, Minneapolis, MN on 10/3/2016 Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
22,298 software cards<p>
DISTRIBUTION
Nationwide <p>

12/21/2016 Merge Cardio Software. Cl II
Company: Merge Healthcare, Inc.
Date of Enforcement Report 12/21/2016
Class II:<p>
PRODUCT
Merge Cardio software. Merge Cardio is a system intended to be used to acquire, store, print, transfer, and archive clinical information including images, Hemodynamic studies and reports, measurements (via import from DICOM Structured Reporting, text files or optical character recognition of measurements captured on images) and cardiology signal (waveform) data.
Recall Number Z-0729-2017<p>
REASON
If images are sent without an order in the system, they will be matched with the latest order on the current patient/modality matching potentially resulting in the matching of the report to the incorrect accession number (but still associated to the correct patient).<p>
RECALLING FIRM/MANUFACTURER

Merge Healthcare, Inc., Hartland, WI on 3/28/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
198 sites potentially have the effected versions<p>
DISTRIBUTION
Nationwide <p>

12/21/2016 Merge Cardio Software. Cl II
Company: Merge Healthcare, Inc.
Date of Enforcement Report 12/21/2016
Class II:<p>
PRODUCT
Merge Cardio software. Merge Cardio is a system intended to be used to acquire, store, print, transfer, and archive clinical information from Camtronics and other vendors systems including images, hemodynamic studies and reports, measurements (via import from DICOM Structured reporting, text files or optical character recognition of measurements captured on images) and cardiology signal (waveform) data
Recall Number Z-0730-2017<p>
REASON
Reporting feature times out after inactivity for more than an hour sending the user back to the study list, which causes all reporting data being entered to be lost.<p>
RECALLING FIRM/MANUFACTURER
Merge Healthcare, Inc., Hartland, WI on 10/1/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
116 sites potentially have the effected versions<p>
DISTRIBUTION
Nationwide <p>

12/21/2016 Olympus HF Cable WA00014A Cl II
Company: Olympus Corporation of the Americas
Date of Enforcement Report 12/21/2016
Class II:<p>
PRODUCT
HF Cable WA00014A, Endoscopic electrosurgical unit and accessories
Recall Number Z-0754-2017<p>
REASON
Software malfunction that results in incorrect generation or display of error codes.<p>
RECALLING FIRM/MANUFACTURER
Olympus Corporation of the Americas, Center Valley, PA on 11/3/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
494 units<p>
DISTRIBUTION
Nationwide <p>

12/21/2016 MicroScan LabPro Cl II
Company: Beckman Coulter Inc.
Date of Enforcement Report 12/21/2016
Class II:<p>
PRODUCT
MicroScan LabPro Data Management System. Intended to manage both microbial identification (ID) and antimicrobial agent susceptibility testing (AST) data generated from MicroScan instruments or manually entered microbiology test results, for use by trained laboratory personnel.
Recall Number Z-0768-2017<p>

REASON
Beckman Coulter has received and confirmed reports of an intermittent and unexpected behavior when loading new panels into a WalkAway instrument using LabPro Data Management System version 4.42. The issue could cause workflow interruption with a potential of delaying reporting results due to the inability to begin processing new panels.<p>
RECALLING FIRM/MANUFACTURER
Beckman Coulter Inc. Brea, CA.on 10/25/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
131 units (130 in US)<p>
DISTRIBUTION
Nationwide and Mexico<p>

12/14/2016 Philips Ingenuity CT 728326 Cl II
Company: Philips Medical Systems, Inc.
Date of Enforcement Report 12/14/2016
Class II:<p>
PRODUCT
Ingenuity CT 728326 Computed Tomography X-ray systems intended to produce cross-sectional images of the body by computer reconstruction of X-ray transmission data taken at different angles and planes. These devices may include signal analysis and display equipment, patient and equipment supports, components, and accessories
Recall Number Z-0697-2017<p>
REASON
Software error due to the filament on timer.<p>
RECALLING FIRM/MANUFACTURER
Philips Medical Systems, Inc., Cleveland, OH on 11/12/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
371<p>
DISTRIBUTION
Nationwide and Internationally<p>

12/14/2016 Philips Ingenuity Core 128 728323, Cl II
Company: Philips Medical Systems, Inc.
Date of Enforcement Report 12/14/2016
Class II:<p>
PRODUCT
Ingenuity Core 128 728323 Computed Tomography X-ray systems
Recall Number Z-0696-2017<p>
REASON
Software error due to the filament on timer.<p>
RECALLING FIRM/MANUFACTURER
Philips Medical Systems, Inc., Cleveland, OH on 11/12/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
509<p>
DISTRIBUTION
Nationwide and Internationally<p>

12/14/2016 Philips Ingenuity Core 728321, Cl II
Company: Philips Medical Systems, Inc.
Date of Enforcement Report 12/14/2016
Class II:<p>
PRODUCT
Ingenuity Core 728321 Computed Tomography X-ray systems intended to produce cross-sectional images of the body by computer reconstruction of X-ray transmission data taken at different angles and planes. These devices may include signal analysis and display equipment, patient and equipment supports, components, and accessories
Recall Number Z-0695-2017<p>
REASON
Software error due to the filament on timer.<p>
RECALLING FIRM/MANUFACTURER
Philips Medical Systems, Inc., Cleveland, OH on 11/12/2016. Voluntary: Firm Initiated recall is ongoing.
<p>
VOLUME OF PRODUCT IN COMMERCE
337<p>
DISTRIBUTION
Nationwide and Internationally<p>

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12/14/2016 Philips Brilliance 64 728232 , Cl II
Company: Philips Medical Systems, Inc.
Date of Enforcement Report 12/14/2016
Class II:<p>
PRODUCT
Brilliance 64 728232 Computed Tomography X-ray systems intended to produce cross-sectional images of the body by computer reconstruction of X-ray transmission data taken at different angles and planes. These devices may include signal analysis and display equipment, patient and equipment supports, components, and accessories
Recall Number Z-0694-2017<p>
REASON
Software error due to the filament on timer.<p>
RECALLING FIRM/MANUFACTURER
Philips Medical Systems, Inc., Cleveland, OH on 11/12/2016. Voluntary: Firm Initiated recall is ongoing.
<p>
VOLUME OF PRODUCT IN COMMERCE
18<p>
DISTRIBUTION
Nationwide and Internationally<p>

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12/14/2016 Philips Brilliance 64 728231, Cl II
Company: Philips Medical Systems, Inc.
Date of Enforcement Report 12/14/2016
Class II:<p>
PRODUCT
Brilliance 64 728231 Computed Tomography X-ray systems intended to produce cross-sectional images of the body by computer reconstruction of X-ray transmission data taken at different angles and planes. These devices may include signal analysis and display equipment, patient and equipment supports, components, and accessories
Recall Number Z-0693-2017<p>
REASON
Software error due to the filament on timer.<p>
RECALLING FIRM/MANUFACTURER

Philips Medical Systems, Inc., Cleveland, OH on 11/12/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
184<p>
DISTRIBUTION
Nationwide and Internationally<p>

12/14/2016 RayStation 4.0, 4.5, 4.7 and 5.0 Cl II
Company:RAYSEARCH LABORATORIES AB
Date of Enforcement Report 12/14/2016
Class II:<p>
PRODUCT
RayStation 4.0, 4.5, 4.7 and 5.0; Radiation Therapy Treatment Planning SystemProduct Usage:RayStation is a software system designed for treatment planning and analysis of radiation therapy. The treatment plans provide treatment unit set-up parameters and estimates of dose distributions expected during the proposed treatment, and may be used to administer treatments
Recall Number Z-0721-2017<p>
REASON
Software anomaly; an issue was found with the proton Pencil Beam Scanning (PBS) dose calculation in RayStation 4.0, 4.5, 4.7 and 5.0. For treatment plans with a combination of range shifter, large air gap and beams that enter the patient surface at an oblique angle, the dose calculation accuracy may be less than expected.<p>
RECALLING FIRM/MANUFACTURER
RAYSEARCH LABORATORIES AB, Stockholm, Sweden on 11/9/2016 Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
66 units<p>
DISTRIBUTION
US Nationwide Distribution in the states of California, Florida, Illinois, Louisiana, Michigan, New Jersey, Tennessee, Texas, Washington<p>

12/14/2016 Merge PACS software Cl II
Company: Merge Healthcare, Inc.
Date of Enforcement Report 12/14/2016
Class II:<p>
PRODUCT
Merge PACS software. Merge PACS (Picture Archiving Communication System) is designed and marketed for soft copy reading, communication and storage of studies produced by digital modalities, including digital mammography.
Recall Number Z-0726-2017<p>
REASON
Cut lines on the image may present horizontally rather than vertically..<p>
RECALLING FIRM/MANUFACTURER
Merge Healthcare, Inc., Hartland, WI on 3/28/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
537 sites potentially have the affected versions<p>
DISTRIBUTION
Nationwide and Internationally<p>

12/14/2016 Siemens ADVIA 560, Cl II
Company: Siemens Healthcare Diagnostics, Inc.
Date of Enforcement Report 12/14/2016
Class II:<p>
PRODUCT
ADVIA 560 Hematology Systems, Siemens Material Number (SMN) 11170842, IVD.
Recall Number Z-0723-2017<p>
REASON
Siemens is investigating an issue which may cause an incorrect result to be reported. Siemens received two reports of multiple discordant records for the same Sample ID in the ADVIA 560 Hematology System database that occurred during the installation of the systems. The database should only contain one record of a Sample ID number for any given time and date. If there are multiple records for the same Sample ID, it is possible that multiple results may be manually or automatically sent to the Laboratory Information System (LIS), printed or displayed on the results report screen.<p>
RECALLING FIRM/MANUFACTURER
Siemens Healthcare Diagnostics, Inc., Tarrytown, NY on 10/21/2016 Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
US: 23 systems; Foreign: 141 systems<p>
DISTRIBUTION
Nationwide and Internationally<p>

12/14/2016 RaySearch Radiation Treatment Planning
Cl II
Company:RAYSEARCH LABORATORIES AB
Date of Enforcement Report 12/14/2016
Class II:<p>
PRODUCT
Radiation Therapy Treatment Planning System Product Usage: RayStation is a software system designed for treatment planning and analysis of radiation therapy.
Recall Number Z-0720-2017<p>
REASON
An error may occur with the display of dose computed on images other than the planning CT (auxiliary CT) when using multiple patient cases in RayStation 5. If a CT image set with the same Frame of Reference as the displayed auxiliary CT set exists in another case, the dose display may be incorrect. When the error occurs, the display of dose in patient views, including the maximum dose position, the dynamic isodose lines and the dose grid may be incorrect. The dose value normally displayed in the upper left corner when pointing in the 2D view may be incorrect or missing.<p>
RECALLING FIRM/MANUFACTURER
RAYSEARCH LABORATORIES AB, Stockholm, Sweden on 10/112016 Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
540 units<p>
DISTRIBUTION
Nationwide<p>

12/14/2016 SynCardia 5000 Series Freedom Drivers Cl II
Company: SynCardia Systems Inc.
Date of Enforcement Report 12/14/2016
Class II:<p>
PRODUCT
5000 Series Freedom Drivers. Freedom Driver System for Temporary Total Artificial Heart (TAH-t). Part

number 595000-001
Recall Number Z-0659-2017<p>
REASON
The Main Printed Circuit Board Assembly (PCBA) of the affected Freedom Drivers may fail and cause the Freedom Driver to stop functioning without visual or audible alarms, resulting in the loss of life-sustaining function.<p>
RECALLING FIRM/MANUFACTURER
SynCardia Systems Inc., tuscon, AZ on 10/21/2016 Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
5<p>
DISTRIBUTION
US distribution to Virginia and Arizona.<p>

12/14/2016 Siemens SOMATOM Force: Cl II
Company: Siemens Medical Solutions USA, Inc
Date of Enforcement Report 12/14/2016
Class II:<p>
PRODUCT
SOMATOM Force, System x-ray, tomography, computed
Recall Number Z-0962-2017<p>
REASON
Siemens is providing software update versionVA50A_SP3 to address the software bugs thatwere identified through normal field monitoringand the Global Complaint Handling Process.Correction for the problems are as follows:1. Correction to volumetricmisrepresentations of high contrastobjects when using ADMIRE.2. Correction to highly sporadic scanaborts due to temporarily tubecurrents at 0mA.3.<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc., Malvern, PA on 10/20/2016 Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
48<p>
DISTRIBUTION
Nationwide <p>

12/14/2016 Medtronic 37751 Recharger Cl II
Company: Medtronic Neuromodulation
Date of Enforcement Report 12/14/2016
Class II:<p>
PRODUCT
Model 37751 Recharger Product Usage: The Medtronic 37751 Recharger is a hand-held device used to charge the battery in a patient s neurostimulator. It includes a display to provide information on the charging system. The charging system consists of the Model 37751 Recharger, an AC power supply and power cord (Model 37761) and an antenna.
Recall Number Z-0700-2017<p>
REASON
Medtronic has identified an increased number of complaints from customers involving reports of Rechargers (Medtronic Model 37751 Recharger, which is included in Models 37754 and 97754 Charging Systems,Spinal Cord Stimulation)that are in an unresponsive error state, where the Recharger is non-functional with a blank display screen and is beeping every 5 seconds. Medtronic has determined all Rechargers manufactured starting in November 2014 (indicated by serial numbers beginning with NKA4 or NKU4) are more susceptible to this error state.<p>
RECALLING FIRM/MANUFACTURER
Medtronic Neuromodulation, Minneapolis, MN on 12.3/2016 Voluntary: Firm Initiated recall is ongoing.

<p>
VOLUME OF PRODUCT IN COMMERCE
42,887<p>
DISTRIBUTION
Nationwide and Internationally. <p>

12/14/2016 Merge eFilm, eFilm Lite Workstation Cl II
Company: Merge Healthcare, Inc.
Date of Enforcement Report 12/14/2016
Class II:<p>
PRODUCT
Merge, eFilm Workstation and eFilm Lite eFilm Workstation with Modules is a software application that is used for viewing medical images. eFilm Workstation with Modules receives digital images and data from various sources (including but not limited to CT, MR, US, RF units, computed and direct radiographic devices, secondary capture devices, scanners, imaging gateways or imaging sources). eFilm Workstation with Modules can be used to communicate, process and display medical images. Users have access to various image processing and measurement tools to assist them in viewing images. In addition, users can overlay templates on medical images to aid in preoperative planning. eFilm Workstation with Modules can be integrated with an institution s existing HIS or RIS for a fully integrated electronic patient record. Typical users of eFilm Workstation with Modules are trained medical professionals, including but not limited to radiologists, technologists and clinicians
Recall Number Z-0707-2017<p>
REASON
A product issues happens for RF projection images. If user measures on RF image, .cal (Calibration) is not displayed and measurement is not correct. The .cal label is not displayed on the projection images after calibration is performed which should be present if the measurement is presented based on Pixel Spacing.<p>
RECALLING FIRM/MANUFACTURER
Merge Healthcare, Inc., Hartland, WI on 10/20/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
2163 <p>
DISTRIBUTION
Nationwide and Internationally<p>

12/7/2016 Elekta Monaco RTP System Cl II
Company: Elekta, Inc.
Date of Enforcement Report 12/7/2016
Class II:<p>
PRODUCT
Monaco RTP System; Used to make treatment plans for patients with prescriptions for external beam radiation therapy.
Recall Number Z-0660-2017<p>
REASON
Incorrect Dose when using the reset function.<p>
RECALLING FIRM/MANUFACTURER
Elekta, Inc., Atlanta, GA on 11/25/2016 Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
671<p>
DISTRIBUTION
Nationwide and Internationally. <p>

12/7/2016 Merge Hemo software Cl II
Company: Merge Healthcare, Inc.
Date of Enforcement Report 12/7/2016
Class II:<p>
PRODUCT
Merge Hemo software. Merge Hemo monitors, measures, and records physiologic data from a human patient undergoing a cardiac catheterization procedure. The Monitoring System is for the monitoring of vital parameters including ECG, SpO2, invasive blood pressure, temperature, NIBP and CO2, and for the evaluation of resting ECG, arrhythmias, ST-segments and cardiac output. Some systems are built and designed to measure End Tidal CO2. The system is intended for use in hospital cardiac catheterization laboratories
Recall Number Z-0665-2017<p>
REASON
The application may crash during the cath lab procedure.<p>
RECALLING FIRM/MANUFACTURER
Merge Healthcare, Inc., Hartland, WI on 11/28/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
192 sites potentially have the affected version <p>
DISTRIBUTION
Nationwide <p>

12/7/2016 Merge FlexConnect software Cl II
Company: Merge Healthcare, Inc.
Date of Enforcement Report 12/7/2016
Class II:<p>
PRODUCT
Merge FlexConnect software, a component of Merge LIS. Merge FlexConnect is middleware used in conjunction with Merge LIS to facilitate connection to external applications
Recall Number Z-0664-2017<p>
REASON
Communication protocols interfacing with the affected software version with some select instruments were not properly handled, preventing data captured by these instructions to be processed by the rest of the LIS software.<p>
RECALLING FIRM/MANUFACTURER
Merge Healthcare, Inc., Hartland, WI on 11/28/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
324 sites potentially have the affected version <p>
DISTRIBUTION
Nationwide <p>

11/30/2016 Merge RadSuite. Cl II
Company: Merge Healthcare, Inc.
Date of Enforcement Report 11/30/2016
Class II:<p>
PRODUCT
Merge RadSuite,f/k/a: Emageon Advanced Visualization , RadSuite versions 8.30.7.8, 8.30.7.9, 8.30.8, and 8.31. Advanced Visualization (Image Viewing) includes: Full featured 2D imaging, 3D surface and volume rendering, Real-time Multi-Planar Reformatting (MPR), Real-time oblique imaging, Integrated image fusion, JPEG2000-based Adaptive Bandwidth Streaming, JPEG and Key Image Note export, Presentation States, Annotation and measurement tools, Automated linking, Display protocols, Enterprise Worklist, prior study management, softcopy viewing of digital mammography images provided that only 5 MP monitors with a cleared 510(k) are used and that digitized secondary captures of these images are not viewed for assisting in diagnosis, utilization of thirdparty electronic orthopedic

templates, the display of Standard Uptake Value, recording voice reports using third party, plug-in software, and user configurable settings for viewing digital medical images and corresponding data The application provides a means to distribute, display, and store diagnostic-quality medical images in electronic format. The system displays traditional 2D and reconstructed 3D radiological images using Webenabled viewers over both local and wide area networks. The application provides workflow integration capabilities for health care enterprises, wherein: ¿ Radiologists can view, annotate, and tag studies as diagnostically Read. ¿ Referring physicians can view patient images and radiologists annotations. ¿ Tertiary care physicians, medical technologists, and information technology professionals can receive patient records
Recall Number Z-0614-2017<p>
REASON
It was reported by a customer that RadSuite images are not appearing as readable images. This product malfunction has the potential to result in delay in care and a possible re-exposure of the patient to radiation (x-ray)..<p>
RECALLING FIRM/MANUFACTURER
Merge Healthcare, Inc., Hartland, WI on 11/18/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
29 <p>
DISTRIBUTION
Nationwide Distribution including AL, CA, FL,IN, MI, MO, NY, PA, TN, and WI.<p>

11/23/2016 Siemens SOMATOM Definition Flash Cl II
Company: Siemens Medical Solutions USA, Inc
Date of Enforcement Report 11/23/2016
Class II:<p>
PRODUCT
SOMATOM Definition Flash, Computed tomography x-ray system The Siemens SOMATOM Definition AS/ AS+ (Project P46) systems are intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data from either the same axial plane taken at different angles or spiral planes* taken at different angles
Recall Number Z-0608-2017<p>
REASON
Siemens is releasing a software update that provides bug-fixes to improve system performance for customers with SOMATOM Definition AS, SOMATOM Definition Edge, SOMATOM Definition Flash Systems with software version VA48A_SP2 and Care Contrast license correction of potential safety issues.<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc., Malvern, PA on 11/17/2016 Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
7 systems<p>
DISTRIBUTION
Nationwide distribution to MI, NY, CA, KY, ND, and NE. <p>

11/23/2016 Siemens SOMATOM Definition Edge Cl II
Company: Siemens Medical Solutions USA, Inc
Date of Enforcement Report 11/23/2016
Class II:<p>
PRODUCT
SOMATOM Definition Edge, Computed tomography x-ray system The Siemens SOMATOM Definition AS/ AS+ (Project P46) systems are intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data from either the same axial plane taken at different angles or spiral planes* taken at different angles

Recall Number Z-0607-2017<p>
REASON
Siemens is releasing a software update that provides bug-fixes to improve system performance for customers with SOMATOM Definition AS, SOMATOM Definition Edge, SOMATOM Definition Flash Systems with software version VA48A_SP2 and Care Contrast license correction of potential safety issues.<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc., Malvern, PA on 11/17/2016 Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
7 systems<p>
DISTRIBUTION
Nationwide distribution to MI, NY, CA, KY, ND, and NE. <p>

11/23/2016 Siemens SOMATOM Definition AS Cl II

Company: Siemens Medical Solutions USA, Inc
Date of Enforcement Report 11/23/2016
Class II:<p>
PRODUCT
SOMATOM Definition AS, Computed tomography x-ray system The Siemens SOMATOM Definition AS/ AS+ (Project P46) systems are intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data from either the same axial plane taken at different angles or spiral planes* taken at different angles
Recall Number Z-0606-2017<p>
REASON
Siemens is releasing a software update that provides bug-fixes to improve system performance for customers with SOMATOM Definition AS, SOMATOM Definition Edge, SOMATOM Definition Flash Systems with software version VA48A_SP2 and Care Contrast license correction of potential safety issues.<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc., Malvern, PA on 11/17/2016 Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
7 systems<p>
DISTRIBUTION
Nationwide distribution to MI, NY, CA, KY, ND, and NE. <p>

11/23/2016 Merge PACS software. Cl II

Company: Merge Healthcare, Inc.
Date of Enforcement Report 11/23/2016
Class II:<p>
PRODUCT
Merge PACS software. Product Usage: Merge PACS (Picture Archiving Communication System) is designed and marketed for soft copy reading, communication and storage of studies produced by digital modalities, including digital mammography.
Recall Number Z-0599-2017<p>
REASON
The software did not show unviewed images when the last view was skipped. The physician may potentially misdiagnose when not all images are available for viewing..<p>
RECALLING FIRM/MANUFACTURER
Merge Healthcare, Inc., Hartland, WI on 11/16/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
534 sites potentially have the affected software <p>

DISTRIBUTION
Nationwide and Canada<p>

11/23/2016 Merge iConnect Access software. CI II
Company: Merge Healthcare, Inc.
Date of Enforcement Report 11/23/2016
Class II:<p>
PRODUCT
MergeMerge LIS software
Recall Number Z-0611-2017<p>
REASON
Software displayed incorrect prior reports in the viewport area, only when more than one prior study (2 or more) was viewed.<p>
RECALLING FIRM/MANUFACTURER
Merge Healthcare, Inc., Hartland, WI on 11/17/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
60 sites potentially have the affected software <p>
DISTRIBUTION
Sites Nationwide and internationally<p>

11/23/2016 MEVION S250 CI II
Company: Mevion Medical Systems, Inc.
Date of Enforcement Report 11/23/2016
Class II:<p>
PRODUCT
MEVION S250 Product Usage: Proton Radiation Therapy System
Recall Number Z-0411-2017<p>
REASON
Software defect:2D projection of contours in Verity. The defect causes structures to appear off from their true position in the DRR and the radiograph with an error that increases with the distance of the structure from isocenter.<p>
RECALLING FIRM/MANUFACTURER
Mevion Medical Systems, Inc., Littleton, MA on 11/14/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
6 <p>
DISTRIBUTION
US Nationwide Distribution in the states of: FL, MO, NJ, OH, OK<p>

11/23/2016 The ORCHESTRA PLUS Programmer. CI II
Company: Sorin Group USA, Inc.
Date of Enforcement Report 11/23/2016
Class II:<p>
PRODUCT
The ORCHESTRA PLUS Programmer A portable device, equipped with a microprocessor used to program and interrogate Sorin implantable pacemakers and defibrillators. The programmer also provides measurement, ECG display and report printing functions that are essential for monitoring implant patients.
Recall Number Z-0413-2017<p>
REASON
Sorin Group USA, Inc. announces a voluntary field action for the ORCHESTRA Programmer and ORCHESTRA PLUS Programmer because the residual longevity estimate may be less accurate.<p>
RECALLING FIRM/MANUFACTURER

Sorin Group USA, Inc., Arvada, CO on 11/15/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
586 programmers <p>
DISTRIBUTION
Programmers were distributed nationwide, to VA/govt/military, Canadian, and other foreign consignees.<p>

11/23/2016 Merge LIS software. Cl II
Company: Merge Healthcare, Inc.
Date of Enforcement Report 11/23/2016
Class II:<p>
PRODUCT
MergeMerge LIS software
Recall Number Z-0399-2017<p>
REASON
There is a potential for duplicate container numbers to be created for patients..<p>
RECALLING FIRM/MANUFACTURER
Merge Healthcare, Inc., Hartland, WI on 11/11/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
413 sites potentially have the affected software <p>
DISTRIBUTION
Nationwide, the Virgin Islands and the Bahamas<p>

11/23/2016 Accu-Chek Connect Diabetes Management App Cl II
Company: Roche Diabetes Care
Date of Enforcement Report 11/23/2016
Class II:<p>
PRODUCT
Version 1.2.0 of Accu-Chek Connect Diabetes Management App (iOS) released on July 11, 2016
Recall Number Z-0586-2017<p>
REASON
Roche Diabetes Care, Inc. initiated a voluntary recall for the version 1.2.0 of Accu-Chek Connect Diabetes Management App (iOS), released on July 11, 2016, due to the software containing a programming error (bug) in the Bolus Advisor feature, which could lead to an incorrect insulin bolus recommendation.<p>
RECALLING FIRM/MANUFACTURER
Roche Diabetes Care., Indianapolis, IN on 11/16/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
7,909 downloads of iOS version 1.2.0 of the Accu-Chek Connect Diabetes Management App in the US and 8,775 downloads Internationally<p>
DISTRIBUTION
Nationwide <p>

11/16/2016 TBS iNsight Version v.3.0.1 Cl II
Company:Medimaps Group
Date of Enforcement Report 11/16/2016
Class II:<p>
PRODUCT
TBS iNsight Version v.3.0.1 Product Usage: TBS iNsight is a medical device software that is installed on bone densitometers for analysis of bone microarchitecture and osteoporosis management..
Recall Number Z-0369-2017<p>
REASON

The FRAX adjusted for TBS values are not correct when: The FRAX feature is activated in TBS iNsight; and TBS has been computed from a spine scan where some vertebrae were excluded.<p>
RECALLING FIRM/MANUFACTURER
Medimaps Group, Switzerland on 11/5/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
15 units in US<p>
DISTRIBUTION
Nationwide and Internationally<p>

11/16/2016 Roche COBAS INTEGRA Cl II
Company: Roche Diagnostics Operations, Inc.
Date of Enforcement Report 11/16/2016
Class II:<p>
PRODUCT
Roche COBAS INTEGRA c111 Analyzer, Chemistry (Photometric, Discrete), for clinical use Product Usage: The Roche COBAS INTEGRA c111 analyzer is an in-vitro diagnostic analyzer capable of performing clinical chemistry, specific protein and electrolyte tests. Analytes are measured photometrically or turbidimetrically. The analyzer also has an optional ISE module for measuring sodium, potassium and chloride.
Recall Number Z-0387-2017<p>
REASON
cobas c 111 analyzers (catalog numbers 04777433001 and 04528778001) with software versions up to and including 4.20 may encounter the following alarm: 7002: 108000572, A software error occurred. This alarm is generated due to a measurement timing error. Under very rare conditions, the instrument may process two tests in the same cuvette if the run restarts. If a used cuvette is used again result of the test(s) will be erroneous. These erroneous results may not be flagged. Falsely low or high patient results may lead to incorrect diagnostic measures and medical therapeutic decisions. The medical risk depends on the parameter.<p>
RECALLING FIRM/MANUFACTURER
Roche Diagnostics Operations, Inc., Indianapolis, IN on 11/9/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
139<p>
DISTRIBUTION
Nationwide <p>

11/9/2016 Xhibit Central Station, Model 96102 Cl II
Company: Spacelabs Healthcare Inc
Date of Enforcement Report 11/9/2016
Class II:<p>
PRODUCT
Xhibit Central Station, Model 96102. Intended use is to provide clinicians with central monitoring of adult, pediatric and neonatal patient data of patients connected to networked Spacelabs Healthcare patient monitors and telemetry transmitters.
Recall Number Z-0332-2017<p>
REASON
The firm received reports of telemetry SpO2 numerics dropping off the Xhibit Central display. Desaturation, high, and low limit alarms work normally.<p>
RECALLING FIRM/MANUFACTURER
Spacelabs Healthcare Inc., Snoqualmie, WA on 11/2/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
343 units<p>

DISTRIBUTION
Nationwide and Internationally<p>

11/9/2016 Symbiq Two Channel Infuser, Cl II
Company:Hospira Inc..
Date of Enforcement Report 11/9/2016
Class II:<p>
PRODUCT
Symbiq Two Channel Infuser; an Rx medical device infusion pump used to administer I.V. fluids;
Product List Number 16027
Recall Number Z-0354-2017<p>
REASON
Hospira has received reports of Malfunction S205 Backup Battery Failure alarms in Symbiq v3.13 pumps. This issue to an incorrect installation of components on some of the Power Supply Controller (PSC) Boards distributed prior to September 2012. On pumps where incorrect installation of components has occurred, the backup battery power discharges and subsequently, the battery cannot be charged. Because of the battery depletion, or lack of charge, a visual and audible warning alarm, S205, is displayed. An S205 alarm is intended to notify the customer that the coin call battery, powering the backup buzzer, may need to be charged or replaced.<p>
RECALLING FIRM/MANUFACTURER
Hospira Inc., Lake Forest, IL on 11/3/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
15,285 <p>
DISTRIBUTION
Nationwide and Canada<p>

11/9/2016 Symbiq One Channel Infuser, Cl II
Company:Hospira Inc..
Date of Enforcement Report 11/9/2016
Class II:<p>
PRODUCT
Symbiq One Channel Infuser; an Rx medical device infusion pump used to administer I.V. fluids;
Product List Number 16026
Recall Number Z-0353-2017<p>
REASON
Hospira has received reports of Malfunction S205 Backup Battery Failure alarms in Symbiq v3.13 pumps. This issue to an incorrect installation of components on some of the Power Supply Controller (PSC) Boards distributed prior to September 2012. On pumps where incorrect installation of components has occurred, the backup battery power discharges and subsequently, the battery cannot be charged. Because of the battery depletion, or lack of charge, a visual and audible warning alarm, S205, is displayed. An S205 alarm is intended to notify the customer that the coin call battery, powering the backup buzzer, may need to be charged or replaced.<p>
RECALLING FIRM/MANUFACTURER
Hospira Inc., Lake Forest, IL on 11/3/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
20,311 <p>
DISTRIBUTION
Nationwide and Canada<p>

11/3/2016 da Vinci Xi" Surgical System; Cl II
Company: Intuitive Surgical, Inc.
Date of Enforcement Report 11/32016
Class II:<p>
PRODUCT
a Vinci¿ Xi" Surgical System, model number IS4000, A70_P5x with P5 Software; General and Plastic Surgery: The Intuitive Surgical Endoscope Instrument Control System (da Vinci Surgical System, Model IS4000) is intended to assist in the accurate control of Intuitive Surgical Endoscopic Instruments including rigid endoscopes, blunt and sharp endoscopic dissectors, scissors, scalpels, forceps/pick-ups, needle holders, endoscopic retractors, electrocautery and accessories for endoscopic manipulation of tissue, including grasping, cutting, blunt and sharp dissection, approximations, ligation, electrocautery, suturing and delivery and placement of microware and cryogenic ablation probes and accessories, during urologic surgical procedures, general laparoscopic surgical procedures, gynecologic laparoscopic surgical procedures, general thoracoscopic surgical procedures and thoracoscopically-assisted cardiotomy procedures.
Recall Number Z-0315-2017<p>
REASON
Intuitive Surgical has identified a software anomaly in the da Vinci Xi P5 software that can result in unexpected master movement and potential instrument tip movement under certain circumstances.<p>
RECALLING FIRM/MANUFACTURER
Intuitive Surgical, Inc., Sunnyvale, CA on 10/26/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
677 devices <p>
DISTRIBUTION
Nationwide and Internationally<p>

11/3/2016 enGen Laboratory Automation System Cl II
Company: Ortho-Clinical Diagnostics
Date of Enforcement Report 11/3/2016
Class II:<p>
PRODUCT
enGen Laboratory Automation System (Product Code ENGEN) configured with Thermo Scientific Centrifuge Module and TCAutomation Software Version 3.6.1 and Below; IVD. --- Thermo Scientific Centrifuge Module has Product Code 952040-EG 6844097. The VITROS 5,1 FS Chemistry System with enGen Laboratory Automation System is intended for use in the in vitro quantitative measurement of a variety of analytes of clinical interest, using both VITROS Chemistry Products Slides (colorimetric endpoint, rate, ion-selective electrode, and immunorate methods) and VITROS Chemistry Products MicroTip liquid reagents (spectrophotometric and spectrophotometric immunoassay methods).
 Recall Number Z-0300-2017<p>
REASON
Ortho confirmed that it is possible for the mis-association of sample identification and assay results due to an error with Thermo Fishers centrifuge module. It is possible for mis-associated assay results to be reported from the laboratory prior to the identification of the Cross Check error on the enGen Laboratory Automation System. Assay results associated with the wrong patient and reported out of the laboratory could lead to inappropriate intervention with the potential for serious injury to the patient..<p>
RECALLING FIRM/MANUFACTURER
Ortho-Clinical Diagnostics, Rochester, NY on 9/22/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
60<p>
DISTRIBUTION
Nationwide and Internationally<p>

11/3/2016 Symbiq Two Channel Infuser, Cl II
Company: Hospira, Inc.
Date of Enforcement Report 11/3/2016
Class II:<p>
PRODUCT
Symbiq One Channel Infuser; an Rx medical device infusion pump used to administer I.V. fluids Device is a general purpose infusion pump designed to deliver fluids, solutions, medications, agents, nutritionals, electrolytes, blood and blood products for parenteral administration; and various solution through enteral, intravenous, intra-arterial, subcutaneous, and pathways.
Recall Number Z-0306-2017<p>
REASON
Symbiq Infusers have the potential to experience a white screen during titration of a Keep Vein Open (KVO) delivery. This can allow the clinician to select the "NEXT" button prior to completion of the programming. If this error occurs, a delay in therapy could occur and potentially result in significant injury..<p>
RECALLING FIRM/MANUFACTURER
Hospair, Inc., Lake Forest, IL on 10/24/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
35,596 devices <p>
DISTRIBUTION
Nationwide and Canada<p>

11/3/2016 Symbiq One Channel Infuse, Cl II
Company: Hospira, Inc.
Date of Enforcement Report 11/3/2016
Class II:<p>
PRODUCT
Symbiq One Channel Infuser; an Rx medical device infusion pump used to administer I.V. fluids Device is a general purpose infusion pump designed to deliver fluids, solutions, medications, agents, nutritionals, electrolytes, blood and blood products for parenteral administration; and various solution through enteral, intravenous, intra-arterial, subcutaneous, and pathways.
Recall Number Z-0305-2017<p>
REASON
Symbiq Infusers have the potential to experience a white screen during titration of a Keep Vein Open (KVO) delivery. This can allow the clinician to select the "NEXT" button prior to completion of the programming. If this error occurs, a delay in therapy could occur and potentially result in significant injury..<p>
RECALLING FIRM/MANUFACTURER
Hospair, Inc., Lake Forest, IL on 10/24/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
35,596 devices <p>
DISTRIBUTION
Nationwide and Canada<p>

10/26/2016 Merge Fusion Workstation; Cl II
Company: Merge Healthcare, Inc.
Date of Enforcement Report 10/26/2016
Class II:<p>
PRODUCT
Fusion Workstation.; Indicated for the transmission and review of radiological images.
Recall Number Z-0294-2017<p>
REASON
After a period of time running Fusion Workstation, the Hounsfield measurement tool will report incorrect

values.<p>
RECALLING FIRM/MANUFACTURER
Merge Healthcare, Inc., Hartland, WI on 10/20/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
13 sites potentially have the affected versions <p>
DISTRIBUTION
AZ, CA, ID, IL, IN, MI, MN, and NJ..<p>

10/26/2016 Philips IntelliVue MX40 802 Monitor Cl II
Company: Philips Electronics North America Corporation
Date of Enforcement Report 10/26/2016
Class II:<p>
PRODUCT
Philips IntelliVue MX40 Patient Monitor: IntelliVue MX40 802.11a/b/g Indicated for use by health care professionals whenever there is a need for monitoring the physiological parameters of patients. Intended for monitoring and recording of, and to generate alarms for, multiple physiological parameters of adults and pediatrics in hospital environments and during transport inside hospitals
Recall Number Z-0293-2017<p>
REASON
Philips IntelliVue MX40 Patient Wearable Monitor Configuration Setting Disables Generation and Delivery of ECG Alarms to PIIC iX<p>
RECALLING FIRM/MANUFACTURER
hilips Electronics North America Corporation , Andover, MA on 10/20/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
2212 units<p>
DISTRIBUTION
Nationwidewide and Internationally<p>

10/26/2016 Philips IntelliVue MX40 Patient Monitor: , Cl II
Company: Philips Electronics North America Corporation
Date of Enforcement Report 10/26/2016
Class II:<p>
PRODUCT
Philips IntelliVue MX40 Patient Monitor: IntelliVue MX40 Smart-hopping (2.4GHz) Indicated for use by health care professionals whenever there is a need for monitoring the physiological parameters of patients. Intended for monitoring and recording of, and to generate alarms for, multiple physiological parameters of adults and pediatrics in hospital environments and during transport inside hospitals
Recall Number Z-0292-2017<p>
REASON
Philips IntelliVue MX40 Patient Wearable Monitor Configuration Setting Disables Generation and Delivery of ECG Alarms to PIIC iX<p>
RECALLING FIRM/MANUFACTURER
hilips Electronics North America Corporation , Andover, MA on 10/20/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
1824 units<p>
DISTRIBUTION
Nationwidewide and Internationally<p>

10/26/2016 Philips IntelliVue MX40 Patient Monitor, Cl II

Company: Philips Electronics North America Corporation
Date of Enforcement Report 10.262016
Class II:<p>
PRODUCT
Philips IntelliVue MX40 Patient Monitor: IntelliVue MX40 WMTS Smart-hopping (1.4GHz) Product Number: 865350 Exchange part: 453564262491 453564262511 453564615311 453564615331 453564262571 453564262591 USA only SW Revisions: B.05.28, B.05.29, and B.05.32 Indicated for use by health care professionals whenever there is a need for monitoring the physiological parameters of patients. Intended for monitoring and recording of, and to generate alarms for, multiple physiological parameters of adults and pediatrics in hospital environments and during transport inside hospitals
Recall Number Z-0291-2017<p>
REASON
Philips IntelliVue MX40 Patient Wearable Monitor Configuration Setting Disables Generation and Delivery of ECG Alarms to PIIC iX<p>
RECALLING FIRM/MANUFACTURER
hilips Electronics North America Corporation , Andover, MA on 10/20/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
9804 units<p>
DISTRIBUTION
Nationwidewide and Internationally<p>

10/26/2016 Merge CADstream software; Cl II

Company: Merge Healthcare, Inc.
Date of Enforcement Report 9/14/2016
Class II:<p>
PRODUCT
CADstream software Product Usage: CADstream is an image processing system designed to assist in the visualization, analysis, and reporting of magnetic resonance imaging (MRI) studies. CADstream also is intended to provide workflow efficiency and interventional planning tools.
Recall Number Z-0118-2017<p>
REASON
Customers may experience an issue with the software study preferences when changes are made to the study protocol, resulting in incorrect patient follow-up.<p>
RECALLING FIRM/MANUFACTURER
Merge Healthcare, Inc., Hartland, WI on 10/18/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
844 sites potentially have the affected versions <p>
DISTRIBUTION
Nationwide.<p>

10/21/2016 FDA Multidata Discontinue Use Letter

FDA issued a letter to Radiation Oncologists, Medical Physicists, Dosimetrists, and Radiation Therapists to discontinue use of devicesfrom Multidata Systems. This company has had a history of issues and has been under consent decree. This letter relates to release of uncleared products. Multidata is the company that was involved in patient deaths in Panama in 2003 which the it was reported that the company claimed it was due to misuse at the time while others asserted risk controls were inadequate.

10/19/2016 Medtronic Navigation O-arm, Cl II
Company: Medtronic Navigation Inc.
Date of Enforcement Report 10/12/2016
Class II:<p>
PRODUCT
Medtronic Navigation O-arm O2 Surgical Imaging System Product Catalog Number: BI-700-02000 Product Usage: The O-arm Surgical Imaging System is a multi-dimensional surgical imaging platform that is designed for use in spine, orthopaedic, and trauma-related surgeries. It provides real-time, intra-operative imaging of a patients anatomy with high quality images and a large field-of-view in both two and three dimensions I
Recall Number Z-0070-2017<p>
REASON
O-arm O2 Surgical Imaging System Spatial calibration may be erroneous in Stealth Station navigated images<p>
RECALLING FIRM/MANUFACTURER
Medtronic Navigation, Inc., Littleton, MA on 10/11/2016 Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
14 units<p>
DISTRIBUTION
Nationwide and Switzerland<p>

10/19/2016 Fujifilm Synapse PACS, Software versions,
Cl II
Company: Siemens Healthcare Diagnostics, Inc.
Date of Enforcement Report 10/19/2016
Class II:<p>
PRODUCT
Fujifilm Synapse PACS, Software versions: 4.0.xxx, 4.1.xxx, version 4.2.xxx, version 4.3.xxx Medical imaging and information management system, SYNAPSE allows the archiving and distribution of image information from all modalities
Recall Number Z-0073-2017<p>
REASON
Image data for a patients image may not be correct.<p>
RECALLING FIRM/MANUFACTURER
Siemens Healthcare Diagnostics, Inc. Tarrytown, NY on 10.12/2016 Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
251 units<p>
DISTRIBUTION
Nationwide <p>

10/19/2016 Radiation Therapy Treatment Planning
System, Cl II
Company: RAYSEARCH LABORATORIES AB
Date of Enforcement Report 10/12/2016
Class II:<p>
PRODUCT
Radiation Therapy Treatment Planning System, Model 5.0
Recall Number Z-0079-2017<p>
REASON
For a treatment plan consisting of multiple beam sets, the table for ROI plan dose statistics in the report may show the statistics for a beam set dose. The error can only be triggered when using a report template where statistics for a beam set dose is included as the last dose statistics prior to the plan

dose statistics. less...<p>
RECALLING FIRM/MANUFACTURER
RAYSEARCH LABORATORIES AB, Stockholm, Sweden on 10/13/2016 Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
491 units<p>
DISTRIBUTION
AZ, CA, FL, MT, NC NY, TX, OH & WA<p>

10/19/2016 ADVIA Centaur XPT Immunoassay System,Cl II
Company: Siemens Healthcare Diagnostics, Inc.
Date of Enforcement Report 10/19/2016
Class II:<p>
PRODUCT
ADVIA Centaur XPT Immunoassay System
Recall Number Z-0072-2017<p>
REASON
The ADVIA Centaur¿ XPT default setting for the Daily Maintenance Task (Daily Cleaning Procedure) frequency may have the Daily Maintenance Task frequency set to, As needed instead of Daily. Not performing the daily maintenance may impact any assay and can be detected through monitoring of quality control and calibration results. Systems running in a language other than English are not impacted.<p>
RECALLING FIRM/MANUFACTURER
Siemens Healthcare Diagnostics, Inc. Tarrytown, NY on 4/28/2016 Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
292 systems<p>
DISTRIBUTION
Nationwide and Internationally<p>

10/16/2016 Elekta Monaco RTP System Cl II
Company: Elekta, Inc.
Date of Enforcement Report 10/19/2016
Class II:<p>
PRODUCT
Monaco RTP System The Monaco system is used to make treatment plans for patients with prescriptions for external beam radiation therapy. The system calculates dose for photon treatment plans and displays, on-screen and in hard-copy, two or three dimensional radiation dose distribution inside patients for given treatment plan set-ups
Recall Number Z-0076-2016<p>
REASON
PWhen creating 3D plans using either MU or Dose weighting modes, if the user changes the Physician's Intent Rx Dose and/or the number of fractions, and then modifies the wedge angle, the MU value is scaled incorrectly..<p>
RECALLING FIRM/MANUFACTURER
Elekta inc., Atlanta, GA on 10/13/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
365<p>
DISTRIBUTION
Nationwide and Internationally<p>

10/12/2016 RayStation 2.5, 3.0, 3.5, 4.0, 4.5, 4.7, 5.0 Cl II
Company: RAYSEARCH LABORATORIES AB
Date of Enforcement Report 10/12/2016
Class II:<p>
PRODUCT
RayStation 2.5, 3.0, 3.5, 4.0, 4.5, 4.7, 5.0 and 4.3 (InverseArc 1.0) -- Radiation Therapy Treatment Planning System RayStation is a software system designed for treatment planning and analysis of radiation therapy. The treatment plans provide treatment unit set-up parameters and estimates of dose distributions expected during the proposed treatment, and may be used to administer treatments after review and approval by the intended user. The system functionality can be configured based on user needs.
Recall Number Z-0038-2017<p>
REASON
RaySearch became aware of the problem as it was discovered in cooperation with a customer experimenting with the dose calculation on a phantom. The correction concerns two issues found with the dose calculation when using a region of interest (ROI) of type Fixation or Support with material override within the patient outline (External ROI) in RayStation 2.5, 3.0, 3.5, 4.0, 4.5, 4.7, 5.0 and 4.3 (InverseArc 1.0)<p>
RECALLING FIRM/MANUFACTURER
RAYSEARCH LABORATORIES AB, Stockholm, Sweden on 10/4/2016 Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
USA: 522 units, OUS 846 units<p>
DISTRIBUTION
Nationwide<p>

10/12/2016 Celesteion PCA-9000rV2 CT Scanner Cl II
Company: Toshiba America Medical Systems, Inc
Date of Enforcement Report 10/12/2016
Class II:<p>
PRODUCT
Toshiba America Medical Systems, Inc . Celesteion PCA-9000rV2 CT Scanner
Recall Number Z-0049-2017<p>
REASON
It has been found that if the scan range extends beyond the maximum Field of View (FOV), a reconstruction operation error may occur. As a result, scanning may be interrupted and rebooting of the system may be necessary. Please note that this issue has not occurred in the U.S.<p>
RECALLING FIRM/MANUFACTURER
Toshiba America Medical Systems, Inc., Tustin, CA on 10/6/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
165<p>
DISTRIBUTION
Nationwide <p>

10/12/2016 Aquilion LB TSX-201A/2, 3 CT Scanner Cl II
Company: Toshiba America Medical Systems, Inc
Date of Enforcement Report 10/12/2016
Class II:<p>
PRODUCT
Toshiba America Medical Systems, Inc . Aquilion LB TSX-201A/2, 3 CT Scanner
Recall Number Z-0048-2017<p>
REASON

It has been found that if the scan range extends beyond the maximum Field of View (FOV), a reconstruction operation error may occur. As a result, scanning may be interrupted and rebooting of the system may be necessary. Please note that this issue has not occurred in the U.S.<p>
RECALLING FIRM/MANUFACTURER
Toshiba America Medical Systems, Inc., Tustin, CA on 10/6/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
165<p>
DISTRIBUTION
Nationwide <p>

10/12/2016 Aquilion RXL TSX-1 01 AIR, U CT Scanner Cl II

Company: Toshiba America Medical Systems, Inc
Date of Enforcement Report 10/12/2016
Class II:<p>
PRODUCT
Toshiba America Medical Systems, Inc . Aquilion RXL TSX-1 01 AIR, U CT Scanner Diagnostic imaging systems indicated to acquire and display cross sectional volumes of the whole body, to include the head.
Recall Number Z-0047-2017<p>
REASON
It has been found that if the scan range extends beyond the maximum Field of View (FOV), a reconstruction operation error may occur. As a result, scanning may be interrupted and rebooting of the system may be necessary. Please note that this issue has not occurred in the U.S.<p>
RECALLING FIRM/MANUFACTURER
Toshiba America Medical Systems, Inc., Tustin, CA on 10/6/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
165<p>
DISTRIBUTION
Nationwide <p>

10/12/2016 Aquilion Lightning TSX-035A CT Scanner Cl II

Company: Toshiba America Medical Systems, Inc
Date of Enforcement Report 10/12/2016
Class II:<p>
PRODUCT
Toshiba America Medical Systems, Inc. Aquilion Lightning TSX-035A CT Scanner.
Recall Number Z-0046-2017<p>
REASON
It has been found that if the scan range extends beyond the maximum Field of View (FOV), a reconstruction operation error may occur. As a result, scanning may be interrupted and rebooting of the system may be necessary. Please note that this issue has not occurred in the U.S.<p>
RECALLING FIRM/MANUFACTURER
Toshiba America Medical Systems, Inc., Tustin, CA on 10/6/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
165<p>
DISTRIBUTION
Nationwide <p>

10/5/2016 Spacelabs Xhibit Telemetry Receiver Cl II
Company: Spacelabs Helathcare Inc.
Date of Enforcement Report 10/5/2016
Class II:<p>
PRODUCT
Spacelabs Healthcare Xhibit Telemetry Receiver (XTR), Model 96280. Xhibit Telemetry Receivers (XTR) must be connected to an Xhibit Central Station for the display of patient vital signs.
Recall Number Z-2886-2016<p>
REASON
The firm received multiple reports of Xhibit Telemetry System going offline or locking up. In addition, short-duration asystole alarms may not display an audio and visual alarm as reported from a single Canadian hospital.<p>
RECALLING FIRM/MANUFACTURER
Spacelabs Healthcare Inc., Snoqualmie, WA on 9/26/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
316 XTR units total (248 units in the US and 68 units outside US)<p>
DISTRIBUTION
Nationwide and Internationally<p>

10/5/2016 Siemens Syngo.plaza VB10A, Picture Archiving Cl II
Company: Siemens Medical Solutions USA, Inc
Date of Enforcement Report 10/5/2016
Class II:<p>
PRODUCT
Syngo.plaza VB10A, Picture Archiving and Communication System
Recall Number Z-2892-2016<p>
REASON
Software upgrade to eliminate several issues<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc., Malvern, PA on 9/27/2016 Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
47 systems<p>
DISTRIBUTION
Nationwide <p>

10/5/2016 Siemens Syngo.plaza, Picture Archiving Cl II
Company: Siemens Medical Solutions USA, Inc
Date of Enforcement Report 10/5/2016
Class II:<p>
PRODUCT
Syngo.plaza, Picture Archiving and Communication System.
Recall Number Z-2891-2016<p>
REASON
Software upgrade to eliminate several issues<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc., Malvern, PA on 9/27/2016 Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
47 systems<p>
DISTRIBUTION

Nationwide <p>

10/5/2016 Siemens Syngo RT Therapis Accelerator Cl II
Company: Siemens Medical Solutions USA, Inc
Date of Enforcement Report 10/5/2016
Class II:<p>
PRODUCT
Syngo RT Therapist, Accelerator, Linear, Medical Syngo RT Therapist is a software application whose indication for use includes the viewing, processing, filming, and archiving of medical images. It also permits patient data management, patient selection/setup, patient positioning verification, treatment planning, treatment delivery/verification, and treatment recording
Recall Number Z-2878-2016<p>
REASON
Software patch installation to address several safety issues<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc., Malvern, PA on 9/23/2016 Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
103 accelerators<p>
DISTRIBUTION
Nationwide <p>

10/5/2016 Siemens PRIMUS Linear Accelerators, Cl II
Company: Siemens Medical Solutions USA, Inc
Date of Enforcement Report 10/5/2016
Class II:<p>
PRODUCT
RTISTE, Accelerator, Linear, Medical The intended use of the SIEMENS branded ARTISTETM family of linear accelerator systems is to deliver X-Ray photon and electron radiation for the therapeutic treatment of cancer.
Recall Number Z-2877-2016<p>
REASON
Software patch installation to address several safety issues<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc., Malvern, PA on 9/23/2016 Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
103 accelerators<p>
DISTRIBUTION
Nationwide <p>

10/5/2016 Siemens ARTISTE Linear Accelerators Cl II
Company: Siemens Medical Solutions USA, Inc
Date of Enforcement Report 10/5/2016
Class II:<p>
PRODUCT
ARTISTE, Accelerator, Linear, Medical The intended use of the SIEMENS branded ARTISTETM family of linear accelerator systems is to deliver X-Ray photon and electron radiation for the therapeutic treatment of cancer.
Recall Number Z-2876-2016<p>
REASON
Software patch installation to address several safety issues<p>
RECALLING FIRM/MANUFACTURER

Siemens Medical Solutions USA, Inc., Malvern, PA on 9/23/2016 Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
103 accelerators<p>
DISTRIBUTION
Nationwide <p>

10/5/2016 Spacelabs Healthcare Xhibit Central Station
Cl II
Company: Spacelabs Helathcare Inc.
Date of Enforcement Report 10/5/2016
Class II:<p>
PRODUCT
Spacelabs Healthcare Xhibit Central Station, Model 96102. Xhibit Telemetry Receivers (XTR) must be connected to an Xhibit Central Station for the display of patient vital signs.
Recall Number Z-2885-2016<p>
REASON
The firm received multiple reports of Xhibit Telemetry System going offline or locking up. In addition, short-duration asystole alarms may not display an audio and visual alarm as reported from a single Canadian hospital.<p>
RECALLING FIRM/MANUFACTURER
Spacelabs Healthcare Inc., Snoqualmie, WA on 9/26/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
798 units total (488 units in the US and 310 units outside US)<p>
DISTRIBUTION
Nationwide and Internationally<p>

10/5/2016 CareLink iPro Version 1.10 Cl II
Company: Medtronic Inc.
Date of Enforcement Report 10/5/2016
Class II:<p>
PRODUCT
CareLink iPro Version 1.10, Catalog No. MMT-7340 With data obtained from the iPro2 recorder and blood glucose meter, the CareLink iPro software retrospectively calibrates sensor data and provides reports of continuous glucose information. CareLink iPro reports show up to seven calendar days of study data. The reports are created in PDF format, so they can easily be printed or stored electronically.
Recall Number Z-2898-2016<p>
REASON
Medtronic MiniMed is recalling the CareLink iPro Therapy Management Software due to a time stamp error.<p>
RECALLING FIRM/MANUFACTURER
Medtronic Inc., Northridge, CA on 9/27/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
33 units<p>
DISTRIBUTION
TN, MN, and WA<p>

10/5/2016 Alaris Syringe Module Model 8110, Cl II
Company: CareFusion 303 Inc.
Date of Enforcement Report 10/52016
Class II:<p>
PRODUCT

Alaris Syringe Module Model 8110 with software version 9.15 The Alaris Syringe Pump module is part of the Alaris System. The syringe pump delivers fluids in a manner similar to current syringe pumps on the market. Up to four Alaris Syringe pump modules can be connected to the Alaris PC unit which is the central programming, monitoring and power supply component for the Alaris System. The syringe pump uses standard, single-use administration sets and syringes with luer-lock connectors.
Recall Number Z-2879-2016<p>
REASON
A software anomaly with the Alaris Syringe module software version 9.15 may cause an infusion to unexpectedly stop when the Syringe module is transitioning from one rate to another.<p>
RECALLING FIRM/MANUFACTURER
CareFusion 303, Inc., San Diego, CA on 9/32016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
12.000 units <p>
DISTRIBUTION
Nationwide, Canada, Australia and United Arab Emirates and Canada <p>

9/28/2016 Merge CADstream software, CI II
Company: Merge Healthcare, Inc.
Date of Enforcement Report 9/28/2016
Class II:<p>
PRODUCT
CADstream software. Product Usage: CADstream is an image processing system designed to assist in the visualization, analysis, and reporting of magnetic resonance imaging (MRI) studies. CADstream also is intended to provide workflow efficiency and interventional planning tools.
Recall Number Z-2871-2016<p>
REASON
An incorrect biopsy or missed target could result if the incorrect grid is selected within the application..<p>
RECALLING FIRM/MANUFACTURER
Merge Healthcare, Inc., Hartland, WI on 9/22/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
1349 sites <p>
DISTRIBUTION
Nationwide<p>

9/28/2016 Siemens Syngo.via , CI II
Company: Siemens Medical Solutions USA, Inc
Date of Enforcement Report 9/28/2016
Class II:<p>
PRODUCT
Syngo.via picture archiving and communication system Syngo via is a software solution intended to be used for viewing, manipulation, communication, and storage of medical images.
Recall Number Z-2853-2016<p>
REASON
Software error. Incorrect values for the volume calculation from a freehand VOI at the customer site. In volume calculations of prostate as well as in volume calculations of liver were too high.<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc., Malvern, PA on 9/21/2016 Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
338 systems<p>
DISTRIBUTION
Nationwide <p>

9/28/2016 Siemens Syngo.x , Cl II
Company: Siemens Medical Solutions USA, Inc
Date of Enforcement Report 9/28/2016
Class II:<p>
PRODUCT
Syngo.x picture archiving and communication system Syngo.x is a software solution intended to be used for viewing, manipulation, communication, and storage of medical images
Recall Number Z-2852-2016<p>
REASON
Software error. Incorrect values for the volume calculation from a freehand VOI at the customer site. In volume calculations of prostate as well as in volume calculations of liver were too high.<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc., Malvern, PA on 9/21/2016 Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
338 systems<p>
DISTRIBUTION
Nationwide <p>

9/28/2016 Philips Expression Information Portal Cl II
Company:Invivo Corporation
Date of Enforcement Report 9/28/2016
Class II:<p>
PRODUCT
Hospira MedNet Medication Management Suite software, version 6.1, List Numbers 16037-64-02 and 16037-64-03, in combination with the SapphirePlus 13.1x infusion pump Hospira MedNet Medication Management Suite is intended to facilitate networked communication between compatible computer systems and Hospital infusion pumps..
Recall Number Z-2790-2016<p>
REASON
Frozen Display Numerics and Disabled Menu Keys after extended run time. This customer notification was sent August 22, 2014.<p>
RECALLING FIRM/MANUFACTURER
Invivo Corporation, Orlando, FL on 9/21/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
639 units<p>
DISTRIBUTION
Nationwide and Internationally<p>

9/21/2016 Siemens RAPIDLab 1265 Cl II
Company: Siemens Healthcare Diagnostics, Inc.
Date of Enforcement Report 9/21/2016
Class II:<p>
PRODUCT
RAPIDLab 1265 Blood Gas Analyzer Siemens Material Number (SMN): 10321852, 10470366, 10491395
Recall Number Z-2803-2016<p>
REASON
There is a potential for the first and/or last name of one patient to be printed with Patient ID and result data from a different patient, even though those fields have been turned Off for the system<p>
RECALLING FIRM/MANUFACTURER
Siemens Healthcare Diagnostics, Inc., Norwood, MA on 9/14 2016 Voluntary: Firm Initiated recall is

ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
2602 units<p>
DISTRIBUTION
Nationwide and Internationally <p>

9/21/2016 Siemens RAPIDLab 1260 Cl II
Company: Siemens Healthcare Diagnostics, Inc.
Date of Enforcement Report 9/21/2016
Class II:<p>
PRODUCT
RAPIDLab 1260 Blood Gas Analyzer Siemens Material Number (SMN): 10321846, 10491394
Recall Number Z-2802-2016<p>
REASON
There is a potential for the first and/or last name of one patient to be printed with Patient ID and result data from a different patient, even though those fields have been turned Off for the system<p>
RECALLING FIRM/MANUFACTURER
Siemens Healthcare Diagnostics, Inc., Norwood, MA on 9/14 2016 Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
114 units<p>
DISTRIBUTION
Nationwide and Internationally <p>

9/21/2016 Siemens RAPIDLab 1245 Cl II
Company: Siemens Healthcare Diagnostics, Inc.
Date of Enforcement Report 9/21/2016
Class II:<p>
PRODUCT
RAPIDLab 1245 Blood Gas Analyzer Siemens Material Number (SMN): 10321844, 10337179, 10491393
Recall Number Z-2801-2016<p>
REASON
There is a potential for the first and/or last name of one patient to be printed with Patient ID and result data from a different patient, even though those fields have been turned Off for the system<p>
RECALLING FIRM/MANUFACTURER
Siemens Healthcare Diagnostics, Inc., Norwood, MA on 9/14 2016 Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
197 units<p>
DISTRIBUTION
Nationwide and Internationally <p>

9/21/2016 Siemens RAPIDLab 1240 Cl II
Company: Siemens Healthcare Diagnostics, Inc.
Date of Enforcement Report 9/21/2016
Class II:<p>
PRODUCT
Siemens RAPIDLab 1240 Blood Gas Analyzer Siemens Material Number (SMN): 10321840, 10491392
Recall Number Z-2800-2016<p>
REASON
There is a potential for the first and/or last name of one patient to be printed with Patient ID and result data from a different patient, even though those fields have been turned Off for the system<p>

RECALLING FIRM/MANUFACTURER
Siemens Healthcare Diagnostics, Inc., Norwood, MA on 9/14 2016 Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
144 units<p>
DISTRIBUTION
Nationwide and Internationally <p>

9/21/2016 Siemens RAPIDPoint 500 Cl II
Company: Siemens Healthcare Diagnostics, Inc.
Date of Enforcement Report 9/21/2016
Class II:<p>
PRODUCT
Siemens RAPIDPoint 500 Blood Gas Analyzer Siemens Material Number (SMN): 10492730, 10696855, 10696857, 10697306
Recall Number Z-2799-2016<p>
REASON
There is a potential for the first and/or last name of one patient to be printed with Patient ID and result data from a different patient, even though those fields have been turned Off for the system<p>
RECALLING FIRM/MANUFACTURER
Siemens Healthcare Diagnostics, Inc., Norwood, MA on 9/14 2016 Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
6786 units<p>
DISTRIBUTION
Nationwide and Internationally <p>

9/21/2016 Siemens RAPIDPoint 405 Cl II
Company: Siemens Healthcare Diagnostics, Inc.
Date of Enforcement Report 9/21/2016
Class II:<p>
PRODUCT
Siemens RAPIDPoint 405 Blood Gas Analyzer nBili Siemens Material Number (SMN): 10282093, 10310464, 10314817, 1031 7193, 10318999, 10320055, 10321238, 10322347, 10328278, 10328302, 10336784
Recall Number Z-2798-2016<p>
REASON
There is a potential for the first and/or last name of one patient to be printed with Patient ID and result data from a different patient, even though those fields have been turned Off for the system<p>
RECALLING FIRM/MANUFACTURER
Siemens Healthcare Diagnostics, Inc., Norwood, MA on 9/14 2016 Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
2910 units<p>
DISTRIBUTION
Nationwide and Internationally <p>

9/21/2016 Siemens RAPIDPoint 400 Cl II
Company: Siemens Healthcare Diagnostics, Inc.
Date of Enforcement Report 9/21/2016
Class II:<p>
PRODUCT
Siemens RAPIDPoint¿ 400 Blood Gas Analyzer Siemens Material Number (SMN):

10291507,10314585, 10318899,10321239, 10322654,10324081, 10328803, 10331381 , 10339634
Recall Number Z-2797-2016<p>
REASON
There is a potential for the first and/or last name of one patient to be printed with Patient ID and result data from a different patient, even though those fields have been turned Off for the system<p>
RECALLING FIRM/MANUFACTURER
Siemens Healthcare Diagnostics, Inc., Norwood, MA on 9/14 2016 Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
492 units<p>
DISTRIBUTION
Nationwide and Internationally <p>

9/21/2016 Hospira MedNet Cl II
Company: Hospira Inc.
Date of Enforcement Report 9/21/2016
Class II:<p>
PRODUCT
Hospira MedNet Medication Management Suite software, version 6.1, List Numbers 16037-64-02 and 16037-64-03, in combination with the SapphirePlus 13.1x infusion pump Hospira MedNet Medication Management Suite is intended to facilitate networked communication between compatible computer systems and Hospital infusion pumps..
Recall Number Z-2790-2016<p>
REASON
Hospira MedNet 6.1 software, in combination with the SapphirePlus 13.1x infusion pump, may result in incorrect bolus amount calculations for drugs whose concentrations are listed in Million Units..<p>
RECALLING FIRM/MANUFACTURER
Hospira Inc., Lake Forest, IL on 9/13/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
20<p>
DISTRIBUTION
Nationwide and Canada<p>

9/21/2016 Endura MR Mass Spectrometer Cl II
Company: Thermo Finnigan LLC.
Date of Enforcement Report 9/21/2016
Class II:<p>
PRODUCT
Endura MR Mass Spectrometer u using software versions Endura MD Software 1.0 and 1.0 SP1. In vitro diagnostic medical device used to identify and quantify inorganic and organic compounds in the human body. Chemistry: In vitro diagnostic medical device used to identify and quantify inorganic and organic compounds in the human body.
Recall Number Z-2775-2016<p>
REASON
Thermo Fisher has determined that the Endura MD mass spectrometer instrument control software versions 1.0 and 1.0 SP! have a software defect which affect data accuracy.<p>
RECALLING FIRM/MANUFACTURER
Thermo Finnigan LLC, San Jose, CA on 9/9/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
6<p>
DISTRIBUTION
US including FL, NY and Internationally to Japan.<p>

9/21/2016 ORTHO VITROS Chemistry Products
Calibrator Cl III
Company: Ortho-Clinical Diagnostics
Date of Enforcement Report 9/21/2016
Class III:<p>
PRODUCT
The VITROS¿ Chemistry Products Calibrator Kit 31, Lot 3155 used in conjunction with: VITROS¿ Chemistry Products HbA1c Reagent Kit, Generation 6 (GEN 6) and Assay Data Disk (ADD), Data Release Versions (DRV) 5873, 5874, 5875, or 5876, is used to calibrate the VITROS 5,1 FS Chemistry System, VITROS 4600 Chemistry System and the VITROS 5600 Integrated System for the determination of percent glycated hemoglobin (HbA1c) in human whole blood.
Recall Number Z-2804-2016<p>
REASON
There is an incorrect value (data/calibration mathematics) on ADDs. This incorrect value will prevent a successful calibration of the assay.<p>
RECALLING FIRM/MANUFACTURER
Ortho-Clinical Diagnostics, Rochester, NY on 9/14/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
520 Units <p>
DISTRIBUTION
Nationwide and Internationally<p>

9/14/2016 Merge RadSuite software; Cl II
Company: Merge Healthcare, Inc.
Date of Enforcement Report 9/14/2016
Class II:<p>
PRODUCT
Merge RadSuite software. Radiological image processing system.
Recall Number Z-2715-2016<p>
REASON
When RadSuite is used with IPID (Issuer of Patient ID) as a part of the "Patient Identifier," it is possible in some circumstances that the demographics of one patient will be applied to a study or studies for another patient..<p>
RECALLING FIRM/MANUFACTURER
Merge Healthcare, Inc., Hartland, WI on 9/2/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
10 sites <p>
DISTRIBUTION
AL, MI, MO, PA, TN, and TX..<p>

9/7/2016 Merge Cardio software. Cl II
Company: Merge Healthcare, Inc.
Date of Enforcement Report 9/7/2016
Class II:<p>
PRODUCT
Merge Cardio software. The firm name on the label is Merge Healthcare, Hartland, WI. Image processing system.
Recall Number Z-2709-2016<p>
REASON
A report can be confirmed with the incorrect patient demographics resulting in it being saved under the incorrect patient record in the Electronic Medical Record (EMR)..<p>
RECALLING FIRM/MANUFACTURER
Merge Healthcare, Inc., Hartland, WI on 9/1/2016. Voluntary: Firm Initiated recall is ongoing. <p>

VOLUME OF PRODUCT IN COMMERCE
116 customers potentially have the affected versions<p>
DISTRIBUTION
US Distribution to: CO and OK.<p>

9/7/2016 Elekta HexaPOD evo RT System, Cl II
Company: Elekta, Inc.
Date of Enforcement Report 8/31/2016
Class II:<p>
PRODUCT
HexaPOD evo RT System Product Usage: The intended use of the device is the control of accurate patient positioning with assistance of a 3D Tracking System in a radiotherapy environment.
Recall Number Z-2691-2016<p>
REASON
Potentially unrecognized incorrect position of the treatment couch in 3D workflow, i.e. the HexaPOD has not moved fully to the 3D position.<p>
RECALLING FIRM/MANUFACTURER
Elekta inc., Atlanta, GA on 8/18/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
13<p>
DISTRIBUTION
US Nationwide in the states of LA, PA, WA, and the countries of: Australia, Denmark, France, India, Italy, and Japan.<p>

9/7/2016 Elekta Monaco RTP System, Cl II
Company: Elekta, Inc.
Date of Enforcement Report 8/31/2016
Class II:<p>
PRODUCT
Monaco RTP System Used to make treatment plans for patients with prescriptions for external beam radiation therapy.
Recall Number Z-2712-2016<p>
REASON
In a specific workflow where contours are edited (enlarged, moved, copied, etc.) and then the contour is deleted on some slices and saved in the same session, it is possible that the deleted contours are still present which would not be the intent of the planner.<p>
RECALLING FIRM/MANUFACTURER
Elekta inc., Atlanta, GA on 9/1/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
3,012 units<p>
DISTRIBUTION
Nationwide and Internationally <p>

9/7/2016 Merge iConnect Enterprise Archive Cl II
Company: Merge Healthcare, Inc.
Date of Enforcement Report 9/7/2016
Class II:<p>
PRODUCT
iConnect Enterprise Archive. The firm name on the label is Merge Healthcare, Hartland, WI. iConnect Enterprise Archive is intended for use as a vendor neutral archive for storage and communications of medical images and data.
Recall Number Z-2686-2016<p>
REASON

Interventional Radiology (IR) images are stored as JPEG2k Lossless in Merge Enterprise Archive (EA) and are not displaying correctly in RadSuite..<p>
RECALLING FIRM/MANUFACTURER
Merge Healthcare, Inc., Hartland, WI on 8/29/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
96 sites potentially have the affected versions for both products <p>
DISTRIBUTION
US Distribution to: CO and OK.<p>

9/7/2016 Merge RadSuite software Cl II
Company: Merge Healthcare, Inc.
Date of Enforcement Report 9/7/2016
Class II:<p>
PRODUCT
RadSuite software. The firm name on the label is Merge Healthcare, Hartland, WI. RadSuite provides a means to distribute, display, and store diagnostic-quality medical images in electronic format.
Recall Number Z-2685-2016<p>
REASON
Interventional Radiology (IR) images are stored as JPEG2k Lossless in Merge Enterprise Archive (EA) and are not displaying correctly in RadSuite..<p>
RECALLING FIRM/MANUFACTURER
Merge Healthcare, Inc., Hartland, WI on 8/29/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
96 sites potentially have the affected versions for both products <p>
DISTRIBUTION
US Distribution to: CO and OK.<p>

9/7/2016 Nidek SPECULAR MICROSCOPE CEM-530 Cl II
Company: Nidek Inc
Date of Enforcement Report 9/7/2016
Class II:<p>
PRODUCT
SPECULAR MICROSCOPE CEM-530; Software version 1.08 and 1.09. Opthalmic: The NIDEK Specular Microscope CEM-530 provides non-contact, high magnification image capture of endothelium enabling observation of the size and shape of cells. Information such as the number of endothelial cells, cell density, and cell area is analyzed through the captured images,
Recall Number Z-2711-2016<p>
REASON
Software version 1.08 and 1.09 for the Specular Microscope CEM 530 included a change of analysis results feature that was not reviewed and approved by the FDA.<p>
RECALLING FIRM/MANUFACTURER
Nidek Inc., Fremont, CA on 9/1/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
29 devices<p>
DISTRIBUTION
Nationwide <p>

9/7/2016 Siemens ADVIA Chemistry XPT Cl II
Company: Siemens Healthcare Diagnostics, Inc.
Date of Enforcement Report 9/7/2016
Class II:<p>
PRODUCT

ADVIA Chemistry XPT, SMN 10723034, IVD. --- This issue affects only the ADVIA Chemistry Hemoglobin A1c_3 Automated Pretreatment (A1c_3) results when HbA1c values are reported in International Federation of Clinical Chemistry (IFCC) equivalent units (HbA1cR). The ADVIA Chemistry XPT System is an automated, clinical chemistry analyzer that runs tests on serum, plasma, urine, or cerebral spinal fluid in random access and batch modes at a throughput rate of both 1800 photometric tests per hour and 600 electrolyte (ISE) tests per hour
Recall Number Z-2704-2016<p>
REASON
Siemens identified an issue with the ratio equation provided on the ADVIA Chemistry XPT System Software Test Definition (TDef) Version 1.0 disks (SMN: 11127343 and 11222123). This issue affects only the ADVIA Chemistry Hemoglobin A1c_3 Automated Pretreatment (A1c_3) results when HbA1c values are reported in International Federation of Clinical Chemistry (IFCC) equivalent units (HbA1cR). The ratio equation used to calculate ADVIA Chemistry Hemoglobin A1c_3 Automated Pretreatment (A1c_3) results in IFCC units contains an error. The error results in falsely depressed HbA1cR results. .<p>
RECALLING FIRM/MANUFACTURER
Siemens Healthcare Diagnostics, Inc., Tarrytown, NY on 8/30/2016 Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
Domestic: 32 units; Foreign: 197 units<p>
DISTRIBUTION
Nationwide and Internationally <p>

9/7/2016 GECentricity Laboratory Core Lab System 4.1
Cl II
Company: GE Healthcare It
Date of Enforcement Report 9/7/2016
Class II:<p>
PRODUCT
Centricity Laboratory Core Lab System 4.1 The Centricity Laboratory System is intended to be an information system designed to support the clinical and administrative activities associated with the provision and utilization of clinical laboratory services and facilities, e.g., the storing and delivering of analytical results. It is a specially designed data program application (software), which is supplied for installation in existing mainframe or decentralized computers or a computer network.
Recall Number Z-2671-2016<p>
REASON
The Centricity Laboratory removes free-text notes on a master panel when the user deletes the slave panel. The deletion of a slave panel will (auto slash) the corresponding test (item) results on the master panel. Additionally, the displayed and HL7 results show neither the appropriate abnormal flag value nor the reference range values, when using large_num.g >7 to report numeric results. <p>
RECALLING FIRM/MANUFACTURER
Ge Healthcare IT, Barrington, IL on 8/26/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
17<p>
DISTRIBUTION
Nationwide and Internationally<p>

9/7/2016 TANGO Infinity, Cl III
Company: Bio-Rad Laboratories, Inc.
Date of Enforcement Report 9/7/2016
Class III:<p>
PRODUCT
TANGO Infinity, catalog # 850000010, Software version 1.2

Recall Number B-0746-16<p>
REASON
TANGO Infinity System, with a defect or glitch allowing an incorrect microplate type, was distributed.<p>
RECALLING FIRM/MANUFACTURER
Bio-Rad Laboratories, Inc. , Redmond, WA on 9/1/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
20 devices<p>
DISTRIBUTION
CA, FL, GA, MA, MD, MN, NC, NY, PA, TX, VA and WA DC. <p>

8/31/2016 NovaPACS Cl II
Company: Merge Healthcare, Inc.
Date of Enforcement Report 8/31/2016
Class II:<p>
PRODUCT
NovaPACS versions 8.4.7, 8.5.3, and 8.5.6. Distributed by Novarad Corporation. Picture archiving and communication system (PACS) Product Usage NovaPACS is a picture archiving and communication system software that retrieves, archives, distributes, and displays images and data from all common modalities. NovaPACS uses a variety of workstations, including a Technologist Workstation,
Recall Number Z-2659-2016<p>
REASON
Potential for RadSuite AV viewer to skip image slices when the user presses page up or page down when the viewer displays multiple viewports and the user has mouse focused on any viewport other than the first viewport..<p>
RECALLING FIRM/MANUFACTURER
Novarad Corporation, American Fork, UT on 8/25/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
90<p>
DISTRIBUTION
Nationwide and Internationally <p>

8/31/2016 Merge RadSuite software Cl II
Company: Merge Healthcare, Inc.
Date of Enforcement Report 8/31/2016
Class II:<p>
PRODUCT
RadSuite software. The firm name on the label is Merge Healthcare, Hartland, WI.
Recall Number Z-2627-2016<p>
REASON
Potential for RadSuite AV viewer to skip image slices when the user presses page up or page down when the viewer displays multiple viewports and the user has mouse focused on any viewport other than the first viewport..<p>
RECALLING FIRM/MANUFACTURER
Merge Healthcare, Inc, Hartland, WI on 8/23/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
25 sites have the affected version<p>
DISTRIBUTION
Distribution was made to AL, AZ, CA, IL, MD, MA, MI, MO, NV, NJ, NC, OH, PA, TN, and VA. Government distribution was made to OK. There was no foreign/military distribution. <p>

8/31/2016 CARESCAPE VC150 Vital Signs Monitor Cl II
Company: INNOKAS MEDICAL OY
Date of Enforcement Report 8/31/2016
Class II:<p>
PRODUCT
CARESCAPE VC150 Vital Signs Monitor; Intended to monitor a single patient's vital signs at the site of care.
Recall Number Z-2604-2016<p>
REASON
A software error on released software versions 1.6.12, 1.6.12F and 1.6.16 may give wrong time data to measurements.<p>
RECALLING FIRM/MANUFACTURER
INNOKAS MEDICAL OY, KEMPELE , Finland on 8/19/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
1458 units<p>
DISTRIBUTION
AR, AZ, FL, IN, LA, MA, MI, NC, NJ, NM, NY, OH, PA, TN, WI <p>

8/31/2016 Siemens SOMATOM Definition Edge, Cl II
Company: Siemens Medical Solutions USA, Inc
Date of Enforcement Report 8/31/2016
Class II:<p>
PRODUCT
SOMATOM Definition Edge with software version VA48A-SP2; Model # 8098027 computed tomography x-ray system
Recall Number Z-2626-2016<p>
REASON
Due to an internal communication error between the firmware and the software of the components, the planned CT scan executes properly, but the injector is not started. Therefore, the contrast agent is not injected and the desired examination result is not achieved. This error only affects the automatic mode or coupled mode and does not affect the manual control of the injector.<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc., Malvern, PA on 8/23/2016 Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
4 systems<p>
DISTRIBUTION
Distributed to: MI, NY, CA, KY, ND, NE <p>

8/31/2016 Siemens SOMATOM Definition Flash, Cl II
Company: Siemens Medical Solutions USA, Inc
Date of Enforcement Report 8/31/2016
Class II:<p>
PRODUCT
SOMATOM Definition Flash with software version VA48A-SP2; Model # 10590000, computed tomography x-ray system.
Recall Number Z-2625-2016<p>
REASON
Due to an internal communication error between the firmware and the software of the components, the planned CT scan executes properly, but the injector is not started. Therefore, the contrast agent is not injected and the desired examination result is not achieved. This error only affects the automatic mode or coupled mode and does not affect the manual control of the injector.<p>

RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc., Malvern, PA on 8/23/2016 Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
2 systems<p>
DISTRIBUTION
Distributed to: MI, NY, CA, KY, ND, NE <p>

8/31/2016 Siemens SOMATOM Definition AS, Cl II
Company: Siemens Medical Solutions USA, Inc
Date of Enforcement Report 8/31/2016
Class II:<p>
PRODUCT
SOMATOM Definition AS with software version VA48A-SP2; Model # 10430603, computed tomography x-ray system.
Recall Number Z-2624-2016<p>
REASON
Due to an internal communication error between the firmware and the software of the components, the planned CT scan executes properly, but the injector is not started. Therefore, the contrast agent is not injected and the desired examination result is not achieved. This error only affects the automatic mode or coupled mode and does not affect the manual control of the injector.<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc., Malvern, PA on 8/23/2016 Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
1 units<p>
DISTRIBUTION
Distributed to: MI, NY, CA, KY, ND, NE <p>

8/31/2016 Philips Ingenuity Core128 Model 728323, Cl II
Company: Philips Medical Systems, Inc.
Date of Enforcement Report 8/31/2016
Class II:<p>
PRODUCT
Ingenuity Core128 Model number 728323 Product Usage: Computed Tomography X-ray systems intended to produce cross-sectional images of the body by computer reconstruction of X-ray transmission data taken at different angles and planes.
Recall Number Z-2658-2016<p>
REASON
After upgrading to 3.6.7 software version via FCO72800643, during reconstruction of gated helical scans, the planned anatomy can be cut off on the CT images. This issue can occur on gated CT helical reconstruction that is not planned at iso-center (0,0). If the region of interest is not visualized in the images, a CT rescan may be performed.<p>
RECALLING FIRM/MANUFACTURER
Philips Medical Systems, Inc., Cleveland, OH on 8/25/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
3<p>
DISTRIBUTION
Nationwide <p>

8/31/2016 Philips Ingenuity Core Model 728321, Cl II
Company: Philips Medical Systems, Inc.
Date of Enforcement Report 8/31/2016
Class II:<p>
PRODUCT
Ingenuity Core Model number 728321 Product Usage: Computed Tomography X-ray systems intended to produce cross-sectional images of the body by computer reconstruction of X-ray transmission data taken at different angles and planes.
Recall Number Z-2657-2016<p>
REASON
After upgrading to 3.6.7 software version via FCO72800643, during reconstruction of gated helical scans, the planned anatomy can be cut off on the CT images. This issue can occur on gated CT helical reconstruction that is not planned at iso-center (0,0). If the region of interest is not visualized in the images, a CT rescan may be performed.<p>
RECALLING FIRM/MANUFACTURER
Philips Medical Systems, Inc., Cleveland, OH on 8/25/2016. Voluntary: Firm Initiated recall is ongoing.
<p>
VOLUME OF PRODUCT IN COMMERCE
30<p>
DISTRIBUTION
Nationwide <p>

8/31/2016 Philips Brilliance 16 Power, Model 728246, Cl II
Company: Philips Medical Systems, Inc.
Date of Enforcement Report 8/31/2016
Class II:<p>
PRODUCT
Brilliance CT 16 Power, Model number 728240 Product Usage: Computed Tomography X-ray systems intended to produce cross-sectional images of the body by computer reconstruction of X-ray transmission data taken at different angles and planes.
Recall Number Z-2656-2016<p>
REASON
After upgrading to 3.6.7 software version via FCO72800643, during reconstruction of gated helical scans, the planned anatomy can be cut off on the CT images. This issue can occur on gated CT helical reconstruction that is not planned at iso-center (0,0). If the region of interest is not visualized in the images, a CT rescan may be performed.<p>
RECALLING FIRM/MANUFACTURER
Philips Medical Systems, Inc., Cleveland, OH on 8/25/2016. Voluntary: Firm Initiated recall is ongoing.
<p>
VOLUME OF PRODUCT IN COMMERCE
50<p>
DISTRIBUTION
Nationwide <p>

8/31/2016 Philips Brilliance 16, Model number 728246, Cl II
Company: Philips Medical Systems, Inc.
Date of Enforcement Report 8/31/2016
Class II:<p>
PRODUCT
Brilliance 16, Model number 728246 Product Usage: Computed Tomography X-ray systems intended to produce cross-sectional images of the body by computer reconstruction of X-ray transmission data

taken at different angles and planes.
Recall Number Z-2655-2016<p>
REASON
After upgrading to 3.6.7 software version via FCO72800643, during reconstruction of gated helical scans, the planned anatomy can be cut off on the CT images. This issue can occur on gated CT helical reconstruction that is not planned at iso-center (0,0). If the region of interest is not visualized in the images, a CT rescan may be performed.<p>
RECALLING FIRM/MANUFACTURER
Philips Medical Systems, Inc., Cleveland, OH on 8/25/2016. Voluntary: Firm Initiated recall is ongoing.
<p>
VOLUME OF PRODUCT IN COMMERCE
192<p>
DISTRIBUTION
Nationwide <p>

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8/31/2016 Brilliance CT Big Bore CT Model 728244Cl ll
Company: Philips Medical Systems, Inc.
Date of Enforcement Report 8/31/2016
Class II:<p>
PRODUCT
Brilliance BigBore Radiology CT Model number 728244 Product Usage: Computed Tomography X-ray systems intended to produce cross-sectional images of the body by computer reconstruction of X-ray transmission data taken at different angles and planes.
Recall Number Z-2654-2016<p>
REASON
After upgrading to 3.6.7 software version via FCO72800643, during reconstruction of gated helical scans, the planned anatomy can be cut off on the CT images. This issue can occur on gated CT helical reconstruction that is not planned at iso-center (0,0). If the region of interest is not visualized in the images, a CT rescan may be performed.<p>
RECALLING FIRM/MANUFACTURER
Philips Medical Systems, Inc., Cleveland, OH on 8/25/2016. Voluntary: Firm Initiated recall is ongoing.
<p>
VOLUME OF PRODUCT IN COMMERCE
24<p>
DISTRIBUTION
Nationwide <p>

_____

8/31/2016 Philips Brilliance CT Big Bore Oncology,, Cl ll
Company: Philips Medical Systems, Inc.
Date of Enforcement Report 8/31/2016
Class II:<p>
PRODUCT
Brilliance CT Big Bore Oncology, Model number 728243 Product Usage: Computed Tomography X-ray systems intended to produce cross-sectional images of the body by computer reconstruction of X-ray transmission data taken at different angles and planes.
Recall Number Z-2653-2016<p>
REASON
After upgrading to 3.6.7 software version via FCO72800643, during reconstruction of gated helical scans, the planned anatomy can be cut off on the CT images. This issue can occur on gated CT helical reconstruction that is not planned at iso-center (0,0). If the region of interest is not visualized in the images, a CT rescan may be performed.<p>
RECALLING FIRM/MANUFACTURER
Philips Medical Systems, Inc., Cleveland, OH on 8/25/2016. Voluntary: Firm Initiated recall is ongoing.

<p>
VOLUME OF PRODUCT IN COMMERCE
33<p>
DISTRIBUTION
Nationwide <p>

8/31/2016 Philips Brilliance 64 CT Model number 72823,
Cl II
Company: Philips Medical Systems, Inc.
Date of Enforcement Report 8/31/2016
Class II:<p>
PRODUCT
Brilliance 64 CT Model number 728231 Product Usage: Computed Tomography X-ray systems intended to produce cross-sectional images of the body by computer reconstruction of X-ray transmission data taken at different angles and planes.
Recall Number Z-2652-2016<p>
REASON
After upgrading to 3.6.7 software version via FCO72800643, during reconstruction of gated helical scans, the planned anatomy can be cut off on the CT images. This issue can occur on gated CT helical reconstruction that is not planned at iso-center (0,0). If the region of interest is not visualized in the images, a CT rescan may be performed.<p>
RECALLING FIRM/MANUFACTURER
Philips Medical Systems, Inc., Cleveland, OH on 8/25/2016. Voluntary: Firm Initiated recall is ongoing.
<p>
VOLUME OF PRODUCT IN COMMERCE
283<p>
DISTRIBUTION
Nationwide <p>

8/31/2016 Siemens RAPIDPoint¿ 500 v2.2.2A , Cl II
Company: Siemens Healthcare Diagnostics Inc
Date of Enforcement Report 8/30/2016
Class II:<p>
PRODUCT
Siemens RAPIDPoint¿ 500 v2.2.2A Software Upgrade Kit; SMN 11066719, Software Version 2.2A The RAPIDPoint 500 system is designed for professional use in a point-of care or laboratory environment. This system tests blood gases, electrolytes, metabolites, total hemoglobin, and hemoglobin derivatives in arterial, venous, and capillary whole blood samples. The following parameters are tested: pH, pC02, p02, Na+, K+, Ca++, Cl-, glucose, lactate, tHb, F02Hb, FCOHb, FMetHb, FHHb, nBili
Recall Number Z-2601-2016<p>
REASON
Some v2.2.2 upgrade kits include a dialysate mode which not cleared/approved for shipment in the United States<p>
RECALLING FIRM/MANUFACTURER
Siemens Healthare Diagnostics Inc , Norwood, MA on 8/19/2016 Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
76<p>
DISTRIBUTION
Nationwide <p>

8/30/2016 Stryker 120 V Neptune 3 Rover, Cl II
Company: Stryker Instruments Div. of Stryker Corporation
Date of Enforcement Report 8/30/2016
Class II:<p>
PRODUCT
120 V Neptune 3 Rover, Model Number: 0703-001-000
Recall Number Z-2630-2016<p>
REASON
Stryker initiated a voluntary recall of the 120 V Neptune 3 Rover on 07/01/2016, due to a potential for the device to experience system errors causing the device to shutdown if high levels of electromagnetic interference are present in the operating room.<p>
RECALLING FIRM/MANUFACTURER
Stryker Instruments Div. of Stryker Corporation, Porage, MI on 8/23/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
78<p>
DISTRIBUTION
Domestic:MI, CA, ID, IA VA/DOD: None Foreign: None <p>

8/30/2016 HomeChoice automated peritoneal dialysis, Cl II
Company: Baxter Healthcare Corp.
Date of Enforcement Report 8/30/2016
Class II:<p>
PRODUCT
1) The HomeChoice automated peritoneal dialysis system. Dataplate located on the device is labeled in part: Baxter. 2) The HomeChoice PRO automated peritoneal dialysis system. Dataplate located on the device is labeled in part: Baxter. The HomeChoice/HomeChoice Pro Automated Personal Cycler peritoneal dialysis system is intended for automatic control of dialysate solution exchange in the treatment of pediatric and adult renal failure patients undergoing peritoneal dialysis.
Recall Number Z-2609-2016<p>
REASON
In systems with version 10.4 software Initial Drain logic, the device will attempt to drain the patient to empty at the beginning of therapy (initial drain). The operator can stop, but cannot bypass, the active Initial Drain. This is to mitigate against Unintended Increased Intraperitoneal Volume (IIVP). This can cause serious problems in patients with unrelated a co-morbid condition of ascites.<p>
RECALLING FIRM/MANUFACTURER
Baxter Healthcare Corp. , Deerfield, IL on 8/2/2016. Voluntary: Firm Initiated recall is complete. <p>
VOLUME OF PRODUCT IN COMMERCE
1) Product Codes 5C4471 and 5C4471R: Approximately 48,600 units; *** 2) Product Codes 5C8310 and 5C8310R: Approxiamtely 16,990 units<p>
DISTRIBUTION
Nationwide and internationally<p>

8/24/2016 Xario 100 Diagnostic Ultrasound System, Cl II
Company: Toshiba American Medical Systems
Date of Enforcement Report 8/24/2016
Class II:<p>
PRODUCT
Xario 100 Diagnostic Ultrasound System, TUS-X100; Xario 200 Diagnostic Ultrasound System, TUS-X200.
Recall Number Z-2542-2016<p>

REASON
Toshiba American Medical Systems (TAMS) is recalling the Xario Diagnostics Ultrasound System because it may become hot because of a software error.<p>
RECALLING FIRM/MANUFACTURER
Toshiba American Medical Systems , Tustin, CA on 8/4/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
93<p>
DISTRIBUTION
Nationwide <p>

8/24/2016 Merge Unity Z3D software, CI II
Company: Merge Healthcare, Inc.
Date of Enforcement Report 8/24/2016
Class II:<p>
PRODUCT
Merge Unity Z3D software. Merge Unity PACS (formerly DR Systems PACS) is a medical image and information management system that allows viewing, selection, processing, printing, telecommunications , and media interchange of medical images from a variety of diagnostic imaging systems.
Recall Number Z-2551-2016<p>
REASON
The software is unable to accurately determine the calcium score of scans with a slice thickness not equal to 3 mm.<p>
RECALLING FIRM/MANUFACTURER
Merge Healthcare, Inc, Hartland, WI on 7/23/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
9 sites potentially have the affected versions<p>
DISTRIBUTION
US Distribution to states of: CA, PA, TX, and MT.<p>

8/24/2016 iConnect Access used with Ortho PACS sw, CI II
Company: Merge Healthcare, Inc.
Date of Enforcement Report 8/24/2016
Class II:<p>
PRODUCT
iConnect Access used with Ortho PACS software provides medical specialists with access to diagnostic quality images, reports, and various types of patient data over conventional TCP/IP (e.g., internet) networks.
Recall Number Z-2532-2016<p>
REASON
Studies that are viewed in iConnect Access that originate on Merge PACS / Ortho PACS may not display the correct current patient demographics if there has been a PDE (Patient / Study Demographic Edit) performed after the images were ingested in PACS.<p>
RECALLING FIRM/MANUFACTURER
Merge Healthcare, Inc, Hartland, WI on 1/30/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
146 sites potentially have the affected versions for both products<p>
DISTRIBUTION
Distribution was made to medical facilities nationwide and to one foreign medical facility in New Zealand. There was no military or government distribution. <p>

8/24/2016 iConnect Access used with Merge PACS sw, Cl II
Company: Merge Healthcare, Inc.
Date of Enforcement Report 8/24/2016
Class II:<p>
PRODUCT
iConnect Access used with Merge PACS software provides medical specialists with access to diagnostic quality images, reports, and various types of patient data over conventional TCP/IP (e.g., internet) networks.
Recall Number Z-2531-2016<p>
REASON
Studies that are viewed in iConnect Access that originate on Merge PACS / Ortho PACS may not display the correct current patient demographics if there has been a PDE (Patient / Study Demographic Edit) performed after the images were ingested in PACS.<p>
RECALLING FIRM/MANUFACTURER
Merge Healthcare, Inc, Hartland, WI on 1/30/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
146 sites potentially have the affected versions for both products<p>
DISTRIBUTION
Distribution was made to medical facilities nationwide and to one foreign medical facility in New Zealand. There was no military or government distribution. <p>

8/24/2016 AB SCIEX QTRAP 4500MD, Cl II
Company: AB Sciex
Date of Enforcement Report 8/24/2016
Class II:<p>
PRODUCT
AB SCIEX QTRAP 4500MD LC/MS/MS System Mass Spectrometer for In-Vitro Diagnostic Use. Instrument Part Number (REF): 5031231 3200MD series and 4500MD series are mass spectrometers intended to identify inorganic or organic compounds (e.g., lead, mercury, and drugs) in human specimens by ionizing the compound under investigation and separating the resulting ions by means of an electrical and magnetic field according to their mass. It is intended for in vitro diagnostic purposes. For in vitro diagnostic use.
Recall Number Z-2529-2016<p>
REASON
MultiQuant MD software where under certain conditions a user can be presented with incorrect quantitative results when using the Sum Multiple Ions feature.<p>
RECALLING FIRM/MANUFACTURER
AB Sciex, Framingham, MA on 6/16/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
28 units <p>
DISTRIBUTION
Nationwide and Internationally<p>

8/24/2016 AB SCIEX Triple Quad 4500MD, Cl II
Company: AB Sciex
Date of Enforcement Report 8/24/2016
Class II:<p>
PRODUCT
AB SCIEX Triple Quad 4500MD LC/MS/MS System. Mass Spectrometer for In-Vitro Diagnostic Use. Instrument Part Number (REF): 5031257 3200MD series and 4500MD series are mass spectrometers intended to identify inorganic or organic compounds (e.g., lead, mercury, and drugs) in human specimens by ionizing the compound under investigation and separating the resulting ions by means of

an electrical and magnetic field according to their mass. It is intended for in vitro diagnostic purposes. For in vitro diagnostic use.
Recall Number Z-2528-2016<p>
REASON
MultiQuant MD software where under certain conditions a user can be presented with incorrect quantitative results when using the Sum Multiple Ions feature.<p>
RECALLING FIRM/MANUFACTURER
AB Sciex, Framingham, MA on 6/16/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
121 units <p>
DISTRIBUTION
Nationwide and Internationally<p>

8/24/2016 AB SCIEX 3200MD QTRAP, Cl II
Company: AB Sciex
Date of Enforcement Report 8/24/2016
Class II:<p>
PRODUCT
AB SCIEX 3200MD QTRAP¿ LC/MS/MS System Mass Spectrometer for In-Vitro Diagnostic Use. Instrument Part Number (REF): 5024500 3200MD series and 4500MD series are mass spectrometers intended to identify inorganic or organic compounds (e.g., lead, mercury, and drugs) in human specimens by ionizing the compound under investigation and separating the resulting ions by means of an electrical and magnetic field according to their mass. It is intended for in vitro diagnostic purposes. For in vitro diagnostic use.
Recall Number Z-2527-2016<p>
REASON
MultiQuant MD software where under certain conditions a user can be presented with incorrect quantitative results when using the Sum Multiple Ions feature.<p>
RECALLING FIRM/MANUFACTURER
AB Sciex, Framingham, MA on 6/16/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
2 units <p>
DISTRIBUTION
Nationwide and Internationally<p>

8/24/2016 AB Sciex API 3200MD, Cl II
Company: AB Sciex
Date of Enforcement Report 8/24/2016
Class II:<p>
PRODUCT
AB Sciex API 3200MD" LC/MS/MS System. In-Vitro Diagnostic Instrument Part Number (REF): 5024501 3200MD series and 4500MD series are mass spectrometers intended to identify inorganic or organic compounds (e.g., lead, mercury, and drugs) in human specimens by ionizing the compound under investigation and separating the resulting ions by means of an electrical and magnetic field according to their mass. It is intended for in vitro diagnostic purposes. For in vitro diagnostic use.
Recall Number Z-2526-2016<p>
REASON
MultiQuant MD software where under certain conditions a user can be presented with incorrect quantitative results when using the Sum Multiple Ions feature.<p>
RECALLING FIRM/MANUFACTURER
AB Sciex, Framingham, MA on 6/16/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
124 units <p>

DISTRIBUTION
Nationwide and Internationally<p>

8/24/2016 GE Centricity PACS Workstation, Cl II
Company: Ge Healthcare It
Date of Enforcement Report 8/24/2016
Class II:<p>
PRODUCT
GE Centricity PACS Workstation, versions 3.1.1.x through 3.2.1.x Picture Archiving and Communication System Used as a primary diagnostic and analysis tool for diagnostic images by trained healthcare professionals, including radiologists, physicians, technologists, clinicians and nurses. Also used as a clinical review workstation throughout the healthcare facility. The workstation interface provides the user with a means to display, manipulate, archive, print and export images when connected with the Centricity PACS infrastructure.
Recall Number Z-23579-2016<p>
REASON
While merging exams in a test instance, merges carry forward in the production system, when the middle tier is configured to the wrong IP address of the Centricity Exam Manager. When a current and historical exam are opened at the same time, the system asynchronously tries to access the operation specifying how each image should be grouped, causing random image-series grouping errors.<p>
RECALLING FIRM/MANUFACTURER
Ge Healthcare IT, Barrington, IL Recall Initiation Date:11/15/2012. Center Classification Date: 08/17/2016 Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
498 units<p>
DISTRIBUTION
Nationwide and Internationally<p>

8/24/2016 ORTHO ProVue Analyzers, Cl II
Company: Ortho-Clinical Diagnostics
Date of Enforcement Report 8/24/2016
Class II:<p>
PRODUCT
ORTHO ProVue Analyzers; Product Code MTS213784; Unique Device Identifier (GTIN) 10758750006014
Recall Number B-0686-16<p>
REASON
ORTHO ProVue Analyzers, with suboptimal reference images and/or Brillo values outside of specification, were distributed.<p>
RECALLING FIRM/MANUFACTURER
Ortho-Clinical Diagnostics, Rochester, NY on 6/14/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
23 analyzers <p>
DISTRIBUTION
Nationwide and Canada<p>

8/17/2016 Philips Ingenuity Core128 Model No. 728323, Cl II
Company: Philips Medical Systems, Inc.
Date of Enforcement Report 8/17/2016
Class II:<p>
PRODUCT
Ingenuity Core Model No. 728323; To produce cross-sectional images of the body.

Recall Number Z-2384-2016<p>
REASON
Software issues in v4.1.3/4.1.4/4.1.5 in the Philips Ingenuity CT products that could affect the performance of the equipment.<p>
RECALLING FIRM/MANUFACTURER
Philips Medical Systems, Inc., Cleveland, OH on 4/29/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
380 Units<p>
DISTRIBUTION
Nationwide and Internationally <p>

8/17/2016 Merge PACS software imaging Cl II
Company: Merge Healthcare, Inc.
Date of Enforcement Report 8/17/2016
Class II:<p>
PRODUCT
Merge PACS software. The firm name on the label is Merge Healthcare, Inc., Hartland, WI. Intended to create and display two-dimensional and three-dimensional images of anatomy from a series of digitally acquired images.
Recall Number Z-2363-2016<p>
REASON
When measuring a lesion on an unmagnified mammography image then performing the same measurement on an image magnified by the Hologic imager (different image), the measurements are not the same.p>
RECALLING FIRM/MANUFACTURER
Merge Healthcare, Inc, Hartland, WI on 2/5/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
49 sites potentially have the affected versions<p>
DISTRIBUTION
USA and Australia<p>

8/17/2016 Merge PACS software Cl II
Company: Merge Healthcare, Inc.
Date of Enforcement Report 8/17/2016
Class II:<p>
PRODUCT
Merge PACS software. Product was distributed under the AMICAS label, Brighton, MA, but labeling was later changed to Merge Healthcare, Hartland, WI.
Recall Number Z-2379-2016<p>
REASON
The patient name in the Halo title bar and the thumbnails do not match the name on displayed images.<p>
RECALLING FIRM/MANUFACTURER
Merge Healthcare, Inc, Hartland, WI on 1/20/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
93 sites have the affected version<p>
DISTRIBUTION
The software was distributed to medical facilities nationwide. Government distribution was made to MN. Foreign distribution was made to Australia and to the United Kingdom. There was no military distribution <p>

8/17/2016 Siemens Artis, Cl II
Company: Siemens Medical Solutions USA, Inc
Date of Enforcement Report 8/17/2016
Class II:<p>
PRODUCT
Artis zee/ zeego, Artis Q/ Q.zen, stand alone system, software controlled Model numbers: 10094135, 10094137, 10094139, 10094141, 10280959, 10848281, 10848282, 10848283, 10848353, 10848255 Artis zee / zeego and Q/ Q.zen is a family of dedicated angiography systems developed for single and biplane diagnostic imaging and interventional procedures including, but not limited to, pediatric and obese patients. Procedures that can be performed with the Artis zee / zeego and Q/ Q.zen include cardiac angiography, neuro angiography, general angiography, rotational angiography, operating room angiography, multipurpose angiography and whole body radiographic/fluoroscopic procedures. Artis zee / zeego and Q/ Q.zen can also support the acquisition of position triggered imaging for spatial data synthesis.
Recall Number Z-2344-2016<p>
REASON
Due to an error in the 19 Live Display, image reproduction may fail in the examination room and the potential exists for the loss of images immediately after system startup.<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc., Malvern, PA on 7/7/2016 Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
51 units<p>
DISTRIBUTION
Nationwide <p>

8/17/2016 Siemens Stratus CS STAT, Cl II
Company: Siemens Healthcare Diagnostics, Inc.
Date of Enforcement Report 8/17/2016
Class II:<p>
PRODUCT
Stratus CS STAT Fluorometric Analyzer-microproc essor-controlled instrument that measures certain analytes in body fluids for in vitro diagnostic use. Assays include ~hCG, CRP, CKMB, cTNI, D-Dimer, Myoglobin, and pBNP. SMN: 10444834, 10453531
Recall Number Z-2525-2016<p>
REASON
Software defect, where either an Above Assay Range or an inaccurate value could potentially be reported, in the Stratus CS Acute Care Diagnostics System regarding TestPak calibration and quality control (QC) status when a TestPak is due to expire within 48 hours.<p>
RECALLING FIRM/MANUFACTURER
Siemens Healthcare Diagnostics, Inc. , Norwood, MA on 6/22/2016 Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
977 units<p>
DISTRIBUTION
Nationwide and Internationally<p>

8/17/2016 Philips MX 16-slice SKD, Cl II
Company: Philips Medical Systems, Inc.
Date of Enforcement Report 8/17/2016
Class II:<p>
PRODUCT
MX 16-slice SKD whole body computed tomography X-ray system. Imaging diagnostic tool.

Recall Number Z-2347-2016<p>
REASON
The following issues have been found in MX 16-slice systems with software version 1.1.4.21426: 1. During the filming operation on MX16-slice console software, the clipboard used for copying and pasting images is not cleared between patients. If the operator fails to copy the current patient s images before pasting, a previous patient s images may be present in the clipboard and be copied onto the film of the current patient. 2. During the Bolus Tracking scan, if the Auto Voice in Tracker scan is enabled, the Tracker scan will be aborted unexpectedly and the diagnostic scan after the tracker scan needs to be manually started. 3. If the scan protocol with SAS (Spiral Auto Start) function is selected to plan the scan, the SAS option may not be displayed on the Contrast tab of the scan protocol parameter area or the SAS option is displayed but not enabled as pre-configured in the protocol. This issue only occurs on the first helical scan after system startup that applies SAS function.<p>
RECALLING FIRM/MANUFACTURER
Philips Medical Systems, Inc., Cleveland, OH on 4/20/2016. Voluntary: Firm Initiated recall is ongoing.
<p>
VOLUME OF PRODUCT IN COMMERCE
80 Units<p>
DISTRIBUTION
Nationwide and Internationally <p>

8/17/2016 Philips MX 16-slice, Cl II
Company: Philips Medical Systems, Inc.
Date of Enforcement Report 8/17/2016
Class II:<p>
PRODUCT
MX 16-slice whole body computed tomography X-ray system. Imaging diagnostic tool.
Recall Number Z-2346-2016<p>
REASON
The following issues have been found in MX 16-slice systems with software version 1.1.4.21426: 1. During the filming operation on MX16-slice console software, the clipboard used for copying and pasting images is not cleared between patients. If the operator fails to copy the current patient s images before pasting, a previous patient s images may be present in the clipboard and be copied onto the film of the current patient. 2. During the Bolus Tracking scan, if the Auto Voice in Tracker scan is enabled, the Tracker scan will be aborted unexpectedly and the diagnostic scan after the tracker scan needs to be manually started. 3. If the scan protocol with SAS (Spiral Auto Start) function is selected to plan the scan, the SAS option may not be displayed on the Contrast tab of the scan protocol parameter area or the SAS option is displayed but not enabled as pre-configured in the protocol. This issue only occurs on the first helical scan after system startup that applies SAS function.<p>
RECALLING FIRM/MANUFACTURER
Philips Medical Systems, Inc., Cleveland, OH on 4/20/2016. Voluntary: Firm Initiated recall is ongoing.
<p>
VOLUME OF PRODUCT IN COMMERCE
899 Units<p>
DISTRIBUTION
Nationwide and Internationally <p>

8/17/2016 Philips Ingenuity Core Model No. 728321;, Cl II
Company: Philips Medical Systems, Inc.
Date of Enforcement Report 8/17/2016
Class II:<p>
PRODUCT
Ingenuity Core Model No. 728321; To produce cross-sectional images of the body.

Recall Number Z-2383-2016<p>
REASON
Software issues in software versions v4.1.3/4.1.4/4.1.5 in the Philips Brilliance 64 and Ingenuity CT products that could affect the performance of the equipment.<p>
RECALLING FIRM/MANUFACTURER
Philips Medical Systems, Inc., Cleveland, OH on 4/29/2016. Voluntary: Firm Initiated recall is ongoing.
<p>
VOLUME OF PRODUCT IN COMMERCE
276 Units<p>
DISTRIBUTION
Nationwide and Internationally <p>

8/17/2016 Philips Brilliance iCT SP Model No. 728311, Cl II

Company: Philips Medical Systems, Inc.
Date of Enforcement Report 8/17/2016
Class II:<p>
PRODUCT
Brilliance iCT SP Model No. 728311; To produce cross-sectional images of the body.
Recall Number Z-2382-2016<p>
REASON
Software issues found in v4.1 .3/4.1.5 in the Philips Brilliance iCT/ iCT SP products that could affect the performance of the equipment.<p>
RECALLING FIRM/MANUFACTURER
Philips Medical Systems, Inc., Cleveland, OH on 4/29/2016. Voluntary: Firm Initiated recall is ongoing.
<p>
VOLUME OF PRODUCT IN COMMERCE
57 Units<p>
DISTRIBUTION
Nationwide and Internationally <p>

8/17/2016 Philips Brilliance iCT, Model No. 728306 Cl II

Company: Philips Medical Systems, Inc.
Date of Enforcement Report 8/17/2016
Class II:<p>
PRODUCT
Brilliance iCT, Model No. 728306; To produce cross-sectional images of the body.
Recall Number Z-2381-2016<p>
REASON
Software issues in versions v4.1 .3/4.1.5 in the Philips Brilliance iCT) iCT SP products that, could affect the performance of the equipment.<p>
RECALLING FIRM/MANUFACTURER
Philips Medical Systems, Inc., Cleveland, OH on 4/29/2016. Voluntary: Firm Initiated recall is ongoing.
<p>
VOLUME OF PRODUCT IN COMMERCE
335 Units<p>
DISTRIBUTION
Nationwide and Internationally <p>

8/17/2016 PhilipsBrilliance 64 CT Model 728231 Cl II
Company: Philips Medical Systems, Inc.
Date of Enforcement Report 8/17/2016
Class II:<p>
PRODUCT
Brilliance 64 CT Model 728231; To produce cross-sectional images of the body.
Recall Number Z-2380-2016<p>
REASON
Software issues found in software versions v4.1.3/4.1.4/4.1.5 in the Philips Brilliance 64 products that could affect the performance of the equipment.<p>
RECALLING FIRM/MANUFACTURER
Philips Medical Systems, Inc., Cleveland, OH on 4/29/2016. Voluntary: Firm Initiated recall is ongoing.
<p>
VOLUME OF PRODUCT IN COMMERCE
150<p>
DISTRIBUTION
Nationwide and Internationally <p>

8/17/2016 Philips Ingenuity Core Cl II
Company: Philips Medical Systems, Inc.
Date of Enforcement Report 8/17/2016
Class II:<p>
PRODUCT
Ingenuity Core Computed Tomography X-ray systems X-ray systems is intended to produce cross-sectional images of the body by computer reconstruction of X-ray transmission data taken at different angles and planes.
Recall Number Z-2371-2016<p>
REASON
Software defect causing intermittently slow response of Host.<p>
RECALLING FIRM/MANUFACTURER
Philips Medical Systems, Inc., Cleveland, OH on 3/24/2016. Voluntary: Firm Initiated recall is ongoing.
<p>
VOLUME OF PRODUCT IN COMMERCE
29 units<p>
DISTRIBUTION
Nationwide and Internationally <p>

8/17/2016 Philips Brilliance CT 16, Cl II
Company: Philips Medical Systems, Inc.
Date of Enforcement Report 8/17/2016
Class II:<p>
PRODUCT
Brilliance CT 16 Power Computed Tomography X-ray systems X-ray systems is intended to produce cross-sectional images of the body by computer reconstruction of X-ray transmission data taken at different angles and planes.
Recall Number Z-2370-2016<p>
REASON
Software defect causing intermittently slow response of Host.<p>
RECALLING FIRM/MANUFACTURER
Philips Medical Systems, Inc., Cleveland, OH on 3/24/2016. Voluntary: Firm Initiated recall is ongoing.
<p>
VOLUME OF PRODUCT IN COMMERCE
55 units<p>

DISTRIBUTION
Nationwide and Internationally <p>

8/17/2016 Philips Brilliance 16, Cl II
Company: Philips Medical Systems, Inc.
Date of Enforcement Report 8/17/2016
Class II:<p>
PRODUCT
Brilliance 16 Computed Tomography X-ray systems X-ray systems is intended to produce cross-sectional images of the body by computer reconstruction of X-ray transmission data taken at different angles and planes.
Recall Number Z-2369-2016<p>
REASON
Software defect causing intermittently slow response of Host.<p>
RECALLING FIRM/MANUFACTURER
Philips Medical Systems, Inc., Cleveland, OH on 3/24/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
203 units<p>
DISTRIBUTION
Nationwide and Internationally <p>

8/17/2016 Brilliance BigBore Oncology Computed Tomo; Cl II
Company: Philips Medical Systems, Inc.
Date of Enforcement Report 8/17/2016
Class II:<p>
PRODUCT
Brilliance BigBore Oncology Computed Tomography X-ray systems is intended to produce cross-sectional images of the body by computer reconstruction of X-ray transmission data taken at different angles and planes.
Recall Number Z-2367-2016<p>
REASON
Software defect causing intermittently slow response of Host.<p>
RECALLING FIRM/MANUFACTURER
Philips Medical Systems, Inc., Cleveland, OH on 3/24/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
8 units<p>
DISTRIBUTION
Nationwide and Internationally <p>

8/17/2016 Philips Brilliance 64 Computed Tomography; Cl II
Company: Philips Medical Systems, Inc.
Date of Enforcement Report 8/17/2016
Class II:<p>
PRODUCT
Brilliance 64 Computed Tomography X-ray systems is intended to produce cross-sectional images of the body by computer reconstruction of X-ray transmission data taken at different angles and planes.
Recall Number Z-2366-2016<p>
REASON
Software defect causing intermittently slow response of Host.<p>

RECALLING FIRM/MANUFACTURER
Philips Medical Systems, Inc., Cleveland, OH on 3/24/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
318 units<p>
DISTRIBUTION
Nationwide and Internationally <p>

8/10/2016 Philips IntelliVue Patient Monitor, Cl II
Company: Philips Electronics North America Corporation
Date of Enforcement Report 8/10/2016
Class II:<p>
PRODUCT
IntelliVue Patient Monitor Product Usage: The monitors are indicated for use by health care professionals whenever there is a need for monitoring the physiological parameters of patients. The monitors are intended to be used for monitoring and recording of, and to generate alarms for, multiple physiological parameters of adults, pediatrics, and neonates. The monitors are intended for use by trained healthcare professionals in a hospital environment.
Recall Number Z-2328-2016<p>
REASON
If an affected Patient Monitor has been powered on continuously for several months, any displayed waveforms will contain outdated data and therefore fail to reflect the patient s current condition.<p>
RECALLING FIRM/MANUFACTURER
hilips Electronics North America Corporation , Andover, MA on 7/26/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
50,495<p>
DISTRIBUTION
Nationwidewide<p>

8/10/2016 Medtronic Navigation MACH AxiEM, Cl II
Company: Medtronic Navigation, Inc.
Date of Enforcement Report 8/10/2016
Class II:<p>
PRODUCT
MACH AxiEM Cranial Treon. The software application is sent in CD format with an IFU, wrapped in plastic with a label for shipping purposes. Product Usage: The StealthStation System is intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. The StealthStation System is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure such as the skull, a long bod, or vertebra can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.
Recall Number Z-2319-2016<p>
REASON
Medtronic Navigation, Inc. announces a voluntary field action for the Medtronic Navigation StealthStation Software applications affected by Neurologica BodyTom/CereTom floor-based scanners.<p>
RECALLING FIRM/MANUFACTURER
Medtronic Navigation, Inc. , Louisville, OH on 7/18/2016 Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
27<p>
DISTRIBUTION
Nationwide and Internationally<p>

8/10/2016 Medtronic Navigation MACH Cranial Treon,
Cl II
Company: Medtronic Navigation, Inc.
Date of Enforcement Report 8/10/2016
Class II:<p>
PRODUCT
MACH Cranial Treon. The software application is sent in CD format with an IFU, wrapped in plastic with a label for shipping purposes. Product Usage: The StealthStation System is intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. The StealthStation System is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure such as the skull, a long bod, or vertebra can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.
Recall Number Z-2318-2016<p>
REASON
Medtronic Navigation, Inc. announces a voluntary field action for the Medtronic Navigation StealthStation Software applications affected by Neurologica BodyTom/CereTom floor-based scanners.<p>
RECALLING FIRM/MANUFACTURER
Medtronic Navigation, Inc. , Louisville, OH on 7/18/2016 Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
27<p>
DISTRIBUTION
Nationwide and Internationally<p>

8/10/2016 Medtronic Navigation Fusion ENT Application
Cl II
Company: Medtronic Navigation, Inc.
Date of Enforcement Report 8/10/2016
Class II:<p>
PRODUCT
Fusion ENT Application. The software application is sent in CD format with an IFU, wrapped in plastic with a label for shipping purposes. Product Usage: The StealthStation System is intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. The StealthStation System is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure such as the skull, a long bod, or vertebra can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.
Recall Number Z-2317-2016<p>
REASON
Medtronic Navigation, Inc. announces a voluntary field action for the Medtronic Navigation StealthStation Software applications affected by Neurologica BodyTom/CereTom floor-based scanners.<p>
RECALLING FIRM/MANUFACTURER
Medtronic Navigation, Inc. , Louisville, OH on 7/18/2016 Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
27<p>
DISTRIBUTION
Nationwide and Internationally<p>

8/10/2016 Medtronic Navigation Synergy Spine, Cl II
Company: Medtronic Navigation, Inc.
Date of Enforcement Report 8/10/2016
Class II:<p>
PRODUCT
Synergy Spine. The software application is sent in CD format with an IFU, wrapped in plastic with a label for shipping purposes. Product Usage: The StealthStation System is intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. The StealthStation System is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure such as the skull, a long bod, or vertebra can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.
Recall Number Z-2316-2016<p>
REASON
Medtronic Navigation, Inc. announces a voluntary field action for the Medtronic Navigation StealthStation Software applications affected by Neurologica BodyTom/CereTom floor-based scanners.<p>
RECALLING FIRM/MANUFACTURER
Medtronic Navigation, Inc. , Louisville, OH on 7/18/2016 Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
27<p>
DISTRIBUTION
Nationwide and Internationally<p>

8/10/2016 Medtronic Navigation S7 MACH FrameLink, Cl II
Company: Medtronic Navigation, Inc.
Date of Enforcement Report 8/10/2016
Class II:<p>
PRODUCT
S7 MACH FrameLink. The software application is sent in CD format with an IFU, wrapped in plastic with a label for shipping purposes. Product Usage: The StealthStation System is intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. The StealthStation System is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure such as the skull, a long bod, or vertebra can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.. The software application is sent in CD format with an IFU, wrapped in plastic with a label for shipping purposes. Product Usage: The StealthStation System is intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. The StealthStation System is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure such as the skull, a long bod, or vertebra can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.
Recall Number Z-2315-2016<p>
REASON
Medtronic Navigation, Inc. announces a voluntary field action for the Medtronic Navigation StealthStation Software applications affected by Neurologica BodyTom/CereTom floor-based scanners.<p>
RECALLING FIRM/MANUFACTURER
Medtronic Navigation, Inc. , Louisville, OH on 7/18/2016 Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
27<p>
DISTRIBUTION

Nationwide and Internationally<p>

8/10/2016 Medtronic Navigation FrameLink, Cl II
Company: Medtronic Navigation, Inc.
Date of Enforcement Report 8/10/2016
Class II:<p>
PRODUCT
FrameLink. The software application is sent in CD format with an IFU, wrapped in plastic with a label for shipping purposes. Product Usage: The StealthStation System is intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. The StealthStation System is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure such as the skull, a long bod, or vertebra can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.. The software application is sent in CD format with an IFU, wrapped in plastic with a label for shipping purposes. Product Usage: The StealthStation System is intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. The StealthStation System is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure such as the skull, a long bod, or vertebra can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.
Recall Number Z-2314-2016<p>
REASON
Medtronic Navigation, Inc. announces a voluntary field action for the Medtronic Navigation StealthStation Software applications affected by Neurologica BodyTom/CereTom floor-based scanners.<p>
RECALLING FIRM/MANUFACTURER
Medtronic Navigation, Inc. , Louisville, OH on 7/18/2016 Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
27<p>
DISTRIBUTION
Nationwide and Internationally<p>

8/10/2016 Medtronic Navigation Synergy Cranial S7, Cl II
Company: Medtronic Navigation, Inc.
Date of Enforcement Report 8/10/2016
Class II:<p>
PRODUCT
Synergy Cranial S7. The software application is sent in CD format with an IFU, wrapped in plastic with a label for shipping purposes. Product Usage: The StealthStation System is intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. The StealthStation System is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure such as the skull, a long bod, or vertebra can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.
Recall Number Z-2313-2016<p>
REASON
Medtronic Navigation, Inc. announces a voluntary field action for the Medtronic Navigation StealthStation Software applications affected by Neurologica BodyTom/CereTom floor-based scanners.<p>
RECALLING FIRM/MANUFACTURER
Medtronic Navigation, Inc. , Louisville, OH on 7/18/2016 Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE

27<p>
DISTRIBUTION
Nationwide and Internationally<p>

8/10/2016 BK Medical ApS Ultrasound System Scanner, Cl II

Company: B-K Medical A/S.
Date of Enforcement Report 8/10/2016
Class II:<p>
PRODUCT
BK Medical ApS Ultrasound System Scanner bk2300 - Model #: bk3500 with software releases 1.2.0, 1.2.1 and 1.2.2. The system is intended for diagnostic ultrasound imaging or fluid flow analysis of the human body, data processing and guidance of puncture and biopsy. The system performs simple geometric measurements and calculations in the following areas: Emergency Medicine, Anesthesia, MSK, Vascular, Cardiology, OB/GYN
Recall Number Z-2325-2016<p>
REASON
In the system (bk3500) software generic volume measurement (HxWxLxl) function the user may be unaware of the calculation factor (1) and assume the generic volume calculation factor is similar to that of the other (prostate, adenoma, testis, kidney, and bladder) volume calculation factors provided in the software.<p>
RECALLING FIRM/MANUFACTURER
B-K Medical A/S, Herlev, Denmark on 6/28/2016 Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
6<p>
DISTRIBUTION
US to TX, FL, and MA. Internationally to Australia <p>

8/10/2016 Merge PACS 6.0 software, Cl II

Company: Merge Healthcare, Inc.
Date of Enforcement Report 8/10/2016
Class II:<p>
PRODUCT
Merge PACS software. The firm name on the label is Merge Healthcare, Hartland, Wisconsin. Merge PACS 6.0 is software intended to create and display two-dimensional and three-dimensional images of anatomy from a series of digitally acquired images.
Recall Number Z-2303-2016<p>
REASON
A migrated study that has annotations will display the annotations, but when a prior study is loaded that should have annotations, the second study will not display annotations.<p>
RECALLING FIRM/MANUFACTURER
Merge Healthcare, Inc. Hartland, WI on 1/30/2016 Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
208 sites <p>
DISTRIBUTION
US (Nationwide) and countries of: Australia, Belgium, Canada, Jordan, New Zealand, and the United Kingdom. <p>

8/10/2016 Merge PACS software, Cl II

Company: Merge Healthcare, Inc.
Date of Enforcement Report 8/10/2016
Class II:<p>
PRODUCT

Merge PACS software. The firm name on the label is Merge Healthcare, Hartland, WI. Intended to create and display two-dimensional and three-dimensional images of anatomy from a series of digitally acquired images.
Recall Number Z-2301-2016<p>
REASON
Studies coming over via telmed were missing patient's DOB, procedure, and referring physician.<p>
RECALLING FIRM/MANUFACTURER
Merge Healthcare, Inc. Hartland, WI on 1/30/2016 Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
109 sites <p>
DISTRIBUTION
USA, New Zealand, and United Kingdom. <p>

8/10/2016 Merge HEMO software, CI II
Company: Merge Healthcare, Inc.
Date of Enforcement Report 8/10/2016
Class II:<p>
PRODUCT
Merge HEMO software
Recall Number Z-2341-2016<p>
REASON
The International Normalized Ratio (INR) value displayed in the study report does not match the value that is imported on the pre-procedure labs screen from HL7<p>
RECALLING FIRM/MANUFACTURER
Merge Healthcare, Inc. Hartland, WI on 7/2/2012 Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
37<p>
DISTRIBUTION
Nationwide <p>

8/3/2016 AUTOCOMP6 High Speed Compounder, CI II
Company: The Metrix Company
Date of Enforcement Report 8/3/2016
Class II:<p>
PRODUCT
AUTOCOMP6 High Speed Compounder
Recall Number Z-2259-2016<p>
REASON
An issue was identified after a redesign of the auto compounding device. The compounder cannot meet the designed accuracy specification when dispensing into bags. After reviewing the initial design of the device, it was determined the dispensing volume validation was not properly done and none of the compounders on the market can meet the stated specifications.<p>
RECALLING FIRM/MANUFACTURER
The Metrix Company on 6/23/2016 Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
323<p>
DISTRIBUTION
Nationwide and Internationally<p>

8/3/2016 AUTOCOMP6 XP High Speed Compounder, Cl II

Company: The Metrix Company
Date of Enforcement Report 8/3/2016
Class II:<p>
PRODUCT
AUTOCOMP6 XP High Speed Compounder REF 58810
Recall Number Z-2258-2016<p>
REASON
An issue was identified after a redesign of the auto compounding device. The compounder cannot meet the designed accuracy specification when dispensing into bags. After reviewing the initial design of the device, it was determined the dispensing volume validation was not properly done and none of the compounders on the market can meet the stated specifications.<p>
RECALLING FIRM/MANUFACTURER
The Metrix Company on 6/23/2016 Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
93 devices<p>
DISTRIBUTION
Nationwide and Internationally<p>

8/3/2016 AUTOCOMP6 XPS High Speed Compounder, Cl II

Company: The Metrix Company
Date of Enforcement Report 8/3/2016
Class II:<p>
PRODUCT
AUTOCOMP6 XPS High Speed Compounder REF 58810
Recall Number Z-2257-2016<p>
REASON
An issue was identified after a redesign of the auto compounding device. The compounder cannot meet the designed accuracy specification when dispensing into bags. After reviewing the initial design of the device, it was determined the dispensing volume validation was not properly done and none of the compounders on the market can meet the stated specifications.<p>
RECALLING FIRM/MANUFACTURER
The Metrix Company on 6/23/2016 Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
16 devices<p>
DISTRIBUTION
Nationwide and Internationally<p>

8/3/2016 GE Imagecast PACS with Centricity RIS-IC, Cl II

Company: Ge Healthcare It
Date of Enforcement Report 8/3/2016
Class II:<p>
PRODUCT
Imagecast PACS with Centricity RIS-IC versions prior to 10.6 Update Package 18 Product Usage: is an image management system intended to be used by trained professionals, including but not limited to physicians, nurses and medical technicians. The system is used with general purpose computing hardware to acquire, transmit, process and store images and data throughout a clinical environment. Data and images are acquired through DICOM compliant imaging devices and modalities. Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretation. Mammographic images may only be interpreted using an FDA approved monitor

that offers at least 5 Mpixel resolution and meets other technical specifications reviewed and accepted by the FDA.
Recall Number Z-2300-2016<p>
REASON
A software defect was discovered that causes images to be out of context with clinical information.<p>
RECALLING FIRM/MANUFACTURER
Ge Healthcare IT, Barrington, IL on 2/18/2016 Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
13<p>
DISTRIBUTION
Nationwide<p>

8/3/2016 Elekta MOSAIQ Oncology Information System, Cl II
Company: Elekta, Inc.
Date of Enforcement Report 8/3/2016
Class II:<p>
PRODUCT
MOSAIQ Oncology Information System
Recall Number Z-2293-2016<p>
REASON
It is possible that a change to an Order Set will not be saved in the current open Care Plan. This can result in a wrong chemo dose in the order.<p>
RECALLING FIRM/MANUFACTURER
Elekta, Inc., Atlanta, GA on 7/15/2016 Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
383<p>
DISTRIBUTION
Nationwide and Internationally<p>

7/27/2016 Carestream Touch Prime, Cl II
Company: Carestream Health Inc
Date of Enforcement Report 7/27/2016
Class II:<p>
PRODUCT
Carestream Touch Prime, Catalog Number 1738830, and Carestream Touch Prime XE, Catalog Number 1738822 --- Common Name: Touch Ultrasound Diagnostic ultrasound imaging or fluid flow analysis of the human body
Recall Number Z-2217-2016<p>
REASON
A software issue related to the generic volume measurement functionality could result in the volume of the subject anatomy being overestimated. For example, measurement results of the anatomy may appear enlarged or distended when it actually is not.<p>
RECALLING FIRM/MANUFACTURER
Carestream Health Inc, Rochester, NY on 7/8/2016 Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
7 units<p>
DISTRIBUTION
US Distribution to states of: GA, IA, and TX; and country of: Italy.<p>

7/27/2016 Syngo.via, Cl II
Company: Siemens Medical Solutions USA, Inc.
Date of Enforcement Report 7/27/2016
Class II:<p>
PRODUCT
Syngo.via, picture archiving and communications system software controlled. Intended to be used for viewing, manipulation, communication, and storage of medical images
Recall NumberZ-2245-2016<p>
REASON
Incorrect values for the volume calculation. Software update VB30B via Update Instructions SY018/16/P to resolve software errors.<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Malvern, PA on 6/23/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
50 units<p>
DISTRIBUTION
Nationwide<p>

7/27/2016 RayStation treatment planning systems, Cl II
Company: RAYSEARCH LABORATORIES AB
Date of Enforcement Report 7/27/2016
Class II:<p>
PRODUCT
RayStation 3.0, RayStation 3.5, RayStation 4.0, RayStation 4.5, RayStation 4.7 and RayStation 5 --- Radiation Therapy Treatment Planning System --- designed for treatment planning and analysis of radiation therapy, provides treatment unit set up parameters and estimates dose distributions.
Recall Number Z-2206-2016<p>
REASON
An issue was found with the evaluation of biological clinical goals in RayStation 3.0, RayStation 3.5, RayStation 4.0, RayStation 4.5, RayStation 4.7 and RayStation 5. Biological clinical goals for an adapted plan based on another planning CT than the original planning CT will show incorrect values. -- To the best of the firm's knowledge, the issue has not caused any patient mistreatment or other incidents. However, the user must be aware of the following information to avoid incorrect plan evaluation during treatment planning. <p>
RECALLING FIRM/MANUFACTURER
RAYSEARCH LABORATORIES AB, Stockholm, Sweden on 7/1/2016 Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
170 units<p>
DISTRIBUTION
California, Connecticut, Delaware, Florida, Hawaii, Maine, Missouri, New York, Ohio, Texas and Washington<p>

7/27/2016 MEDRAD MRXperion MR Injection System, Cl II
Company: Bayer Healthcare
Date of Enforcement Report 7/27/2016
Class II:<p>
PRODUCT
Angiographic Injector and Syringe, MEDRAD MRXperion MR Injection System, MEDRAD MRXperion Sterile Disposable MRI Kit Usage: The MEDRAD MRXperion MR Injection System is a syringe based fluid delivery system indicated for delivery of contrast media and saline during MR applications. It is

intended to be used for the specific purpose of injecting intravenous MR contrast media and saline into the human vascular system for diagnostic studies in magnetic resonance imaging (MRI) applications with MRI scanners that have a magnetic field strength between 0.7 and 3.0 Tesla. Only trained healthcare professionals are intended to operate this device.
Recall Number Z-2244-2016<p>
REASON
Bayer Healthcare is initiating this recall due to complaints that were received from customer sites describing a 4205 error message when the injector is used with a 3T scanner.<p>
RECALLING FIRM/MANUFACTURER
Bayer Healthcare, Indianola on 6/9/2016 Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
42 units<p>
DISTRIBUTION
Internationally; US Distribution to NY<p>

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7/27/2016 Toshiba America Medical Systems Angio WorkS Cl II
Company: Toshiba America Medical Systems Inc.
Date of Enforcement Report 7/27/2016
Class II:<p>
PRODUCT
Toshiba America Medical Systems Angio WorkStation: XIDF-AWS801v6.00, v6.01, and V6.10 System: INFX-8000V Bi-Plane System
Recall Number Z-2188-2016<p>
REASON
During a procedure the Peak Skin Dose (PSD) value was displayed on the DTS larger than the DTS expected value. It was found that the software incorrectly calculated the PSD value when the x-ray condition of the frontal plane and the lateral plane are the same. It incorrectly used in the calculation a dose value from a previous exposure.<p>
RECALLING FIRM/MANUFACTURER
Toshiba America Medical Systems Inc., Tustin, CA on 2/24/2016 Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
23<p>
DISTRIBUTION
US Distribution to the states of : NC, NY, TX, GA, CA, AZ, IL, FL,MA, MO and DE.<p>

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7/27/2016 Triton Infusion Pump, Cl II
Company: WalkMed Infusion LLC
Date of Enforcement Report 7/27/2016
Class II:<p>
PRODUCT
Triton Infusion Pump (model 300000) and Triton FP Infusion Pump (model 400000)The pump (with cushioning foam inserts) is packaged in a single pump box. Four pump boxes are placed in an over-shipper for distribution.
Recall Number Z-2219-2016<p>
REASON
WalkMed Infusion, LLC Announces a Voluntary Field Action of the Triton Infusion Pump (model 300000) and Triton FP Infusion Pump (model 400000) Due to Unapproved Changes to the Software and Specifications of the Triton Infusion Pump (model 300000) and Unapproved Changes to the Intended Use of the Triton FP Infusion Pump (model 400000).<p>
RECALLING FIRM/MANUFACTURER
WalkMed Infusion, LLC, Englewood, CO on 6/14/2016 Voluntary: Firm Initiated recall is ongoing. <p>

VOLUME OF PRODUCT IN COMMERCE
2482 units <p>
DISTRIBUTION
Nationwide to AL, AZ, CA, FL, IL, KS, MA, MD, MS,NJ, OH, PA, TN, TX, UT, and WA. No foreign/VA/govt/military.<p>

7/27/2016 Siemens ADVIA Centaur XPT , CI II
Company: Siemens Healthcare Diagnostics, Inc.
Date of Enforcement Report 7/27/2016
Class II:<p>
PRODUCT
ADVIA¿ Centaur XPT system software versions V1.0.1 (Bundle 1.0.912 SMN 10819704), V1.0.2 (Bundle 1.0.1086 SMN 11219806), V1.0.3 (Bundle 1.0.1108 SMN 11220781) and V1.1 (Bundle 1.1.243 SMN 11221979). Product Usage: This system is intended for professional use in a laboratory environment only. Tests performed using this system are intended for in vitro diagnostic use. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.
Recall Number Z-2256-2016<p>
REASON
Eight (8) issues were identified which may affect the results generated by the system software version<p>
RECALLING FIRM/MANUFACTURER
Siemens Healthcare Diagnostics, Inc. , Tarrytown, NY on7/21/2016 Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
446 units Total (3 domestically & 443 internationally)<p>
DISTRIBUTION
Nationwide and Internationally<p>

7/20/2016 VarianAlign RT Plus, CI II
Company: Varian Medical Systems
Date of Enforcement Report 7/20/2016
Class II:<p>
PRODUCT
Optical Surface Monitoring System{Align RT Plus} This is used on Varian's TrueBeam EDGE; Radiology: The AlignRT Plus system is indicated for use to position and monitor patients relative to the prescribed treatment isocentre, and to Withhold the beam automatically during radiation delivery..
Recall Number Z-2150-2016<p>
REASON
Varian Medical Systems has received reports that unintended changes were made to planned couch parameters, specifically the couch rotation parameter, during patient set-up. This can occur when a user sets a different couch rotation from the plan couch rotation while performing patient alignment with Optical Surface Monitoring System [OSMS].<p>
RECALLING FIRM/MANUFACTURER
Varian Medical System, Palo Alto, CA s on 6/23/2016 Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
21 AlignRT Plus in US, 1 International <p>
DISTRIBUTION
Nationwide and Internationally<p>

7/20/2016 Varian Optical Surface Monitoring System, Cl II

Company: Varian Medical Systems
Date of Enforcement Report 7/20/2016
Class II:<p>
PRODUCT
Optical Surface Monitoring System{OSMS, Varian Private Label} This is used on Varian's TrueBeam EDGE; Radiology: The AlignRT Plus system is indicated for use to position and monitor patients relative to the prescribed treatment isocentre, and to Withhold the beam automatically during radiation delivery.
Recall Number Z-2149-2016<p>
REASON
Varian Medical Systems has received reports that unintended changes were made to planned couch parameters, specifically the couch rotation parameter, during patient set-up. This can occur when a user sets a different couch rotation from the plan couch rotation while performing patient alignment with Optical Surface Monitoring System [OSMS].<p>
RECALLING FIRM/MANUFACTURER
Varian Medical System, Palo Alto, CA s on 6/23/2016 Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
166 OSMS in US, 23 OSMO - International, <p>
DISTRIBUTION
Nationwide and Internationally<p>

7/20/2016 NovaPACS Diagnostic Viewer, Cl II

Company: Novarad Corporation
Date of Enforcement Report 7/20/2016
Class II:<p>
PRODUCT
NovaPACS versions 7.4, 7.5, 7.6, and 8.0, Diagnostic Viewer. Distributed by Novarad Corporation. Picture archiving and communication system (PACS).
Recall Number Z-2151-2016<p>
REASON
Potential for images to be flipped while streaming, which could incorrectly display image orientation markers.<p>
RECALLING FIRM/MANUFACTURER
Novarad Corporation , American Fork, UT on 5/9/2013 Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
2695<p>
DISTRIBUTION
Nationwide and internationally. No Canadian distribution<p>

7/20/2016 Merge OfficePACS software, Cl II

Company: Merge Healthcare, Inc.
Date of Enforcement Report 7/20/2016
Class II:<p>
PRODUCT
Merge OfficePACS software. The firm name on the label is Merge Healthcare, Heartland, WI.
Recall Number Z-2159-2016<p>
REASON
Potential data loss occurs as a result of product archiving not working properly.<p>
RECALLING FIRM/MANUFACTURER
Merge Healthcare, Inc, Hartland, WI on 1/31/16 Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
48 sites have affected software <p>

DISTRIBUTION
Distribution was made to medical facilities located in AL, AZ, CA, CO, CT, FL GA, ID, IL, KY, MA, MO, NE, NH, NJ, NY, NC, OK, PA, SC, TN, VA, and WA. There was no government/militar y/foreign distribution.<p>

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7/20/2016 ORTHO enGen Laboratory Automation System, CI III

Company: Ortho-Clinical Diagnostics
Date of Enforcement Report 7/20/2016
Class II:<p>
PRODUCT
enGen Laboratory Automation System, Product Code engen, Software Versions enGen Select 3.2 and Above and enGen Custom 2.0 and Above; IVD.
Recall Number Z-2143-2016<p>
REASON
f the user selects the Comment or Interpretation option (in the enGEN .gsb file), and the numerical results fall between Negative and Reactive, the IM incorrectly displays the interpretive text as Borderline and sends the incorrect text to the LIS. The IFU states the interpretation term for these numerical result values is Retest?.¿ The difference in terminology exists for US Markets only.<p>
RECALLING FIRM/MANUFACTURER
Ortho-Clinical Diagnostics, Rochester, NY on 5/16/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
30 units <p>
DISTRIBUTION
Nationwide f the user selects the Comment or Interpretation option (in the enGEN .gsb file), and the numerical results fall between Negative and Reactive, the IM incorrectly displays the interpretive text as Borderline and sends the incorrect text to the LIS. The IFU states the interpretation term for these numerical result values is Retest?.¿ The difference in terminology exists for US Markets only..<p>

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7/13/2016 VITROS Chemistry Products Calibrator Kit, Class II

Company: Ortho-Clinical Diagnostics
Date of Enforcement Report 7/13/2016
Class II:<p>
PRODUCT
VITROS Chemistry Products Calibrator Kit 29, REF/Product Code 680 2344, used in conjunction with VITROS Chemistry Products dTIBC Reagent Generation 30 (GEN 30), REF 680 2001, and Assay Data Disk (ADD), REF/Product Code 6801876 (Unique Device No. 10758750001576), Data Release Versions (DRVs) 5870 through 5883 inclusive; IVD --- Ortho-Clinical Diagnostics For in vitro diagnostic use only. VITROS Chemistry Products Calibrator Kit 29 is used to calibrate the VITROS 5,1 FS Chemistry System, the VITROS 4600 Chemistry System and the VITROS 5600 Integrated System for the quantitative measurement of total iron-binding capacity (TIBC) using VITROS Chemistry Products dTIBC Reagent.
Recall Number Z-2119-2016<p>
REASON
Ortho Clinical Diagnostics started receiving customer complaints for biased results when using VITROS dTIBC Reagent GEN 30 product. Ortho' s investigation confirmed that incorrect calibration mathematics were assigned to the Calibrator Kit 29 Lots 2915 and 2995 supporting dTIBC Reagent GEN 30 product.<p>
RECALLING FIRM/MANUFACTURER
Ortho-Clinical Diagnostics, Rochester, NY on 5/24/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
US: 1517; Foreign: 842<p>

DISTRIBUTION
Nationwide and Internationally.<p>

7/13/2016 Medtronic, MyCareLink" Patient Monitor, Cl II
Company: Medtronic Inc., Cardiac Rhythm and Heart Failure .
Date of Enforcement Report 7/13/2016
Class II:<p>
PRODUCT
Medtronic, MyCareLink" Patient Monitor, Model 24950, Rx Only. The MyCareLink Monitor, Model 24950, is a remote monitoring system that interrogates implanted devices and transmits the data to the Care Link Network for viewing by the physician.
Recall NumberZ-2125-2016<p>
REASON
ARecently, a new software version was automatically sent to a subset of Model 24950 MyCareLink Monitors. After release, Medtronic identified an issue with the software that prevents implanted device data from being available to clinicians on the CareLink" Network. While the transmission appears successful to the patient, the transmitted data, including CareAlerts, are not visible to the clinic.<p>
RECALLING FIRM/MANUFACTURER
Medtronic Inc., Cardiac Rhythm and Heart Failure, Mounds View, MN on 5/26/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
262<p>
DISTRIBUTION
Internationally <p>

7/13/2016 ZYTO Select and ZYTO Elite software progra,
Cl II
Company: ZYTO Technologies Inc.
Date of Enforcement Report 7/13/2016
Class II:<p>
PRODUCT
The ZYTO Select and ZYTO Elite software programs are used to rank pairs of galvanic skin response measurements from most coherent (the second scan is closest in time measurement to the baseline original scan) to least coherent (further away from the baseline).
Recall Number Z-2121-2016<p>
REASON
ZYTO Technologies Inc. Announces a Voluntary Recall of the ZYTO Tower and ZYTO Select and Elite Software Due to Claims Exceeding the 510(k) Clearance.<p>
RECALLING FIRM/MANUFACTURER
ZYTO Technologies Inc.,Lindon, UT on 11/23/2015 Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
1252 total <p>
DISTRIBUTION
Nationwide. Canadian and other foreign consignees. No VA/govt/military.<p>

7/13/2016 ZYTO Tower, Cl II
Company: ZYTO Technologies Inc.
Date of Enforcement Report 7/13/2016
Class II:<p>
PRODUCT
The ZYTO Tower is the input device to program the software with various virtual items.
Recall Number Z-2120-2016<p>
REASON

ZYTO Technologies Inc. Announces a Voluntary Recall of the ZYTO Tower and ZYTO Select and Elite Software Due to Claims Exceeding the 510(k) Clearance.<p>
RECALLING FIRM/MANUFACTURER
ZYTO Technologies Inc.,Lindon, UT on 11/23/2015 Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
1252 total <p>
DISTRIBUTION
Nationwide. Canadian and other foreign consignees. No VA/govt/military.<p>

7/6/2016 Philips Ingenuity Core 128 , Cl II
Company: Philips Medical Systems, Inc.
Date of Enforcement Report 7/62016
Class II:<p>
PRODUCT
Ingenuity Core 128-Computed Tomography X-ray system Product Usage: The Ingenuity Core 128 scanner is a whole body Computed Tomography X-ray system intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data taken at different angles and planes...
Recall Number Z-2118-2016<p>
REASON
Philips Healthcare received reports from the field that certain Ingenuity Core 128 systems running software version 3.5.4 exhibited intermittent swirl-like ring artifacts that may appear on reconstructed images. A patient rescan may be required if the images cannot be used for interpretation due to the swirl-like artifact.<p>
RECALLING FIRM/MANUFACTURER
Philips Medical Systems, Inc., Cleveland, OH on 4/1/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
19<p>
DISTRIBUTION
US Nationwide Distribution in the states of CA, FL, ID, KS, MI, NY,OH,TX<p>

7/6/2016 Philips Ingenuity Core, Cl II
Company: Philips Medical Systems, Inc.
Date of Enforcement Report 7/62016
Class II:<p>
PRODUCT
Product Usage: The Ingenuity Core scanner is a whole body Computed Tomography X-ray system intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data taken at different angles and planes.
Recall Number Z-2117-2016<p>
REASON
Philips Healthcare received reports from the field that certain Ingenuity Core systems running software version 3.5.4 exhibited intermittent swirl-like ring artifacts that may appear on reconstructed images. A patient rescan may be required if the images cannot be used for interpretation due to the swirl-like artifact.<p>
RECALLING FIRM/MANUFACTURER
Philips Medical Systems, Inc., Cleveland, OH on 4/1/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
18<p>
DISTRIBUTION
US Nationwide Distribution in the states of CA, FL, ID, KS, MI, NY,OH,TX<p>

7/6/2016 Philips Brilliance 64 CI II
Company: Philips Medical Systems, Inc.
Date of Enforcement Report 7/62016
Class II:<p>
PRODUCT
Brilliance 64, Computed Tomography X-ray system Product Usage: The Brilliance CT 64 scanner is a whole body Computed Tomography X-ray system intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data taken at different angles and planes
Recall Number Z-2116-2016<p>
REASON
Philips Healthcare received reports from the field that certain Brilliance 64 systems running software version 3.5.4 exhibited intermittent swirl-like ring artifacts that may appear on reconstructed images. A patient rescan may be required if the images cannot be used for interpretation due to the swirl-like artifact.<p>
RECALLING FIRM/MANUFACTURER
Philips Medical Systems, Inc., Cleveland, OH on 4/1/2016. Voluntary: Firm Initiated recall is ongoing.
<p>
VOLUME OF PRODUCT IN COMMERCE
94 <p>
DISTRIBUTION
US Nationwide Distribution in the states of CA, FL, ID, KS, MI, NY,OH,TX<p>

7/6/2016 Siemens SYNGO Breast Care, CI II
Company: Siemens Medical Solutions USA, Inc.
Date of Enforcement Report 7/6/2016
Class II:<p>
PRODUCT
SYNGO Breast Care, visualization and image enhancement tools to aid radiologist in the review of digital Mammography images and tomosynthesis datasets.,
Recall NumberZ-2107-2016<p>
REASON
Software issues. Siemens is voluntarily initiating a recall after they became aware of the following system behavior: 1) At times, the view and laterality marker is overlaid by patient demographic information, thus becoming difficult to read. 2) The facility name and address are not shown per default (in the current software versions this information is displayed only when the reader chooses an appropriate image text display mode). <p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Malvern, PA on 6/62016. Voluntary: Firm Initiated recall is onging.
<p>
VOLUME OF PRODUCT IN COMMERCE
29 systems<p>
DISTRIBUTION
Distributed to: CA,NY,TX,OH,CO,NY, TX,CA,NE,NJ,TX,FL, IL,TX,MO,CA,PA,FL, NJ,MO,ND <p>

7/6/2016 Siemens Syngo.plaza, CI II
Company: Siemens Medical Solutions USA, Inc.
Date of Enforcement Report 7/6/2016
Class II:<p>
PRODUCT
Syngo.plaza, Picture archiving and communication system (PACS), Model Numbers - 10863171, 10863172, 10863173,
Recall NumberZ-2088-2016<p>

REASON
Software error in previous software versions in which two references for the same image may exist in the database.<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Malvern, PA on 5/92016. Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
74 systems<p>
DISTRIBUTION
Nationwide <p>

7/6/2016 Alaris System PC Unit Model 8015 Cl II
Company: CareFusion 303 Inc.
Date of Enforcement Report 7/6/2016
Class II:<p>
PRODUCT
Alaris System PC Unit Model 8015 with software versions 9.17 and 9.19; Central programming, monitoring and power supply component for the Alaris System.
Recall Number Z-2064-2016<p>
REASON
A patient weight can be populated incorrectly under certain conditions when using the RESTORE feature to restore infusions running on the Alaris LVP module model 8100 and the Alaris Syringe module model 8110.<p>
RECALLING FIRM/MANUFACTURER
CareFusion 303, Inc., San Diego, CA on 5/12/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
69,693 units <p>
DISTRIBUTION
Nationwide and Canada <p>

6/29/2016 Siemens Biograph 16 TruePoint, Cl II
Company: Siemens Medical Solutions USA, Inc.
Date of Enforcement Report 6/29/2016
Class II:<p>
PRODUCT
Biograph 16 TruePoint, MATERIAL NUMBER 10249555 The Siemens Biograph TruePoint systems are combined X-Ray Computed Tomography (CT) and Positron Emission Tomography (PET) scanners that provide registration and fusion of high resolution physiologic and anatomic information.
Recall NumberZ-2037-2016<p>
REASON
Siemens Medical Solutions, Molecular Imaging has become aware of a potential for unexpected SUV values if a non-Siemens phantom is used for calibration..<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Knoxville, TN on 4/22/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
63 units<p>
DISTRIBUTION
Nationwide <p>

6/29/2016 Siemens SYS IVK, Bio mCT-X 3R->4R
Upgrade, Cl II
Company: Siemens Medical Solutions USA, Inc.
Date of Enforcement Report 6/29/2016
Class II:<p>
PRODUCT
SYS IVK, Bio mCT-X 3R->4R Upgrade, MATERIAL NUMBER 10250745 The Siemens Biograph TruePoint systems are combined X-Ray Computed Tomography (CT) and Positron Emission Tomography (PET) scanners that provide registration and fusion of high resolution physiologic and anatomic information...
Recall NumberZ-2036-2016<p>
REASON
Siemens Medical Solutions, Molecular Imaging has become aware of a potential for unexpected SUV values if a non-Siemens phantom is used for calibration..<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Knoxville, TN on 4/22/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
2 units<p>
DISTRIBUTION
Nationwide <p>

6/29/2016 Siemens SYS IVK, Bio mCT-S(40) 3R->4R
Upgra, Cl II
Company: Siemens Medical Solutions USA, Inc.
Date of Enforcement Report 6/29/2016
Class II:<p>
PRODUCT
SYS IVK, Bio mCT-S(40) 3R->4R Upgrade, MATERIAL NUMBER 10250743 The Siemens Biograph TruePoint systems are combined X-Ray Computed Tomography (CT) and Positron Emission Tomography (PET) scanners that provide registration and fusion of high resolution physiologic and anatomic information..
Recall NumberZ-2035-2016<p>
REASON
Siemens Medical Solutions, Molecular Imaging has become aware of a potential for unexpected SUV values if a non-Siemens phantom is used for calibration..<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Knoxville, TN on 4/22/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
4 units<p>
DISTRIBUTION
Nationwide <p>

6/29/2016 SiemensBiograph mCT-X 3R, Cl II
Company: Siemens Medical Solutions USA, Inc.
Date of Enforcement Report 6/29/2016
Class II:<p>
PRODUCT
Biograph mCT-X 3R, MATERIAL NUMBER 10248673 The Siemens Biograph TruePoint systems are combined X-Ray Computed Tomography (CT) and Positron Emission Tomography (PET) scanners that provide registration and fusion of high resolution physiologic and anatomic information..
Recall NumberZ-2034-2016<p>

REASON
Siemens Medical Solutions, Molecular Imaging has become aware of a potential for unexpected SUV values if a non-Siemens phantom is used for calibration..<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Knoxville, TN on 4/22/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
22 units<p>
DISTRIBUTION
Nationwide <p>

6/29/2016 Siemens Biograph mCT-S(64) 4R, Cl II
Company: Siemens Medical Solutions USA, Inc.
Date of Enforcement Report 6/29/2016
Class II:<p>
PRODUCT
Biograph mCT-S(64) 4R, MATERIAL NUMBER 10248672 The Siemens Biograph TruePoint systems are combined X-Ray Computed Tomography (CT) and Positron Emission Tomography (PET) scanners that provide registration and fusion of high resolution physiologic and anatomic information.
Recall NumberZ-2033-2016<p>
REASON
Siemens Medical Solutions, Molecular Imaging has become aware of a potential for unexpected SUV values if a non-Siemens phantom is used for calibration..<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Knoxville, TN on 4/22/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
127 units<p>
DISTRIBUTION
Nationwide <p>

6/29/2016 SiemensBiograph mCT-S(64) 3R, Cl II
Company: Siemens Medical Solutions USA, Inc.
Date of Enforcement Report 6/29/2016
Class II:<p>
PRODUCT
Biograph mCT-S(64) 3R, MATERIAL NUMBER 10248669 The Siemens Biograph TruePoint systems are combined X-Ray Computed Tomography (CT) and Positron Emission Tomography (PET) scanners that provide registration and fusion of high resolution physiologic and anatomic information.
Recall NumberZ-2032-2016<p>
REASON
Siemens Medical Solutions, Molecular Imaging has become aware of a potential for unexpected SUV values if a non-Siemens phantom is used for calibration..<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Knoxville, TN on 4/22/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
51 units<p>
DISTRIBUTION
Nationwide <p>

6/29/2016 SiemensBiograph mCT-S(40) 4R, Cl II
Company: Siemens Medical Solutions USA, Inc.
Date of Enforcement Report 6/29/2016
Class II:<p>
PRODUCT
Biograph mCT-S(40) 4R, MATERIAL NUMBER 10248671 The Siemens Biograph TruePoint systems are combined X-Ray Computed Tomography (CT) and Positron Emission Tomography (PET) scanners that provide registration and fusion of high resolution physiologic and anatomic information.
Recall NumberZ-2031-2016<p>
REASON
Siemens Medical Solutions, Molecular Imaging has become aware of a potential for unexpected SUV values if a non-Siemens phantom is used for calibration..<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Knoxville, TN on 4/22/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
100 units<p>
DISTRIBUTION
Nationwide <p>

6/29/2016 Siemens Biograph mCT-S(40) 3R, Cl II
Company: Siemens Medical Solutions USA, Inc.
Date of Enforcement Report 6/29/2016
Class II:<p>
PRODUCT
Biograph mCT-S(40) 3R, MATERIAL NUMBER 10248668 The Siemens Biograph TruePoint systems are combined X-Ray Computed Tomography (CT) and Positron Emission Tomography (PET) scanners that provide registration and fusion of high resolution physiologic and anatomic information..
Recall NumberZ-2030-2016<p>
REASON
Siemens Medical Solutions, Molecular Imaging has become aware of a potential for unexpected SUV values if a non-Siemens phantom is used for calibration..<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Knoxville, TN on 4/22/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
47 units<p>
DISTRIBUTION
Nationwide <p>

6/29/2016 SiemensBIOGRAPH mCT S(20)-4R, Cl II
Company: Siemens Medical Solutions USA, Inc.
Date of Enforcement Report 6/29/2016
Class II:<p>
PRODUCT
BIOGRAPH mCT S(20)-4R, MATERIAL NUMBER 10534160 The Siemens Biograph TruePoint systems are combined X-Ray Computed Tomography (CT) and Positron Emission Tomography (PET) scanners that provide registration and fusion of high resolution physiologic and anatomic information.
Recall NumberZ-2029-2016<p>
REASON
Siemens Medical Solutions, Molecular Imaging has become aware of a potential for unexpected SUV values if a non-Siemens phantom is used for calibration..<p>
RECALLING FIRM/MANUFACTURER

Siemens Medical Solutions USA, Inc, Knoxville, TN on 4/22/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
5 units<p>
DISTRIBUTION
Nationwide <p>

6/29/2016 Siemens BIOGRAPH mCT S(20) - 3R, Cl II
Company: Siemens Medical Solutions USA, Inc.
Date of Enforcement Report 6/29/2016
Class II:<p>
PRODUCT
BIOGRAPH mCT S(20) - 3R, MATERIAL NUMBER 10507786 The Siemens Biograph TruePoint systems are combined X-Ray Computed Tomography (CT) and Positron Emission Tomography (PET) scanners that provide registration and fusion of high resolution physiologic and anatomic information.
Recall NumberZ-2028-2016<p>
REASON
Siemens Medical Solutions, Molecular Imaging has become aware of a potential for unexpected SUV values if a non-Siemens phantom is used for calibration..<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Knoxville, TN on 4/22/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
143 units<p>
DISTRIBUTION
Nationwide <p>

6/29/2016 BIOGRAPH mCT Flow Edge-4R Cl II
Company: Siemens Medical Solutions USA, Inc.
Date of Enforcement Report 6/29/2016
Class II:<p>
PRODUCT
BIOGRAPH mCT Flow Edge-4R, MATERIAL NUMBER 10528955 The Siemens Biograph TruePoint systems are combined X-Ray Computed Tomography (CT) and Positron Emission Tomography (PET) scanners that provide registration and fusion of high resolution physiologic and anatomic information.
Recall NumberZ-2027-2016<p>
REASON
Siemens Medical Solutions, Molecular Imaging has become aware of a potential for unexpected SUV values if a non-Siemens phantom is used for calibration..<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Knoxville, TN on 4/22/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
13 units<p>
DISTRIBUTION
Nationwide <p>

6/29/2016 BIOGRAPH mCT Flow Edge-3R, Cl II
Company: Siemens Medical Solutions USA, Inc.
Date of Enforcement Report 6/29/2016
Class II:<p>
PRODUCT
BIOGRAPH mCT Flow Edge-3R, MATERIAL NUMBER 10528954 The Siemens Biograph TruePoint

systems are combined X-Ray Computed Tomography (CT) and Positron Emission Tomography (PET) scanners that provide registration and fusion of high resolution physiologic and anatomic information..
Recall NumberZ-2026-2016<p>
REASON
Siemens Medical Solutions, Molecular Imaging has become aware of a potential for unexpected SUV values if a non-Siemens phantom is used for calibration..<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Knoxville, TN on 4/22/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
2 units<p>
DISTRIBUTION
Nationwide <p>

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6/29/2016 BIOGRAPH mCT Flow 64-3R, Cl II
Company: Siemens Medical Solutions USA, Inc.
Date of Enforcement Report 6/29/2016
Class II:<p>
PRODUCT
BIOGRAPH mCT Flow 64-3R, MATERIAL NUMBER 10529160 The Siemens Biograph TruePoint systems are combined X-Ray Computed Tomography (CT) and Positron Emission Tomography (PET) scanners that provide registration and fusion of high resolution physiologic and anatomic information.
Recall NumberZ-2024-2016<p>
REASON
Siemens Medical Solutions, Molecular Imaging has become aware of a potential for unexpected SUV values if a non-Siemens phantom is used for calibration..<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Knoxville, TN on 4/22/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
12 units<p>
DISTRIBUTION
Nationwide <p>

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6/29/2016 BIOGRAPH mCT Flow 40-3R, Cl II
Company: Siemens Medical Solutions USA, Inc.
Date of Enforcement Report 6/29/2016
Class II:<p>
PRODUCT
BIOGRAPH mCT Flow 40-3R, MATERIAL NUMBER 10529159 The Siemens Biograph TruePoint systems are combined X-Ray Computed Tomography (CT) and Positron Emission Tomography (PET) scanners that provide registration and fusion of high resolution physiologic and anatomic information.
Recall NumberZ-2023-2016<p>
REASON
Siemens Medical Solutions, Molecular Imaging has become aware of a potential for unexpected SUV values if a non-Siemens phantom is used for calibration..<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Knoxville, TN on 4/22/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
9 units<p>
DISTRIBUTION
Nationwide <p>

6/29/2016 Siemens BIOGRAPH mCT Flow 40-3R, Cl II
Company: Siemens Medical Solutions USA, Inc.
Date of Enforcement Report 6/29/2016
Class II:<p>
PRODUCT
BIOGRAPH mCT Flow 40-3R, MATERIAL NUMBER 10529158 The Siemens Biograph TruePoint systems are combined X-Ray Computed Tomography (CT) and Positron Emission Tomography (PET) scanners that provide registration and fusion of high resolution physiologic and anatomic information.
Recall NumberZ-2022-2016<p>
REASON
Siemens Medical Solutions, Molecular Imaging has become aware of a potential for unexpected SUV values if a non-Siemens phantom is used for calibration..<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Knoxville, TN on 4/22/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
3 units<p>
DISTRIBUTION
Nationwide <p>

6/29/2016 BIOGRAPH mCT Flow 20-4R Cl II
Company: Siemens Medical Solutions USA, Inc.
Date of Enforcement Report 6/29/2016
Class II:<p>
PRODUCT
BIOGRAPH mCT Flow 20-4R, MATERIAL NUMBER 10528958 The Siemens Biograph TruePoint systems are combined X-Ray Computed Tomography (CT) and Positron Emission Tomography (PET) scanners that provide registration and fusion of high resolution physiologic and anatomic information.
Recall NumberZ-2021-2016<p>
REASON
Siemens Medical Solutions, Molecular Imaging has become aware of a potential for unexpected SUV values if a non-Siemens phantom is used for calibration..<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Knoxville, TN on 4/22/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
28 units<p>
DISTRIBUTION
Nationwide <p>

6/29/2016 BIOGRAPH mCT Flow 20-3R Cl II
Company: Siemens Medical Solutions USA, Inc.
Date of Enforcement Report 6/29/2016
Class II:<p>
PRODUCT
BIOGRAPH Sys 40-3R to 40-4R, MATERIAL NUMBER 10246388 The Siemens Biograph BIOGRAPH mCT Flow 20-3R, MATERIAL NUMBER 10528956 The Siemens Biograph TruePoint systems are combined X-Ray Computed Tomography (CT) and Positron Emission Tomography (PET) scanners that provide registration and fusion of high resolution physiologic and anatomic information..
Recall NumberZ-2020-2016<p>
REASON
Siemens Medical Solutions, Molecular Imaging has become aware of a potential for unexpected SUV

values if a non-Siemens phantom is used for calibration..<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Knoxville, TN on 4/22/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
9 units<p>
DISTRIBUTION
Nationwide <p>

6/29/2016 BIOGRAPH Sys 40-3R to 40-4R, CI II
Company: Siemens Medical Solutions USA, Inc.
Date of Enforcement Report 6/29/2016
Class II:<p>
PRODUCT
BIOGRAPH Sys 40-3R to 40-4R, MATERIAL NUMBER 10246388 The Siemens Biograph TruePoint systems are combined X-Ray Computed Tomography (CT) and Positron Emission Tomography (PET) scanners that provide registration and fusion of high resolution physiologic and anatomic information.
Recall NumberZ-2018-2016<p>
REASON
Siemens Medical Solutions, Molecular Imaging has become aware of a potential for unexpected SUV values if a non-Siemens phantom is used for calibration..<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Knoxville, TN on 4/22/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
4 units<p>
DISTRIBUTION
Nationwide <p>

6/29/2016 Biograph Sys 16-3R to 16-4R upgrade, CI II
Company: Siemens Medical Solutions USA, Inc.
Date of Enforcement Report 6/29/2016
Class II:<p>
PRODUCT
Biograph Sys 16-3R to 16-4R upgrade, MATERIAL NUMBER 10525581 The Siemens Biograph TruePoint systems are combined X-Ray Computed Tomography (CT) and Positron Emission Tomography (PET) scanners that provide registration and fusion of high resolution physiologic and anatomic information.
Recall NumberZ-2017-2016<p>
REASON
Siemens Medical Solutions, Molecular Imaging has become aware of a potential for unexpected SUV values if a non-Siemens phantom is used for calibration..<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Knoxville, TN on 4/22/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
2 units<p>
DISTRIBUTION
Nationwide <p>

6/29/2016 BIOGRAPH 64-4R TruePoint w/TrueV, CI II
Company: Siemens Medical Solutions USA, Inc.
Date of Enforcement Report 6/29/2016
Class II:<p>
PRODUCT
BIOGRAPH 64-4R TruePoint w/TrueV, MATERIAL NUMBER 10097302 The Siemens Biograph TruePoint systems are combined X-Ray Computed Tomography (CT) and Positron Emission Tomography (PET) scanners that provide registration and fusion of high resolution physiologic and anatomic information.
Recall NumberZ-2015-2016<p>
REASON
Siemens Medical Solutions, Molecular Imaging has become aware of a potential for unexpected SUV values if a non-Siemens phantom is used for calibration..<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Knoxville, TN on 4/22/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
49 units<p>
DISTRIBUTION
Nationwide <p>

6/29/2016 BIOGRAPH 64-3R TruePoint, CI II
Company: Siemens Medical Solutions USA, Inc.
Date of Enforcement Report 6/29/2016
Class II:<p>
PRODUCT
BIOGRAPH 64-3R TruePoint, MATERIAL NUMBER 10097301 The Siemens Biograph TruePoint systems are combined X-Ray Computed Tomography (CT) and Positron Emission Tomography (PET) scanners that provide registration and fusion of high resolution physiologic and anatomic information.
Recall NumberZ-2014-2016<p>
REASON
Siemens Medical Solutions, Molecular Imaging has become aware of a potential for unexpected SUV values if a non-Siemens phantom is used for calibration..<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Knoxville, TN on 4/22/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
16 units<p>
DISTRIBUTION
Nationwide <p>

6/29/2016 SiemensBIOGRAPH 64 - 3 Ring, CI II
Company: Siemens Medical Solutions USA, Inc.
Date of Enforcement Report 6/29/2016
Class II:<p>
PRODUCT
BIOGRAPH 64 - 3 Ring, Material Number 08727450 The Siemens Biograph TruePoint systems are combined X-Ray Computed Tomography (CT) and Positron Emission Tomography (PET) scanners that provide registration and fusion of high resolution physiologic and anatomic information.
Recall NumberZ-2013-2016<p>
REASON
Siemens Medical Solutions, Molecular Imaging has become aware of a potential for unexpected SUV values if a non-Siemens phantom is used for calibration..<p>

RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Knoxville, TN on 4/22/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
15 units<p>
DISTRIBUTION
Nationwide <p>

6/29/2016 Siemens BIOGRAPH 6 TruePoint, CI II
Company: Siemens Medical Solutions USA, Inc.
Date of Enforcement Report 6/29/2016
Class II:<p>
PRODUCT
BIOGRAPH 6 TruePoint, Material Number 10097289 The Siemens Biograph TruePoint systems are combined X-Ray Computed Tomography (CT) and Positron Emission Tomography (PET) scanners that provide registration and fusion of high resolution physiologic and anatomic information.
Recall NumberZ-2012-2016<p>
REASON
Siemens Medical Solutions, Molecular Imaging has become aware of a potential for unexpected SUV values if a non-Siemens phantom is used for calibration..<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Knoxville, TN on 4/22/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
102 units<p>
DISTRIBUTION
Nationwide <p>

6/29/2016 Siemens BIOGRAPH 40-3R to 64-3R Upgrade, CI II
Company: Siemens Medical Solutions USA, Inc.
Date of Enforcement Report 6/29/2016
Class II:<p>
PRODUCT
BIOGRAPH 40-3R to 64-3R Upgrade, Material Number 10246390 The Siemens Biograph TruePoint systems are combined X-Ray Computed Tomography (CT) and Positron Emission Tomography (PET) scanners that provide registration and fusion of high resolution physiologic and anatomic information.
Recall NumberZ-2010-2016<p>
REASON
Siemens Medical Solutions, Molecular Imaging has become aware of a potential for unexpected SUV values if a non-Siemens phantom is used for calibration..<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Knoxville, TN on 4/22/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
1 unit<p>
DISTRIBUTION
Nationwide <p>

6/29/2016 Siemens BIOGRAPH 40 TruePoint, CI II
Company: Siemens Medical Solutions USA, Inc.
Date of Enforcement Report 6/29/2016
Class II:<p>
PRODUCT
BIOGRAPH 40 TruePoint, Material Number 10097303 The Siemens Biograph TruePoint systems are combined X-Ray Computed Tomography (CT) and Positron Emission Tomography (PET) scanners that provide registration and fusion of high resolution physiologic and anatomic information.
Recall NumberZ-2008-2016<p>
REASON
Siemens Medical Solutions, Molecular Imaging has become aware of a potential for unexpected SUV values if a non-Siemens phantom is used for calibration..<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Knoxville, TN on 4/22/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
48 units<p>
DISTRIBUTION
Nationwide <p>

6/29/2016 Siemens BIOGRAPH 40, CI II
Company: Siemens Medical Solutions USA, Inc.
Date of Enforcement Report 6/29/2016
Class II:<p>
PRODUCT
BIOGRAPH 40 - 3 Ring, Material Number 10097233 The Siemens Biograph TruePoint systems are combined X-Ray Computed Tomography (CT) and Positron Emission Tomography (PET) scanners that provide registration and fusion of high resolution physiologic and anatomic information.
Recall NumberZ-2007-2016<p>
REASON
Siemens Medical Solutions, Molecular Imaging has become aware of a potential for unexpected SUV values if a non-Siemens phantom is used for calibration..<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Knoxville, TN on 4/22/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
5 units<p>
DISTRIBUTION
Nationwide <p>

6/29/2016 Siemens Biograph 16 TruePoint TV,, CI II
Company: Siemens Medical Solutions USA, Inc.
Date of Enforcement Report 6/29/2016
Class II:<p>
PRODUCT
Biograph 16 TruePoint TV, Material Number 10249556 The Siemens Biograph TruePoint systems are combined X-Ray Computed Tomography (CT) and Positron Emission Tomography (PET) scanners that provide registration and fusion of high resolution physiologic and anatomic information.
Recall NumberZ-2006-2016<p>
REASON
Siemens Medical Solutions, Molecular Imaging has become aware of a potential for unexpected SUV values if a non-Siemens phantom is used for calibration..<p>
RECALLING FIRM/MANUFACTURER

Siemens Medical Solutions USA, Inc, Knoxville, TN on 4/22/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
36 units<p>
DISTRIBUTION
Nationwide <p>

6/29/2016 Siemens Biograph mCT-X 4R, Cl II
Company: Siemens Medical Solutions USA, Inc.
Date of Enforcement Report 6/29/2016
Class II:<p>
PRODUCT
Biograph mCT-X 4R, MATERIAL NUMBER 10248670 The Siemens Biograph TruePoint systems are combined X-Ray Computed Tomography (CT) and Positron Emission Tomography (PET) scanners that provide registration and fusion of high resolution physiologic and anatomic information.,
Recall NumberZ-2005-2016<p>
REASON
Siemens Medical Solutions, Molecular Imaging has become aware of a potential for unexpected SUV values if a non-Siemens phantom is used for calibration..<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Knoxville, TN on 4/22/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
48 units<p>
DISTRIBUTION
Nationwide <p>

6/29/2016 Fujifilm Synapse PACS, Cl II
Company: Fujifilm Medical Systems U.S.A., Inc.
Date of Enforcement Report 6/29/2016
Class II:<p>
PRODUCT
Fujifilm Synapse PACS software version 4.4.000, Fujifilm Synapse PACS software version 4.4.001, Fujifilm Synapse PACS software version 4.4.004, Fujifilm Synapse PACS software version 4.4.010 and Fujifilm Synapse PACS software version 4.4.020 FUJIFILM Synapse Workstation Software (a Picture Archiving And Communications System) is intended to serve as the primary user interface for the processing of medical images for presentation on displays appropriate to the medical task being performed. Also intended for installation on an off-the-shelf PC networked with Fuji Synapse PACS.
Recall Number Z-2043-2016<p>
REASON
Synapse cannot display image files, DICOM SR files, and/or Annotation files. The "Image Not Loaded" message displays instead<p>
RECALLING FIRM/MANUFACTURER
Fujifilm Medical Systems U.S.A., Inc. Stamford, CT on 5/10/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
27 units <p>
DISTRIBUTION
US Distribution to states of: CA, FL, KS, NE, NY, and PA.<p>

6/29/2016 Leica CytoVision Image Analysis and Capture
Cl II
Company: Leica Biosystems Richmond Inc.
Date of Enforcement Report 6/29/2016
Class II:<p>
PRODUCT
CytoVision Image Analysis and Capture System, an automated cell-locating device. The Cytovision is a rapid metaphase finder, image acquisition and computer aided chromosome analysis system which assists the operator in viewing chromosomes and looking for cellular anomalies. CytoVision enables a qualified Cytogeneticist to rapidly and accurately analyze the chromosome banding pattern.
Recall Number Z-2039-2016<p>
REASON
Systems have an improperly activated Windows 7 OS, even though a valid Windows 7 license was associated with each manufactured system. The system appears to be unlicensed. These systems cannot be re-activated using standard Windows licensing procedures and are requiring checks of each potentially affected system to confirm Windows 7 OS is properly activated.<p>
RECALLING FIRM/MANUFACTURER
Leica Biosystems Richmond Inc, Richmond, IL on 5/2/2016. Voluntary: Firm Initiated recall is ongoing.
<p>
VOLUME OF PRODUCT IN COMMERCE
283 systems <p>
DISTRIBUTION
Nationwide and Internationally<p>

6/22/2016 Leica Biosystems Ariol, Cl II
Company: Leica Biosystems Richmond Inc.
Date of Enforcement Report 6/22/2016
Class II:<p>
PRODUCT
Ariol is an automated scanning microscope and image analysis system. It is intended for in vitro diagnostic use as an aid to the pathologist in the detection, classification, and counting of cells of interest based on particular color, intensity, size, pattern, and shape. This particular Ariol software application is intended to measure, count, and quantitate the percentage and intensity of positively stained nuclei in formalin-fixed paraffin-embedded tissue specimens immunohistochemically stained for Estrogens Receptors or Progesterone Receptors (ER/PR). ER/PR results are indicated for use as and aid in the management, prognosis, and prediction of therapy outcomes of breast cancer.
Recall Number Z-1948-2016<p>
REASON
An issue during the manufacturing process caused systems to have an improperly activated Windows 7 OS, even though a valid Windows 7 license was associated with each manufactured system.<p>
RECALLING FIRM/MANUFACTURER
Leica Biosystems Richmond Inc, richmond, IL on 5/6/2016. Voluntary: Firm Initiated recall is ongoing.
<p>
VOLUME OF PRODUCT IN COMMERCE
33 systems <p>
DISTRIBUTION
Nationwide and Internationally<p>

6/22/2016 LIFEPAK15 monitor/defibrillator Cl II
Company: Physio-Control, Inc.
Date of Enforcement Report 6/22/2016
Class II:<p>
PRODUCT

LIFEPAK15 monitor/defibrillator with End-Tidal C02 (EtC02) feature installed. Part numbers: V15-2-xxxxxx (includes software version 1 and version 2); V15-5-xxxxxx (inclues software version 4). The LIFEPAK 15 monitor/defibrillator is intended for use by trained medical personnel in outdoor and indoor emergency care settings within the environmental conditions specified. The LIFEPAK 15 monitor/defibrillator is designed to be used during ground transportation except when specified otherwise. Manual mode monitoring and therapy functions are intended for use on adult and pediatric patients. Automated external defibrillation mode is intended for use on patients eight years of age and older.
Recall Number Z-193-2016<p>
REASON
The firm became aware that when using EtC02 in the kPa or % setting and in a situation where the reading is above 9.9 kPa, the display of the LIFEPAK 15 respiratory rate may partially obscure a portion of the leading digit of the EtC02 value. This affects all LIFEPAK 15 with an EtC02 feature installed and configured to the kPa or % setting.<p>
RECALLING FIRM/MANUFACTURER
Physio-Control, Inc. , Redmond, WA on 1/27/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
44798 units total (23189 units in US; 21609 units international) <p>
DISTRIBUTION
Nationwide and Internationally <p>

6/15/2016 ExacTrac Vero, Cl II
Company: Brainlab AG
Date of Enforcement Report 6/15/2016
Class II:<p>
PRODUCT
ExacTrac Vero is a Patient Positioning System for Radiation therapy.
Recall Number Z-1729-2016<p>
REASON
Potentially incorrect positioning when using Implanted Marker Detection with Brainlab ExacTrac Vero 3.5<p>
RECALLING FIRM/MANUFACTURER
Brainlab AG, Feldkirchen, Germany on 5/4/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
27 systems <p>
DISTRIBUTION
Distributed in the states of Florida, New York, Texas and Ohio, and in the countries of Belgium, France, Germany, Italy, Japan and South Korea. <p>

6/15/2016 Philips Healthcare Ingenuity Elite xray, Cl II
Company: Philips Healthcare
Date of Enforcement Report 6/15/2016
Class II:<p>
PRODUCT
Philips Healthcare Ingenuity Elite Computed Tomography X-Ray System
Recall Number Z-1719-2016<p>
REASON
Software Defects resulting in: (1) sagittal result shortened for axial scans; (2) single series displayed on console viewer when Creating multi-planner reconstruction; (3) scan length changes with a change in field of view; (4) DoseRight algorithm miscalculations leading to incorrect CTDI values; (5) scan length changes during subsequent axial results, (6) surview scan lengths near 135mm or 184mm<p>
RECALLING FIRM/MANUFACTURER
Philips Healthcare, Andover, MA on 9/6/2015. Voluntary: Firm Initiated recall is ongoing. <p>

VOLUME OF PRODUCT IN COMMERCE
423<p>
DISTRIBUTION
Nationwidewide<p>

6/15/2016 Philips Healthcare Ingenuity Core128 xray,
Cl II
Company: Philips Healthcare
Date of Enforcement Report 6/15/2016
Class II:<p>
PRODUCT
Philips Healthcare Ingenuity Core128 Computed Tomography X-Ray System
Recall Number Z-1718-2016<p>
REASON
Software Defects resulting in: (1) sagittal result shortened for axial scans; (2) single series displayed on console viewer when Creating multi-planner reconstruction; (3) scan length changes with a change in field of view; (4) DoseRight algorithm miscalculations leading to incorrect CTDI values; (5) scan length changes during subsequent axial results, (6) surview scan lengths near 135mm or 184mm<p>
RECALLING FIRM/MANUFACTURER
Philips Healthcare, Andover, MA on 9/6/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
423<p>
DISTRIBUTION
Nationwidewide<p>

6/15/2016 Philips Healthcare Ingenuity CT xray, Cl II
Company: Philips Healthcare
Date of Enforcement Report 6/15/2016
Class II:<p>
PRODUCT
Philips Healthcare Ingenuity CT Computed Tomography X-Ray System
Recall Number Z-1717-2016<p>
REASON
Software Defects resulting in: (1) sagittal result shortened for axial scans; (2) single series displayed on console viewer when Creating multi-planner reconstruction; (3) scan length changes with a change in field of view; (4) DoseRight algorithm miscalculations leading to incorrect CTDI values; (5) scan length changes during subsequent axial results, (6) surview scan lengths near 135mm or 184mm<p>
RECALLING FIRM/MANUFACTURER
Philips Healthcare, Andover, MA on 9/6/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
423<p>
DISTRIBUTION
Nationwidewide<p>

6/15/2016 Philips Healthcare Ingenuity Core xray, Cl II
Company: Philips Healthcare
Date of Enforcement Report 6/15/2016
Class II:<p>
PRODUCT
Philips Healthcare Ingenuity Core Computed Tomography X-Ray System
Recall Number Z-1716-2016<p>
REASON
Software Defects resulting in: (1) sagittal result shortened for axial scans; (2) single series displayed on

console viewer when Creating multi-planner reconstruction; (3) scan length changes with a change in field of view; (4) DoseRight algorithm miscalculations leading to incorrect CTDI values; (5) scan length changes during subsequent axial results, (6) surview scan lengths near 135mm or 184mm<p>
RECALLING FIRM/MANUFACTURER
Philips Healthcare, Andover, MA on 9/6/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
423<p>
DISTRIBUTION
Nationwidewide<p>

6/15/2016 Philips Healthcare Brilliance iCT SP, Cl II
Company: Philips Healthcare
Date of Enforcement Report 6/15/2016
Class II:<p>
PRODUCT
Philips Healthcare Brilliance iCT SP Computed Tomography X-Ray System
Recall Number Z-171Philips Healthcare Brilliance iCT SP Computed Tomography X-Ray System-2016
<p>
REASON
Software Defects resulting in: (1) sagittal result shortened for axial scans; (2) single series displayed on console viewer when Creating multi-planner reconstruction; (3) scan length changes with a change in field of view; (4) DoseRight algorithm miscalculations leading to incorrect CTDI values; (5) scan length changes during subsequent axial results, (6) surview scan lengths near 135mm or 184mm<p>
RECALLING FIRM/MANUFACTURER
Philips Healthcare, Andover, MA on 9/6/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
423<p>
DISTRIBUTION
Nationwidewide<p>

6/15/2016 Philips Healthcare Brilliance iCT xray, Cl II
Company: Philips Healthcare
Date of Enforcement Report 6/15/2016
Class II:<p>
PRODUCT
Philips Healthcare Brilliance iCT Computed Tomography X-Ray System
Recall Number Z-1714-2016<p>
REASON
Software Defects resulting in: (1) sagittal result shortened for axial scans; (2) single series displayed on console viewer when Creating multi-planner reconstruction; (3) scan length changes with a change in field of view; (4) DoseRight algorithm miscalculations leading to incorrect CTDI values; (5) scan length changes during subsequent axial results, (6) surview scan lengths near 135mm or 184mm<p>
RECALLING FIRM/MANUFACTURER
Philips Healthcare, Andover, MA on 9/6/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
423<p>
DISTRIBUTION
Nationwidewide<p>

6/15/2016 Philips Healthcare Brilliance 64, CI II
Company: Philips Healthcare
Date of Enforcement Report 6/15/2016
Class II:<p>
PRODUCT
Philips Healthcare Brilliance 64 Computed Tomography X-Ray System
Recall Number Z-1713-2016<p>
REASON
Software Defects resulting in: (1) sagittal result shortened for axial scans; (2) single series displayed on console viewer when Creating multi-planner reconstruction; (3) scan length changes with a change in field of view; (4) DoseRight algorithm miscalculations leading to incorrect CTDI values; (5) scan length changes during subsequent axial results, (6) surview scan lengths near 135mm or 184mm<p>
RECALLING FIRM/MANUFACTURER
Philips Healthcare, Andover, MA on 9/6/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
423<p>
DISTRIBUTION
Nationwidewide<p>

6/15/2016 Sedecal SA Mobile Diagnost w DR x-ray, CI II
Company: Sedecal USA, Inc.
Date of Enforcement Report 6/15/2016
Class II:<p>
PRODUCT
Sedecal SA Mobile Diagnost w DR x-ray system.
Recall Number Z-1691-2016<p>
REASON
Due to a software defect, the system may sporadically apply the default x ray exposure parameters for an adult (patient type : Normal) even though the patient type " Newborn" was selected and is displayed in the generator control area of the Eleva User Interface..<p>
RECALLING FIRM/MANUFACTURER
Sedecal USA, Inc., Buffalo Grove, IL on 3/23/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
145<p>
DISTRIBUTION
Nationwidewide<p>

6/15/2016 Philips Healthcare DuraDiagnost xray, CI II
Company: Philips Healthcare
Date of Enforcement Report 6/15/2016
Class II:<p>
PRODUCT
Philips Healthcare DuraDiagnost stationary X-ray system.
Recall Number Z-1696-2016<p>
REASON
The detector may signal that it is ready for acquisition when it actually is not, resulting in failure to properly acquire the X-ray image.<p>
RECALLING FIRM/MANUFACTURER
Philips Healthcare, Andover, MA on 11/10/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
5<p>
DISTRIBUTION
Nationwidewide<p>

6/15/2016 Philips Healthcare DigitalDiagnost xray, Cl II
Company: Philips Healthcare
Date of Enforcement Report 6/15/2016
Class II:<p>
PRODUCT
Philips Healthcare DigitalDiagnost stationary X-ray system.
Recall Number Z-1695-2016<p>
REASON
The detector may signal that it is ready for acquisition when it actually is not, resulting in failure to properly acquire the X-ray image.<p>
RECALLING FIRM/MANUFACTURER
Philips Healthcare, Andover, MA on 11/10/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
160<p>
DISTRIBUTION
Nationwidewide<p>

6/15/2016 ORTHO Vitros 6600, Class II
Company: Ortho-Clinical Diagnostics
Date of Enforcement Report 6/15/2016
Class II:<p>
PRODUCT
VITROS 5600 Integrated System, Catalog Number 6802413, Unique Device Identifier No. 10758750002740; and VITROS 5600 Integrated System (refurbished), Catalog Number 6802915, Unique Device Identifier No. 10758750007110; IVD.. Recall Number Z-1914-2016<p>
REASON
Ortho Clinical Diagnostics confirmed a software timing anomaly in which the VITROS 3600 and 5600 Systems may unexpectedly aspirate from or dispense into an unintended sample that may lead to erroneous or contaminated results.<p>
RECALLING FIRM/MANUFACTURER
Ortho-Clinical Diagnostics, Rochester, NY on 4/6/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
VITROS 5600: US: 1161 units, Foreign: 1063 units; VITROS 5600 Refurbished: US: 19 units, Foreign: 38 units <p>
DISTRIBUTION
Nationwide and Internationally.<p>

6/15/2016 ORTHOVitros 3600, Class II
Company: Ortho-Clinical Diagnostics
Date of Enforcement Report 6/15/2016
Class II:<p>
PRODUCT
VITROS 3600 Immunodiagnostic System, Catalog Number 6802783,for use in the in vitro quantitative, semi-quantitative, and qualitative measurement of a variety of analytes of clinical interest, using VITROS Immunodiagnostic Products Reagents. Recall Number Z-1913-2016<p>
REASON
Ortho Clinical Diagnostics confirmed a software timing anomaly in which the VITROS 3600 and 5600 Systems may unexpectedly aspirate from or dispense into an unintended sample that may lead to erroneous or contaminated results.<p>
RECALLING FIRM/MANUFACTURER
Ortho-Clinical Diagnostics, Rochester, NY on 4/6/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE

US: 218 units, Foreign: 587 units <p>
DISTRIBUTION
Nationwide and Internationally.<p>

6/8/2016 Ingenuity Computed Tomography X-ray Cl II
Company: Philips Medical Systems, Inc.
Date of Enforcement Report 6/8/2016
Class II:<p>
PRODUCT
Ingenuity Computed Tomography X-ray Systems, Product Usage: Intended to produce cross-sectional images of the body by computer reconstruction of X-ray transmission data taken at different angles and planes.
Recall Number Z-1875-2016<p>
REASON
The firm became aware of a problem where the system may not map Varian drive after CT user logout/login.<p>
RECALLING FIRM/MANUFACTURER
Philips Medical Systems, Inc., Cleveland, OH on 4/8/2016. Voluntary: Firm Initiated recall is ongoing.
<p>
VOLUME OF PRODUCT IN COMMERCE
215 units<p>
DISTRIBUTION
Nationwide and Internationally<p>

6/8/2016 Ingenuity Core 128 Computed Tomograpy Cl II
Company: Philips Medical Systems, Inc.
Date of Enforcement Report 6/8/2016
Class II:<p>
PRODUCT
Ingenuity Core 128 Computed Tomography X-ray Systems, Product Usage: Intended to produce cross-sectional images of the body by computer reconstruction of X-ray transmission data taken at different angles and planes.
Recall Number Z-1874-2016<p>
REASON
The firm became aware of a problem where the system may not map Varian drive after CT user logout/login.<p>
RECALLING FIRM/MANUFACTURER
Philips Medical Systems, Inc., Cleveland, OH on 4/8/2016. Voluntary: Firm Initiated recall is ongoing.
<p>
VOLUME OF PRODUCT IN COMMERCE
424<p>
DISTRIBUTION
Nationwide and Internationally<p>

6/8/2016 Philips Ingenuity Core Computed Tomography
Cl II
Company: Philips Medical Systems, Inc.
Date of Enforcement Report 6/8/2016
Class II:<p>
PRODUCT
Ingenuity Core Computed Tomograph X-ray Systems, Product Usage: Intended to produce cross-sectional images of the body by computer reconstruction of X-ray transmission data taken at different angles and planes.

Recall Number Z-1873-2016<p>
REASON
The firm became aware of a problem where the system may not map Varian drive after CT user logout/login.<p>
RECALLING FIRM/MANUFACTURER
Philips Medical Systems, Inc., Cleveland, OH on 4/8/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
300<p>
DISTRIBUTION
Nationwide and Internationally<p>

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6/8/2016 Philips Brilliance 64 Computed Tomography
Cl II
Company: Philips Medical Systems, Inc.
Date of Enforcement Report 6/8/2016
Class II:<p>
PRODUCT
Brilliance 64 Computed Tomography X-ray Systems Product Usage: Intended to produce cross-sectional images of the body by computer reconstruction of X-ray transmission data taken at different angles and planes.
Recall Number Z-1872-2016<p>
REASON
The firm became aware of a problem where the system may not map Varian drive after CT user logout/login.<p>
RECALLING FIRM/MANUFACTURER
Philips Medical Systems, Inc., Cleveland, OH on 4/8/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
158 units <p>
DISTRIBUTION
Nationwide and Internationally<p>

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6/1/2016 Siemens Dimension Vista 1500, Cl II
Company: Siemens Healthcare Diagnostics Inc.
Date of Enforcement Report 6/1/2016
Class II:<p>
PRODUCT
Dimension Vista 1500 Intelligent Lab System running on software versions V.3.6.1 SP1 or V.3.6.2, Device listing # D011374, All serial numbers and lots are affected. The Dimension Vista System is an in vitro diagnostic device intended to duplicate manual analytical procedures such as pipetting, mixing, heating, and measuring spectral intensities to determine a variety of analytes in human body fluids. Dimension Vista chemical and immunochemical applications use photometric, turbidimetric, chemiluminescence, nephelometric and integrated ion-selective multisensor technology for clinical use.
Recall NumberZ-1886-2016<p>
REASON
Discrepant patient results on Dimension Vista Intelligent Lab Systems. Siemens Healthcare confirmed a software defect which, in a very specific set of circumstances, results in the Dimension Vista System omitting an aliquot probe rinse between sample aspirations when processing tubes in Sample Racks that are front loaded on the Dimension Vista System.<p>
RECALLING FIRM/MANUFACTURER
Siemens Healthcare Diagnostics Inc., Brookfield, CT on 3/24/2016. Voluntary: Firm Initiated recall is ongoing. <p>

VOLUME OF PRODUCT IN COMMERCE
1300 units<p>
DISTRIBUTION
Nationwide and Puerto Rico <p>

6/1/2016 Siemens Dimension Vista 500, Cl II
Company: Siemens Healthcare Diagnostics Inc.
Date of Enforcement Report 6/1/2016
Class II:<p>
PRODUCT
Dimension Vista 500 Intelligent Lab System running on software versions V.3.6.1 SP1 or V.3.6.2, Device listing # D011374, All serial numbers and lots are affected. The Dimension Vista System is an in vitro diagnostic device intended to duplicate manual analytical procedures such as pipetting, mixing, heating, and measuring spectral intensities to determine a variety of analytes in human body fluids. Dimension Vista chemical and immunochemical applications use photometric, turbidimetric, chemiluminescence, nephelometric and integrated ion-selective multisensor technology for clinical use.
Recall NumberZ-1885-2016<p>
REASON
Discrepant patient results on Dimension Vista Intelligent Lab Systems. Siemens Healthcare confirmed a software defect which, in a very specific set of circumstances, results in the Dimension Vista System omitting an aliquot probe rinse between sample aspirations when processing tubes in Sample Racks that are front loaded on the Dimension Vista System.<p>
RECALLING FIRM/MANUFACTURER
Siemens Healthcare Diagnostics Inc., Brookfield, CT on 3/24/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
1301 units<p>
DISTRIBUTION
Nationwide and Puerto Rico <p>

6/1/2016 elekta iGUIDE System, Cl II
Company: Elekta Inc.
Date of Enforcement Report 6/1/2016
Class II:<p>
PRODUCT
iGUIDE System, for patient positioning, with assistance of a 30 Tracking System in a radiotherapy environment.
Recall NumberZ-1705-2016<p>
REASON
If by mistake the initial pre-treatment imaging was performed BEFORE the HexaPOD was moved to the DRIVE (*START) position, iGUIDE offers the possibility to branch into a specific catch-up workflow, which was implemented to use the initial scan data..<p>
RECALLING FIRM/MANUFACTURER
Elekta Inc., Atlanta, GA on 5/12/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
20<p>
DISTRIBUTION
IL, LA, Austria, Australia, Botswana, Germany, Denmark, France, India, Japan<p>

6/1/2016 Volcano s5, s5i, CORE and CORE Mobile system Cl II
Company:Volcano Corporation
Date of Enforcement Report 6/1/2016
Class II:<p>
PRODUCT
Volcano s5, s5i, CORE and CORE Mobile systems with software version 3.4 and v3.4 software kits. Cardiology: The Volcano Universal (Core /Core Mobile), S5iz Platform Imaging System is used for the qualitative and quantitative evaluation of vascular morphology in the coronary arteries and vessels of the peripheral vasculature.
Recall NumberZ-1813-2016<p>
REASON
Volcano has become aware of an incompatibility issue between Impacted Systems and hospital network scans. In specific circumstances, an impacted System will encounter unexpected data from the hospital network and be forced to reboot.<p>
RECALLING FIRM/MANUFACTURER
Volcano Corporation, Rancho Cordova, CA, on 4/25/2016. Voluntary: Firm Initiated recall is ongoing.
<p>
VOLUME OF PRODUCT IN COMMERCE
5875<p>
DISTRIBUTION
Nationwide and Internationally<p>

6/1/2016 GE Healthcare, Discovery IGS 740, Cl II
Company: GE Medical Systems, LLC
Date of Enforcement Report 6/1/2016
Class II:<p>
PRODUCT
GE Healthcare, Discovery IGS 740. Indicated for use in generating fluoroscopic and rotational images of human anatomy..
Recall NumberZ-1707-2016<p>
REASON
Potential non-recoverable loss of image acquisition. The affected Discovery systems may experience multiple X-Ray abort errors before or during a real-time fluoroscopic Interventional procedure.<p>
RECALLING FIRM/MANUFACTURER
GE Medical Systems, LLC, Waukesha, WI on 4/15/2016. Voluntary: Firm Initiated recall is ongoing.
<p>
VOLUME OF PRODUCT IN COMMERCE
54<p>
DISTRIBUTION
Nationwide and Internationally<p>

6/1/2016 GE Healthcare, Discovery IGS 730 Cl II
Company: GE Medical Systems, LLC
Date of Enforcement Report 6/1/2016
Class II:<p>
PRODUCT
GE Healthcare, Discovery IGS 730. Indicated for use in generating fluoroscopic and rotational images of human anatomy..
Recall NumberZ-1706-2016<p>
REASON
Potential non-recoverable loss of image acquisition. The affected Discovery systems may experience multiple X-Ray abort errors before or during a real-time fluoroscopic Interventional procedure.<p>

RECALLING FIRM/MANUFACTURER
GE Medical Systems, LLC, Waukesha, WI on 4/15/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
54<p>
DISTRIBUTION
Nationwide and Internationally<p>

6/1/2016 cobas EGFR Mutation Test, v2 and cobas cf, Cl II

Company:Roche Molecular Systems, Inc.
Date of Enforcement Report 6/1/2016
Class II:<p>
PRODUCT
cobas¿ EGFR Mutation Test, v2 and cobas¿ cfDNA Sample Preparation Hungarian Translation Instructions for Use
Recall NumberZ-1830-2016<p>
REASON
An error was found within the Hungarian translations of the cobas¿ EGFR Mutation Test v2 Instructions for Use (M/N 07340761001-01HU, Doc Rev. 1.0, Dated 08/2015) and the cobas¿ cfDNA Sample Preparation Kit Instructions for Use (M/N 07573758001-01HU, Doc. Rev. 1.0, Dated 05/2015).<p>
RECALLING FIRM/MANUFACTURER
Roche Molecular Systems, Inc. , Branchburg, NJ on 3/15/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
8 kits<p>
DISTRIBUTION
Hungary<p>

6/1/2016 RayStation Therapy Treatment Planning System Cl II

Company: RAYSEARCH LABORATORIES AB
Date of Enforcement Report 6/1/2016
Class II:<p>
PRODUCT
RayStation Therapy Treatment Planning System Stand-alone Software 3.0, 3.5, 4.0, 4.5 and 4.7., designed for treatment planning and analysis of radiation therapy.
Recall NumberZ-1712-2016<p>
REASON
A software issue with editing tools that use the left mouse button held down, for drawing in and interacting with the patient views and beams eye views. The views can become unsynchronized with the stored data if simultaneously right clicking, pressing Ctrl-S or Ctrl-Z while the left mouse button is held down. This bug does not affect dose computations, which are based on the stored system state.<p>
RECALLING FIRM/MANUFACTURER
RAYSEARCH LABORATORIES AB, Stockholm, Sweden on 2/10/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
1,264 Total units (552 units domestically & 711 units internationally)<p>
DISTRIBUTION
Nationwide and Internationally<p>

5/18/2016 NovaPACS Diagnostic Viewer, Cl II
Company: Novarad Corporation
Date of Enforcement Report 5/18/2016
Class II:<p>
PRODUCT
NovaPACS Diagnostic Viewer versions 8.3.7, 8.4.2, 8.4.3, and 8.4.4. Novarad Corporation
Recall NumberZ-1613-2016<p>
REASON
IThe SUV values that are being calculated in the PET/CT fusion tool are incorrect.<p>
RECALLING FIRM/MANUFACTURER
Novarad Corporation, American fork, UT on 11/16/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
2,386<p>
DISTRIBUTION
Nationwide. 3 Canadian and 33 foreign consignees. No VA/gov/military.<p>

5/18/2016 NeuViz 64 Multi-Slice CT Scanner, Cl II
Company: Neusoft Medical Systems Co., Ltd.
Date of Enforcement Report 5/18/2016
Class II:<p>
PRODUCT
NeuViz 64 Multi-Slice CT Scanner System (consist if two variants: NeuViz 64e, NeuViz 64i)
Recall NumberZ-1650-2016<p>
REASON
It was found by R&D in April, 2014 that there was a defect in NeuViz 64 system software version 1.0.5+P09. The icons of side decubitus didn't meet the patient position description, when the scanner position was set to "Right" in the system setting - scanner options.<p>
RECALLING FIRM/MANUFACTURER
Neusoft Medical Systems Co., Ltd. , Shenyang China on 5/2/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
7 units<p>
DISTRIBUTION
US Distribution - Including Puerto Rico and the states of IL, CT, SC, NE<p>

5/18/2016 Covidien Kangaroo Connect Feeding Pump,Cl II
Company: Medtronic
Date of Enforcement Report 5/18/2016
Class II:<p>
PRODUCT
Covidien Kangaroo Connect Enteral Feeding Pump Item Number: 384400 (US) Intended to provide enteral nutrition to a patient for hospital and acute care settings.. Recall Number Z-1648-2016<p>
REASON
Kangaroo Connect Feeding Pump Occlusion alarms fail to alarm<p>
RECALLING FIRM/MANUFACTURER
Medtronic, North Haven, CT on 4/1/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
223 units<p>
DISTRIBUTION
Worldwide Distribution -- USA, Australia, Canada, France, and Singapore<p>

5/18/2016 Ascom Mobile Monitoring Gateway, Cl II
Company: Acusom US Inc.
Date of Enforcement Report 5/18/2016
Class II:<p>
PRODUCT
Ascom Mobile Monitoring Gateway (versions 4.1.1 and 4.2.0) and Ascom Unite Connect for Nurse Call (version 2.2.0).
Recall Number Z-1638-2016<p>
REASON
Due to a malfunction of software, the secondary module will not automatically take over messaging if the primary module fails after a software upgrade to one of the other affected versions. Messages from GE Carescape/Nurse Call will not forward to handset until primary module is restored.<p>
RECALLING FIRM/MANUFACTURER
Ascom US Inc, Morrisville, NC on 12/10/2015 Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
319<p>
DISTRIBUTION
Nationwide and Internationally<p>

5/11/2016 Syngo Dynamics; Kinetdx Picture Archiving, Cl II
Company: Siemens Medical Solutions USA, Inc.
Date of Enforcement Report 5/11/2016
Class II:<p>
PRODUCT
Syngo Dynamics; Kinetdx Picture Archiving and Communications System
Recall NumberZ-1601-2016<p>
REASON
Siemens has identified changes in default carry forward workflow using VA10B_HF03 version of Syngo Dynamics. If the template design has measurements inside a carry forward-configured report section, this will result in carrying forward the entire section of the report including data from previous studies. This may result in the physician making analysis based on the old measurements.<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Malvern, PA on 4/14/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
84 units<p>
DISTRIBUTION
Nationwide<p>

5/11/2016 Nuvectra, Algovita Spinal Cord Stimulation Cl II
Company: Nuvectra
Date of Enforcement Report 5/11/2016
Class II:<p>
PRODUCT
Nuvectra, Algovita Spinal Cord Stimulation System Clinical Programmer, Model 4500. For use with Algovita Spinal Cord Stimulation Systems. The version of the software in the Clinician Programmer is v1.1.5. The Algovita Spinal Cord Stimulation system consists of a stimulator (EPG or IPG) that is physically and electrically connected to one or more leads inserted into the patient¿¿"s spinal epidural space. The lead delivers electrical stimulation originating at the stimulator with the purpose of blocking pain signals going to the patient¿¿"s brain. The stimulators are rechargeable, and the frequency of recharging is dependent on individual patient¿¿"s use of the system. The Clinician Programmer (CP) is

a hand-held, touch screen device used to create and adjust stimulation parameters that are developed to optimize the therapy for each patient. The CP communicates with the stimulator via the Medical Implant Communication Service (MICS). The CP wirelessly transfers the stimulation parameters to the stimulator. In most clinical settings, the CP can be used by the Health Care Professional to program multiple patient EPGs and IPGs.
Recall Number Z-1600-2016<p>
REASON
If used, the optional Swap feature copies programming parameters from the external pulse generator (EPG) as well as unintended calibration data to the implantable pulse generator (IPG). This may result in the user being unable to recharge the IPG. This safety notice only applies to CPs Model 4500.<p>
RECALLING FIRM/MANUFACTURER
Nuvectra, Blaine, MN, on 4/6/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
17<p>
DISTRIBUTION
Germany<p>

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5/11/2016 Siemens ACUSON SC2000 Ultrasound imaging , Cl II

Company: Siemens Medical Solutions USA, Inc.
Date of Enforcement Report 5/11/2016
Class II:<p>
PRODUCT
ACUSON SC2000 Ultrasound imaging system with software version VB10C and using transesophageal (TEE) transducer Z6Ms, V5Ms or V7M. Model number: 10433816.
Recall NumberZ-1592-2016<p>
REASON
While imaging with a transesophageal (TEE) transducer (Z6Ms, V5Ms, or V7M), user may lose the ability to control the color region of interest, the pulsed wave or continuous wave Doppler gate or cursor, the M-mode cursor, the 2D field of view, or the RES region of interest with the trackball.<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Mountainview, CA on 4/8/2016. Voluntary: Firm Initiated recallis ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
87<p>
DISTRIBUTION
Nationwide and Internationally<p>

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5/11/2016 CARESTREAM Image Suite V4, Cl II

Company: Carestream Health, Inc.
Date of Enforcement Report 5/11/2016
Class II:<p>
PRODUCT
CARESTREAM Image Suite V4; Image Suite V4: DICOM STORE SCP: REF/Catalog # 1056191, DICOM STORE SCP/FOR IMAGE SUITE V4: REF/Catalog # 6566988; Image Suite V4 Bundles: IMAGESUITE STANDALONE PACS: REF/Catalog # 1741289, IMAGESUITE STANDALONE PACS FOR INDIA: REF/Catalog # 1741297; Carestream PRO (Image Suite V4): PRO Medical Wireless GOS System-Desktop: REF/Catalog # 1741891, PRO Wireless System Laptop: REF/Catalog # 1741925, PRO Wireless System - w/o Computer: REF/Catalog # 1741933, PRO Tethered System Desktop: REF/Catalog # 1741941, PRO Tethered System Laptop: REF/Catalog # 1741958, PRO Tether System - w/o Computer: REF/Catalog # 1741966, PRO Fixed System - w/o Computer: REF/Catalog # 1741974, PRO Medical Wireless CsI System-Desktop: REF/Catalog # 1741982, PRO Wireless System Laptop: REF/Catalog # 1742006, PRO Wireless System - w/o Computer: REF/Catalog # 1742014, PRO

Tethered System Desktop: REF/Catalog # 1742022, PRO Tethered System Laptop: REF/Catalog # 1742055, PRO Tether System - w/o Computer: Catalog # 1742063; PRO Fixed System - w/o Computer: REF/Catalog # 1742089 -- Made in U.S.A. by: Carestream Health, Inc., 150 Verona Street, Rochester, NY 14608 --- CLASSIFICATION NAME: System, Image Processing, Radiological The Carestream Image Suite System is an image management system whose intended use is to receive, process, review, display, print and archive images and data from CR and DR modalities. This excludes mammography applications in the United States.
Recall Number Z-1594-2016<p>
REASON
Carestream Health received a complaint related to CARESTREAM Image Suite 4 from a foreign hospital stating that the annotation on the overlay is displayed as "L (Left)", when it should be "R(Right)".<p>
RECALLING FIRM/MANUFACTURER
Carestream Health, Inc.,Rochester, NY on 4/15/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
US: 37 units, Foreign: 269 units<p>
DISTRIBUTION
Nationwide and Internationally<p>

5/11/2016 CARESTREAM Image Suite V3, Cl II
Company: Carestream Health, Inc.
Date of Enforcement Report 5/11/2016
Class II:<p>
PRODUCT
CARESTREAM Image Suite V3: MINI-PACS/F IMG ST/CLASSIC: REF/Catalog # 1036490; MINI-PACS/F IMG ST/POC&VITA: REF/Catalog # 1036508; MINI-PACS/F IMG ST/CLASSIC/INDIA: REF/Catalog # 1036417; MINI-PACS/F IMG ST/ POC&VITA /INDIA: REF/Catalog # 1036425 -- Made in USA by: Carestream Health, Inc. 150 Verona Street, Rochester, NY 14608 --- CLASSIFICATION NAME: System, Image Processing, Radiological The Carestream Image Suite System is an image management system whose intended use is to receive, process, review, display, print and archive images and data from CR and DR modalities. This excludes mammography applications in the United States.
Recall Number Z-1593-2016<p>
REASON
Carestream Health received a complaint related to CARESTREAM Image Suite 4 from a foreign hospital stating that the annotation on the overlay is displayed as "L (Left)", when it should be "R(Right)".<p>
RECALLING FIRM/MANUFACTURER
Carestream Health, Inc.,Rochester, NY on 4/15/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
US: 50 units; Foreign: 2499 units<p>
DISTRIBUTION
Nationwide and Internationally<p>

5/11/2016 Medtronic CareLink" Monitor, Cl II
Company: Medtronic Inc., Cardiac Rhythm and Heart Failure .
Date of Enforcement Report 5/11/2016
Class II:<p>
PRODUCT
Medtronic CareLink" Monitor (2490C) and Medtronic CareLink Express" Monitor (2020B) Product Usage: The 2490C CareLink Home Monitors and 2020B CareLink Express Monitors are remote monitoring systems that interrogate implanted devices and transmit the data to Medtronic s CareLink Network for viewing by the physician. The data is transmitted either through an analog telephone line, a

cellular connection or an internet connection.
Recall NumberZ-1605-2016<p>
REASON
A recent firmware update developed by Medtronic for the 2490C CareLink Monitors and 2020B CareLink Express Monitors included incorrect data on the country analog modem dial-up configuration table used to dial into the CareLink Network. This incorrect data resulted in the removal of the 0 prefix necessary for select countries as well as an incorrect alignment of phone numbers for other select countries.<p>
RECALLING FIRM/MANUFACTURER
Medtronic Inc., Cardiac Rhythm and Heart Failure, Mounds View, MN on 3/31/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
5038<p>
DISTRIBUTION
Internationally <p>

5/11/2016 Alaris PC unit, Model 8015: Cl II
Company: CareFusion 303 Inc..
Date of Enforcement Report 5/11/2016
Class II:<p>
PRODUCT
Alaris PC unit, Model 8015 The Alaris PC unit is the central programming, monitoring and power supply component for the Alaris System..
Recall NumberZ-1606-2016<p>
REASON
The Alaris PC units model 8015 may display a system error code 133.6080 due to failure with the super capacitor (C245) at power up on the Alaris PC unit logic boards.<p>
RECALLING FIRM/MANUFACTURER
CareFusion 303, Inc., San Diego, CA on 3/24/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
23,397 units <p>
DISTRIBUTION
Nationwide and Internationally <p>

5/11/2016 Ab Sciex Analyst MD, Cl II
Company: Ab Sciex
Date of Enforcement Report 5/11/2016
Class II:<p>
PRODUCT
Analyst MD Version 1.6.1 and 1.6.2 Software used with the following instruments: API 3200MD" LC/MS/MS System, Instrument Part Number: 5024501; 3200MD QTRAP¿ LC/MS/MS System, Instrument Part Number: 5024500; Triple Quad" 4500MD LC/MS/MS System, Instrument Part Number: 5031257; QTRAP¿ 4500MD LC/MS/MS System, Instrument Part Number: 5031231 3200MD series and 4500MD series are mass spectrometers intended to identify inorganic or organic compounds (e.g., lead, mercury, and drugs) in human specimens by ionizing the compound under investigation and separating the resulting ions by means of an electrical and magnetic field according to their mass. It is intended for in vitro diagnostic purposes. For in vitro diagnostic us. Recall Number Z-1586-2016<p>
REASON
Wrong quantitative results may be displayed in a report from the device, which may potentially lead to an incorrect patient diagnosis.<p>
RECALLING FIRM/MANUFACTURER
Ab Sciex, Framingham, MA on 2/24/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE

279<p>
DISTRIBUTION
Nationwide and Internationally<p>

**5/4/2016 Siemens ACUSON X700 Ultrasound System,
Cl II**
Company: Siemens Medical Solutions USA, Inc.
Date of Enforcement Report 5/4/2016
Class II:<p>
PRODUCT
ACUSON X700 Ultrasound System with software version 1.0.04. Model numbers: 10658844 ACUSON X700 Ultrasound System 10658846 - ACUSON X700 Ultrasound System (Russia) 10658845 - ACUSON X700 Ultrasound System (Korea) Radiology: The Siemens ACUSON X700 ultrasound imaging system is intended for the following applications: Cardiac (Adult, Pediatric), Transesphageal (Cardiac), Intracardiac, Cerebrovascular, Peripheral Vessel, Abdominal, Renal, Fetal, Abdominal, Intra-operative, Pediatric, Small Organ, Neonatal Cepahalic, Adult Cephalic, Orthopedics, Musculo-skeletal Conventional, Musculo-skeletal Superficial, Pelvic, Obstetrical, Gynecological and Urological applications. The system also provides for the measurement of anatomical structures and for analysis packages that provide information that is used for clinical diagnosis purposes.
Recall NumberZ-1572-2016<p>
REASON
Due to a communication error between the software and V5Ms transducers rotation function, ACUSON X700 ultrasound systems at software versions 1.1.04, display an IMG_15 error message causes the system to lock up, which requires a reboot to recover system operation.<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Mountainview, CA on 9/5/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
4<p>
DISTRIBUTION
Germany, U.A.E., Hungary and Brazil.<p>

5/4/2016 Siemens SOMATOM Force Cl II
Company: Siemens Medical Solutions USA, Inc.
Date of Enforcement Report 5/4/2016
Class II:<p>
PRODUCT
SOMATOM Force, Computed Tomography x-ray system intended to generate and process cross-sectional images of patients by computer reconstruction of x-ray transmission.
Recall NumberZ-1558-2016<p>
REASON
The Neonate Head protocol with the pediatric kernel Hp38 could result in artefacts and possibly lead to a misdiagnosis (i.e. either non-existing blood or liquid is mimicked in the images or actual existing blood or liquid is not depicted as expected). There is also a risk of a potential misdiagnosis in using this protocol for surgery planning.<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Malvern, PA on 4/1/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
37 CT systems<p>
DISTRIBUTION
Nationwide<p>

5/4/2016 NeuViz 16 Multi-Slice CT Scanner System, Cl II
Company: Philips and Neusoft Medical Systems Co., Ltd.
Date of Enforcement Report 5/4/2016
Class II:<p>
PRODUCT
NeuViz 16 Multi-Slice CT Scanner System PN: 989605858501 a whole body computed tomography X-ray system featuring a continuously rotating X-ray tube and detector array with multi-slice capability up to 16 slices simultaneously. Recall Number Z-1573-2016<p>
REASON
The following issues are found in NeuViz 16 systems with software version 1.1.4.21425 and version 1.1.4.21426: 1) During the filming operation on MX 16-slice console software, the clipboard used for copying and pasting images is not cleared between patients. If the operator fails to copy the current patient's images before pasting, a previous patient's image may be present in the clipboard.<p>
RECALLING FIRM/MANUFACTURER
Philips and Neusoft Medical Systems Co., Ltd., Shenyang , China on 3/24/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
73<p>
DISTRIBUTION
NC, OH, NE, SC, TX, LA, PR, MO, FL, CT<p>

5/4/2016 EndoWrist Staplers, Cl II
Company: Intuitive Surgical, Inc.
Date of Enforcement Report 5/4/2016
Class II:<p>
PRODUCT
EndoWrist Stapler 45 and Stapler 30 instruments used on the da Vinci Xi systems (IS4000) with p5 software. General Surgery: The Intuitive Surgical Endoscope Instrument Control System (da Vinci Surgical System, Model IS4000) is intended to assist in the accurate control of Intuitive Surgical Endoscopic Instruments including rigid endoscopes, blunt and sharp endoscopic dissectors, scissors, scalpels, forceps/pick-ups, needle holders, endoscopic retractors, electrocautery and accessories for endoscopic manipulation of tissue, including grasping, cutting, blunt and sharp dissection, approximations, ligation, electrocautery, suturing and delivery and placement of microware and cryogenic ablation probes and accessories, during urologic surgical procedures, general laparoscopic surgical procedures, gynecologic laparoscopic surgical procedures, general thoracoscopic surgical procedures and thoracoscopically-assisted cardiotomy procedures. Recall Number Z-1568-2016<p>
REASON
Potential for unexpected motion of the Xi Stapler jaws on the da Vinci Xi System with p5 software relating to a combination of the p5 software and the surgeon quickly transitioning from the clamp to the fire pedal during use..<p>
RECALLING FIRM/MANUFACTURER
Intuitive Surgical, Inc., Sunnyvale,CA on 3/25/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
68<p>
DISTRIBUTION
Nationwide<p>

5/4/2016 Mindray Panorama Patient Monitoring Network
Cl II
Company: Mindray DS USA, Inc. dba Mindray North America
Date of Enforcement Report 5/4/2016
Class II:<p>
PRODUCT

Panorama Patient Monitoring Network Mindray DS USA The Panorama Patient Monitoring can view recal time, store, print, graph and trend patient clinical and demographic data. The Panoram Patient Monitoring Network can sent independent alarm limits for data send by the bedside monitor.. Recall Number Z-1575-2016<p>
REASON
Panorama Central Station including the work station View Station, View Station and the eGateway will revert to the year 2000 when Daylight Savings Time (DST) occurs on March 13, 2016, or under various conditions.<p>
RECALLING FIRM/MANUFACTURER
Mindray DS USA, Inc. dba Mindray North America, Mahwah, NJ on 3/9/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
1447 units US, 45 units OUS<p>
DISTRIBUTION
Nationwide<p>

5/4/2016 Roche Hand-Held Scanner USB IT3800, Cl II
Company: Roche Molecular Systems
Date of Enforcement Report 5/4/2016
Class II:<p>
PRODUCT
Hand-Held Scanner USB IT3800 For sample identification and tracking when used with various systems. Recall Number Z-1578-2016<p>
REASON
The hand-held barcode scanner model IT3800 used with the COBAS AmpliPrep instrument mis-identified a sample barcode ID.<p>
RECALLING FIRM/MANUFACTURER
Roche Molecular Systems, Branchburg, NJ on 3/3/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
6,939 pieces<p>
DISTRIBUTION
Nationwide<p>

5/4/2016 Philips Visicu eCareCoordinator, Cl II
Company: Philips Visicu
Date of Enforcement Report 5/4/2016
Class II:<p>
PRODUCT
IeCareCoordinator allows the customer to schedule patient tasks (i.e., take weight measurement, take blood pressure). For medical use by professional medical staff. Recall Number Z-1557-2016<p>
REASON
The adherence check generates a software error. Two issues occur as a result of the software error: 1) No adherence flag is generated for that day; 2) No task is generated for the date 14 days later. An error message is generated and forwarded to operations. Subsequently, for days in which no task was generated, patient will not get a reminder on the tablet to take a measurement. .<p>
RECALLING FIRM/MANUFACTURER
Philips Visicu, Baltimore, MD on 3/10/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
9 <p>
DISTRIBUTION
FL, MA, MI, MS, PA, and KS.<p>

5/4/2016 ABX PENTRA 400 and 400C, Cl II
Company: Horiba Instruments Inc
Date of Enforcement Report 5/4/2016
Class II:<p>
PRODUCT
Pentra C400 (version 1.1.2 or lower) The ABX PENTRA 400 and 400C are discrete photometric bench top chemistry analyzers for clinical use. The device is intended to duplicate manual analytical procedures by performing various steps such as pipetting, mixing, heating and measuring color intensity. The device is intended for use in conjunction with certain materials to measure a variety of analytes. Recall Number Z-1554-2016<p>
REASON
Horiba Instruments, Inc. is recalling ABX Pentra 400(version 5.0.8 or lower) and Pentra C400 (version 1.1.2 or lower) because clinical chemistry analyzer malfunctions when the following certain alarms appear on the system.<p>
RECALLING FIRM/MANUFACTURER
Horiba Instruments Inc., Irvine, CA on 2/19/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
201<p>
DISTRIBUTION
Nationwide<p>

4/27/2016 IntelliSpace Portal DX/HX/EX AutoSPECT, Cl II
Company: Philips Medical Systems, Inc.
Date of Enforcement Report 4/27/2016
Class II:<p>
PRODUCT
IntelliSpace Portal DX/HX/EX AutoSPECT Pro Software Application, Philips Medical Systems, Cleveland, OH. Provides software applications used to process, analyze, and display medical images/data Recall Number Z-1506-2016<p>
REASON
The AutoSPECT Pro application was only designed to reconstruct cardiac SPECT data obtained with detectors positioned at 90¿ or 180¿ relative to one another. However, certain gamma cameras allow for other relative detector angles. Data acquired at these other angles will not be correctly reconstructed by AutoSPECT Pro and the results will likely be erroneous..<p>
RECALLING FIRM/MANUFACTURER
Philips Medical Systems, Inc., Cleveland, OH on 3/4/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
33 Units <p>
DISTRIBUTION
Nationwide and Internationally<p>

4/27/2016 PhilipsSpecial Nuclear medicine image displayCl II
Company: Philips Medical Systems, Inc.
Date of Enforcement Report 4/27/2016
Class II:<p>
PRODUCT
Extended Brilliance Workspace NM Special Nuclear medicine image display and processing application suite. AutoSPECT Pro Software Application. Philips Medical Systems, Cleveland, OH. Provides software applications used to process, analyze, and display medical images/data. Recall Number Z-1505-2016<p>

REASON
The AutoSPECT Pro application was only designed to reconstruct cardiac SPECT data obtained with detectors positioned at 90¿ or 180¿ relative to one another. However, certain gamma cameras allow for other relative detector angles. Data acquired at these other angles will not be correctly reconstructed by AutoSPECT Pro and the results will likely be erroneous..<p>
RECALLING FIRM/MANUFACTURER
Philips Medical Systems, Inc., Cleveland, OH on 3/42016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
37 Units <p>
DISTRIBUTION
Nationwide and Internationally<p>

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4/27/2016 Philips Extended Brilliance Workspace NM, Cl II

Company: Philips Medical Systems, Inc.
Date of Enforcement Report 4/27/2016
Class II:<p>
PRODUCT
Extended Brilliance Workspace NM Nuclear medicine image display and processing application suite. AutoSPECT Pro Software Application. Philips Medical Systems, Cleveland, OH. Provides software applications used to process, analyze, and display medical images/data. Recall Number Z-1504-2016 <p>
REASON
The AutoSPECT Pro application was only designed to reconstruct cardiac SPECT data obtained with detectors positioned at 90¿ or 180¿ relative to one another. However, certain gamma cameras allow for other relative detector angles. Data acquired at these other angles will not be correctly reconstructed by AutoSPECT Pro and the results will likely be erroneous..<p>
RECALLING FIRM/MANUFACTURER
Philips Medical Systems, Inc., Cleveland, OH on 3/4/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
126 Units <p>
DISTRIBUTION
Nationwide and Internationally<p>

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4/27/2016 Siemens SOMATOM, Cl II

Company: Siemens Medical Solutions USA, Inc.
Date of Enforcement Report 4/27/2016
Class II:<p>
PRODUCT
Siemens SOMATOM Definition, SOMATOM Definition AS, SOMATOM Definition Flash and SOMATOM Definition Edge; : Intended to produce cross-sectional images of the body.
Recall NumberZ-1521-2016<p>
REASON
Siemens initiated a Customer Advisory Notice on 03/07/2016 to inform customers about actions for bug-fixing the following systems: SOMATOM Definition AS, SOMATOM Definition Flash and SOMATOM Definition Edge, which could possibly cause scan aborts, res cans of patients with additional dose, delayed diagnosis and as worst case scenarios, could possibly cause the need of additional contrast medium..<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Malvern, PA on 3/2/2016. Voluntary: Firm Initiated recall is ongoing. <p>

VOLUME OF PRODUCT IN COMMERCE
1096<p>
DISTRIBUTION
Nationwide<p>

4/27/2016 Siemens SOMATOM Definition Flash;, Cl II
Company: Siemens Medical Solutions USA, Inc.
Date of Enforcement Report 4/27/2016
Class II:<p>
PRODUCT
Siemens SOMATOM Definition Flash: Intended to produce cross-sectional images of the body.
Recall NumberZ-1520-2016<p>
REASON
Siemens initiated a Customer Advisory Notice on 03/07/2016 to inform customers about actions for bug-fixing the following systems: SOMATOM Definition AS, SOMATOM Definition Flash and SOMATOM Definition Edge, which could possibly cause scan aborts, res cans of patients with additional dose, delayed diagnosis and as worst case scenarios, could possibly cause the need of additional contrast medium..<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Malvern, PA on 3/2/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
1096<p>
DISTRIBUTION
Nationwide<p>

4/27/2016 Siemens SOMATOM Definition AS;, Cl II
Company: Siemens Medical Solutions USA, Inc.
Date of Enforcement Report 4/27/2016
Class II:<p>
PRODUCT
Siemens SOMATOM Definition: Intended to produce cross-sectional images of the body.
Recall NumberZ-1519-2016<p>
REASON
Siemens initiated a Customer Advisory Notice on 03/07/2016 to inform customers about actions for bug-fixing the following systems: SOMATOM Definition AS, SOMATOM Definition Flash and SOMATOM Definition Edge, which could possibly cause scan aborts, res cans of patients with additional dose, delayed diagnosis and as worst case scenarios, could possibly cause the need of additional contrast medium..<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Malvern, PA on 3/2/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
1096<p>
DISTRIBUTION
Nationwide<p>

4/27/2016 Siemens SOMATOM Definition, Cl II
Company: Siemens Medical Solutions USA, Inc.
Date of Enforcement Report 4/27/2016
Class II:<p>
PRODUCT
Siemens SOMATOM Definition: Intended to produce cross-sectional images of the body.

Recall NumberZ-1518-2016<p>
REASON
Siemens initiated a Customer Advisory Notice on 03/07/2016 to inform customers about actions for bug-fixing the following systems: SOMATOM Definition AS, SOMATOM Definition Flash and SOMATOM Definition Edge, which could possibly cause scan aborts, res cans of patients with additional dose, delayed diagnosis and as worst case scenarios, could possibly cause the need of additional contrast medium..<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Malvern, PA on 3/2/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
1096<p>
DISTRIBUTION
Nationwide<p>

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4/27/2016 Siemens ADVIA 560 Hematology Systems, Cl II

Company: Siemens Healthcare Diagnostics, Inc.
Date of Enforcement Report 4/13/2016
Class II:<p>
PRODUCT
ADVIA 560 Hematology Systems, Siemens Material Number (SMN) 11170842, IVD The ADVIA 560 Hematology System is a fully-automated, high-quality hematology system for in vitro diagnostic use in clinical laboratories
Recall NumberZ-1500-2016<p>
REASON
TSoftware anomaly; Siemens identified that software version 1.4.2133 on the ADVIA 560 Hematology System does not trigger the following flags: The G or L morphology flags for immature granulocytes (IG) and atypical lymphocytes (ATYP), respectively. The results from patient samples which have immature granulocytes or atypical lymphocytes will not generate the flags when they should..<p>
RECALLING FIRM/MANUFACTURER
Siemens Healthcare Diagnostics, Inc., Tarrytown, NY on 3/10/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
US: 8 systems; Foreign: 64 systems<p>
DISTRIBUTION
Nationwide and Internationally<p>

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4/20/2016 Philips Ingenuity CT, Cl II

Company: Philips Medical Systems, Inc.
Date of Enforcement Report 4/202016
Class II:<p>
PRODUCT
Ingenuity CT Computed Tomography X-ray Systems, Intended to produce cross-sectional images of the body by computer reconstruction of X-ray transmission data taken at different angles and planes Recall Number Z-1356-2016<p>
REASON
The firm was notified of a software error in which the system may not automatically send all image/data series to remote devices..<p>
RECALLING FIRM/MANUFACTURER
Philips Medical Systems, Inc., Cleveland, OH on 2/5/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE

82 Units <p>
DISTRIBUTION
Nationwide and Internationally<p>

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4/20/2016 Philips Ingenuity Core 128, CI II
Company: Philips Medical Systems, Inc.
Date of Enforcement Report 4/202016
Class II:<p>
PRODUCT
Ingenuity Core 128 Computed Tomography X-ray Systems, Intended to produce cross-sectional images of the body by computer reconstruction of X-ray transmission data taken at different angles and planes
Recall Number Z-1355-2016<p>
REASON
The firm was notified of a software error in which the system may not automatically send all image/data series to remote devices..<p>
RECALLING FIRM/MANUFACTURER
Philips Medical Systems, Inc., Cleveland, OH on 2/5/2016. Voluntary: Firm Initiated recall is ongoing.
<p>
VOLUME OF PRODUCT IN COMMERCE
174<p>
DISTRIBUTION
Nationwide and Internationally<p>

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4/20/2016 Philips Ingenuity Core, CI II
Company: Philips Medical Systems, Inc.
Date of Enforcement Report 4/202016
Class II:<p>
PRODUCT
Ingenuity Core Computed Tomography X-ray Systems, Intended to produce cross-sectional images of the body by computer reconstruction of X-ray transmission data taken at different angles and planes
Recall Number Z-1354-2016<p>
REASON
The firm was notified of a software error in which the system may not automatically send all image/data series to remote devices..<p>
RECALLING FIRM/MANUFACTURER
Philips Medical Systems, Inc., Cleveland, OH on 2/5/2016. Voluntary: Firm Initiated recall is ongoing.
<p>
VOLUME OF PRODUCT IN COMMERCE
88<p>
DISTRIBUTION
Nationwide and Internationally<p>

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4/20/2016 Philips Brilliance iCT SP CI II
Company: Philips Medical Systems, Inc.
Date of Enforcement Report 4/202016
Class II:<p>
PRODUCT
Brilliance iCT:SP Computed Tomography X-ray Systems, Intended to produce cross-sectional images of the body by computer reconstruction of X-ray transmission data taken at different angles and planes
Recall Number Z-1353-2016<p>
REASON
The firm was notified of a software error in which the system may not automatically send all image/data series to remote devices..<p>

RECALLING FIRM/MANUFACTURER
Philips Medical Systems, Inc., Cleveland, OH on 2/5/2016. Voluntary: Firm Initiated recall is ongoing.
<p>
VOLUME OF PRODUCT IN COMMERCE
49 units<<p>
DISTRIBUTION
Nationwide and Internationally<p>

4/20/2016 Philips Brilliance iCT, Cl II
Company: Philips Medical Systems, Inc.
Date of Enforcement Report 4/202016
Class II:<p>
PRODUCT
Brilliance iCT:Computed Tomography X-ray Systems, Intended to produce cross-sectional images of the body by computer reconstruction of X-ray transmission data taken at different angles and planes Recall Number Z-1352-2016<p>
REASON
The firm was notified of a software error in which the system may not automatically send all image/data series to remote devices..<p>
RECALLING FIRM/MANUFACTURER
Philips Medical Systems, Inc., Cleveland, OH on 2/5/2016. Voluntary: Firm Initiated recall is ongoing.
<p>
VOLUME OF PRODUCT IN COMMERCE
324 devices<<p>
DISTRIBUTION
Nationwide and Internationally<p>

4/20/2016 Philips Brilliance 64, Cl II
Company: Philips Medical Systems, Inc.
Date of Enforcement Report 4/202016
Class II:<p>
PRODUCT
Brilliance 64:Computed Tomography X-ray Systems, Intended to produce cross-sectional images of the body by computer reconstruction of X-ray transmission data taken at different angles and planes Recall Number Z-1351-2016<p>
REASON
The firm was notified of a software error in which the system may not automatically send all image/data series to remote devices..<p>
RECALLING FIRM/MANUFACTURER
Philips Medical Systems, Inc., Cleveland, OH on 2/5/2016. Voluntary: Firm Initiated recall is ongoing.
<p>
VOLUME OF PRODUCT IN COMMERCE
196 devices<<p>
DISTRIBUTION
Nationwide and Internationally<p>

4/20/2016 Stryker SurgiCounter" scanner, Cl II
Company: Stryker Instruments Div. of Stryker Corporation
Date of Enforcement Report 4/20/2016
Class II:<p>
PRODUCT
SurgiCounter" scanner Product Usage: The SurgiCount Safety Sponge System is indicated for use in counting and recording the number of thermally labeled surgical sponges, laparotomy sponges, and

towels used during surgical procedures.
Recall NumberZ-1379-2016<p>
REASON
The affected SurgiCounter scanner does not correctly interact with the SC360 software. When docked pre/postoperatively, there is a potential for the affected SurgiCounter scanner to display an error message (code=2). Additionally, the SurgiCounter scanner software version number is not appropriately displayed in the SC360 application during installation.<p>
RECALLING FIRM/MANUFACTURER
Stryker Instruments Div. of Stryker Corporation, Portage, MI on 3/1/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
286<p>
DISTRIBUTION
Nationwide <p>

4/20/2016 Alcon VERION Reference Unit, Cl II
Company: Alcon Research, Ltd.
Date of Enforcement Report 4/20/2016
Class II:<p>
PRODUCT
VERION Reference Unit (Vision Planner) Product Usage: The VERION Image Guided system is an advanced surgical planning, imaging and guidance technology designed to provide greater accuracy and efficiency during cataract surgery. It allows eye surgeons to capture a high-resolution, diagnostic reference image of the patient s eye pre-operatively, quickly determine an optimized surgical plan that enables surgeons to see all inclusions and alignment in real-time.
Recall NumberZ-1394-2016<p>
REASON
Alcon is conducting a voluntary medical device correction of all VERION Reference Units (Vision Planner) that are shared with the Alcon LenSx Laser System after receiving reports concerning the inclusion of unplanned arcuates on printed, saved (.pdf) or exported surgical plans..<p>
RECALLING FIRM/MANUFACTURER
Alcon Research, Ltd., Fort Worth, TX on 3/12016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
97 units<p>
DISTRIBUTION
Nationwide and Internationally<p>

4/13/2016 Siemens Picture Archiving and Communication, Cl II
Company: Siemens Medical Solutions USA, Inc.
Date of Enforcement Report 4/13/2016
Class II:<p>
PRODUCT
A Picture Archiving and Communication System (PACS) intended to display, process, read, report, communicate, distribute, store and archive digital medical images, including digital mammography images.
Recall NumberZ-1349-2016<p>
REASON
To inform users about the possible incorrect values for Distance Measurements when using certain modalities in combination with syngo Imaging.<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Malvern, PA on 1/18/2016. Voluntary: Firm Initiated recall is ongoing. <p>

VOLUME OF PRODUCT IN COMMERCE
49 systems<p>
DISTRIBUTION
Nationwide<p>

4/11/2016 G4 Platinum & G5 Mobile Glusoce Monitoring
Class I
Company: Dexcoml Inc.
Date of Enforcement Report 4/11/2016
Class I:<p>
PRODUCT
Name of device: Dexcom G4 PLATINUM Receiver, Dexcom G4 PLATINUM (Pediatric) Receive, Dexcom G4 PLATINUM (Professional) Receiver, Dexcom G4 PLATINUM Receiver with Share, Dexcom G4 PLATINUM (Pediatric) Receiver with Share, Dexcom G5 Mobile Receiver <p>
REASON
Dexcom Inc. is recalling the Continuous Glucose Monitoring Systems because the audible alarm may not activate in the receiver piece when low or high glucose levels (hypoglycemia or hyperglycemia) are detected.
Relying on this product for notification of low or high blood sugar could result in serious adverse consequences, including death as the auditory alarm may not sound and users might not be notified of low or high blood sugar.<p>
RECALLING FIRM/MANUFACTURER
Dräger Medical Inc., 2/23/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
263,520 units nationwide<p>
DISTRIBUTION
Nationwide <p>

4/6/2016 Siemens Artis One, Cl II
Company: Siemens Medical Solutions USA, Inc.
Date of Enforcement Report 4/6/2016
Class II:<p>
PRODUCT
Artis One, Interventional, Fluoroscopic, x-ray system Artis one is an angiography system developed for diagnostic imaging and interventional procedures including, but not limited to, pediatric and obese patients. Procedures that can be performed with the Artis One include cardiac angiography, neuro-angiography, general angiography, rotational angiography, multipurpose angiography and whole body radiographic/fluoroscopic procedures as well as procedures next to the table for patient extremities.
Recall NumberZ-1282-2016<p>
REASON
After importing segmentation results of the left atrium created on the Artis One system, the possibility exists for the results to be mirrored to an electro-anatomical 3D mapping system, CARTO from Biosense Webster Inc.<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Malvern, PA on 3/11/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
1 angiography system<p>
DISTRIBUTION
Michigan<p>

4/6/2016 Siemens Cios Alpha, mobile X-ray system Cl II
Company: Siemens Medical Solutions USA, Inc.
Date of Enforcement Report 4/6/2016
Class II:<p>
PRODUCT
Cios Alpha, mobile X-ray system.
Recall NumberZ-1278-2016<p>
REASON
Software issues on Cios Alpha mobile C-Arm system<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Malvern, PA on 2/19/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
89 systems<p>
DISTRIBUTION
Nationwide Distribution<p>

4/6/2016 MRIdian ViewRay Radiation Therapy System, Cl II
Company: Viewray Incorporated .
Date of Enforcement Report 4/6/2016
Class II:<p>
PRODUCT
MRIdian ViewRay Radiation Therapy System, ViewRay Treatment Planning and Delivery System (also known as the MRIdian¿ System) is indicated for stereotactic radiosurgery and precision radiotherapy for lesions, tumors, and conditions anywhere in the body when radiation treatment is indicated..
Recall NumberZ-1309-2016<p>
REASON
When editing the isocenter or the couch position of the plan while in the treatment workflow (in the Points screen) and re-optimizing, the software will not prompt the user to shift the couch to the new isocenter. As a result there is the potential to deliver dose to the initial isocenter rather than the new location.<p>
RECALLING FIRM/MANUFACTURER
Viewray Incorporated, Oakwood Village, OH on 3/7/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
5 units<p>
DISTRIBUTION
Nationwide and Internationally.<p>

4/6/2016 MicroScan LabPro, Cl II
Company: Beckman Coulter Inc.
Date of Enforcement Report 4/6/2016
Class II:<p>
PRODUCT
MicroScan LabPro Information Manager System, Software Versions 1.0 to 4.41 Catalog No. 10638819, 10638820, 10638823, 10638824, 10638825,10638826, 10714149,10714159, 10805072, 10805073, 10975000, 10975001, 6000-0008, 6000-0026. Japan: 10638819 LabPro v4.11 Software Update Kit 10638820 LabPro v4.11 System Software 10805072 LabPro MBT Non-Connect Systems v4.30 10805073 LabPro MBT Connect Systems v4.30 Canada: 6000-0008 LabPro v4.41 Panel Update-06 Kit 6000-0026 LabPro Connect v4.41 Panel Update-06 Kit 10638823 LabPro v4.11 Software Update Kit 10638825 LabPro v4.11 System Software 10638824 LabPro v4.11 Software Update Kit Europe: 10638824 LabPro v4.11 Software Update Kit 10638826 LabPro v4.11 System Software USA: 10714149, LabPro v4.11 Software Update Kit 10714150 LabPro v4.11 System Software 10975000

ASM LabPro-MBT v4.40 10975001 ASM LabPro-MBT v4.40 for Connect 6000-0008 LabPro v4.41 Panel Update-06 Kit 6000-0026 LabPro Connect v4.41 Panel Update-06 Kit ROW: 6000-0008 LabPro v4.41 Panel Update-06 Kit 10638823 LabPro v4.11 Software Update Kit 10638825 LabPro v4.11 System Software 10638824 LabPro v4.11 Software Update Kit 10638826 LabPro v4.11 System Software Product Usage: LabPro Data Management System is a Microsoft Windows based software program and is intended to manage both microbial identification (ID) and antimicrobial agent susceptibility testing (AST) data generated from MicroScan instruments or manually entered microbiology test results, for use by trained laboratory personnel. LabPro AlertEx is a functional subset of the LabPro Data Management System that analyzes MicroScan ID and AST data, or other predefined parameters, against a series of established rules/alerts and notifies the user of unusual and/or critical conditions, which may warrant further analysis or actions. Recall NumberZ-1269-2016<p>
REASON
Beckman Coulter is recalling the MicroScan LabPro Information Manager System because the software incorrectly allows the operator to manually edit the carbohydrate substrates when manually reading dried overnight gram negative panels with an ID Hold status.<p>
RECALLING FIRM/MANUFACTURER
Beckman Coulter Inc. , Brea, CAon 2/11/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
2,702 units total (1,032 units in US)<p>
DISTRIBUTION
Nationwide and Internationally<p>

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3/30/2016 Siemens syngo X Workplace, Cl II
Company: Siemens Medical Solutions USA, Inc.
Date of Enforcement Report 3/30/2016
Class II:<p>
PRODUCT
syngo X Workplace is a medical workstation for real-time viewing, image manipulation, 3D-visualization, communication, and storage of medical images and data on exchange media. It is used for diagnostic image viewing and post processing during interventional proceduress.
Recall NumberZ-1232-2016<p>
REASON
After importing, the segmentation results appear mirrored at the CARTO system and can't be used for the ablation procedure.<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Malvern, PA on 2/24/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
6<p>
DISTRIBUTION
Nationwide Distribution to IL, NY, MT, and MN.<p>

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3/30/2016 Alaris PC Unit, Infusion Pump: Cl II
Company: CareFusion 303 Inc..
Date of Enforcement Report 3/30/2016
Class II:<p>
PRODUCT
Alaris PC Unit, Infusion Pump Model 8000, Part No. TC10005092.
Recall NumberZ-1239-2016<p>
REASON
CareFusion is recalling the Alaris PC unit because a component on the PC unit power supply may cause a "System Error" or "Missing Battery" error code (120.4630).<p>
RECALLING FIRM/MANUFACTURER

CareFusion 303, Inc., San Diego, CA on 2/24/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
170 units<p>
DISTRIBUTION
Nationwide <p>

3/30/2016 Roche cobas p 512 pre-analytical system, Cl II

Company: Roche Diagnostics Operations, Inc. .
Date of Enforcement Report 3/30/2016
Class II:<p>
PRODUCT
cobas p 512 pre-analytical system Pre-analytical sample handling that includes de-capping, aliquoting and sorting of samples for analysis.
Recall NumberZ-1233-2016<p>
REASON
Due to a false triggering or detection of the lifting gripper READY signal, sample tubes are not correctly placed back in the Rack Tube Transport (RTT) after the decapping process. Therefore, open sample tubes can be dropped in the cobas p 512, spilling the sample material.<p>
RECALLING FIRM/MANUFACTURER
Roche Diagnostics Operations, Inc., Indianapolis, IN on 3/23/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
33<p>
DISTRIBUTION
US Distribution including Puerto Rico and to the states of :TX, OH, TN, AZ, WA, MI and GA <p>

3/30/2016 Toshiba DRAD-3000E FPD Wireless System, Cl II

Company: Toshiba American Medical Systems
Date of Enforcement Report 3/30/2016
Class II:<p>
PRODUCT
Toshiba DRAD-3000E FPD Wireless System Product Usage The DRAD-3000¿ is intended for use with the ceiling-suspended tube support, high voltage generator, and bucky stand or bucky table incorporating a fixed or detachable (portable) flat panel detector for radiography of the head, chest, abdomen, spine, neck, and limbs. This system is used for image acquisition, image display and transmission/output or images to external devices.
Recall NumberZ-1175-2016<p>
REASON
When a user performed radiography using the wireless FPD, a message window appeared on the monitor stating that imaging transmission was not completed with no radiographic image. It also indicated to select the "OK" button to re-acquire the image data or to select the¿'Cancel" button to cancel the re-acquisition. As instructed the user selected "OK" and the same message window appeared.<p>
RECALLING FIRM/MANUFACTURER
Toshiba American Medical Systems Inc, Tustin, CA on 3/21/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
28<p>
DISTRIBUTION
US Distribution <p>

3/30/2016 MHI-TM2000 Linear Accelerator System: Cl II
Company: MITSUBISHI HEAVY INDUSTRIES, LTD.,.
Date of Enforcement Report 3/30/2016
Class II:<p>
PRODUCT
MHI-TM2000 Linear Accelerator System (Software Version 3.0.0 and after) Intended for radiation therapy of lesions, tumors. conditions anywhere in the body where radiation therapy is indicated.
Recall NumberZ-1244-2016<p>
REASON
Due to Operator Console software anomaly, a change in treatment completion status of the last patient of the day may be altered from "Completed (or Discontinued)" to "Untreated" under specific conditions.<p>
RECALLING FIRM/MANUFACTURER
MITSUBISHI HEAVY INDUSTRIES, LTD., HIROSHIMA on 3/24/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
25 devices<p>
DISTRIBUTION
Distributed in the states of Florida, New York, Ohio & Texas, and the countries of France, Germany, Japan, Italy, Korea, & Belgium. <p>

3/23/2016 Siemens Syngo Dynamics, Cl II
Company: Siemens Medical Solutions USA, Inc.
Date of Enforcement Report 3/23/2016
Class II:<p>
PRODUCT
Siemens Syngo Dynamics-a Picture Archiving and Communication System (PACS) Model Numbers: 10091805, 10091807, 10091637, 10091673 intended for acceptance, transfer, display, storage, archive acceptance, transfer, display, storage, archive and manipulation of digital medical images, including quantification and report generation. Not intended for reading of mammography images.
Recall NumberZ-1183-2016<p>
REASON
Siemens' conducting a recall due to a potential issue when using the measurement package of the VA10 version of syngo Dynamics.<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Malvern, PA on 3/17/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
228 units<p>
DISTRIBUTION
US Distribution <p>

3/23/2016 McKesson Horizon Medical Imaging , Cl II
Company: Mckesson Medical Immaging
Date of Enforcement Report 3/23/2016
Class II:<p>
PRODUCT
McKesson Horizon Medical Imaging (HMI) products versions 4.6.1 to including 11.9 and McKesson Radiology (MR) products 12.0 and 12.1.1. Recall Number Z-1182-2016 <p>
REASON
McKesson has identified a design deficiency where under rare circumstances, imported images/studies may re-use a non-unique image directory. This issue may cause incorrect images to be displayed for a patient.<p>

RECALLING FIRM/MANUFACTURER
Mckesson Medical Immaging, Richmond, British Columbia on 3/17/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
631 devices<p>
DISTRIBUTION
Nationwide and Internationally<p>

3/23/2016 Spirit TM Select bed, Cl II
Company: CHG Hospital Beds Inc.
Date of Enforcement Report 3/23/2016
Class II:<p>
PRODUCT
The Spirit TM Select bed is a Med-Surg bed intended to support and transport low to moderate acuity patients in the medical and/or surgical area of the hospital. The Spirit Select bed is also intended for use as a general purpose, variable height hospital bed for general care, post-operative and general medicine wards. The product has a 500 pound safe working load and includes the standard features of an integrated scale and bed exit system, enhanced footboard staff controls for scale and bed exit system and a low bed height of 10.75 inches.
Recall Number Z-1176-2016<p>
REASON
It was identified that in some situations the bed exit alarm may not function as intended. The software code for the bed exit system has the potential to auto-reset erroneously. In some situations, the software code does not allow enough time for the weight value to fall to zero once the patient egresses from the bed, in which case, the bed has the potential to reset the bed exit alarm .<p>
RECALLING FIRM/MANUFACTURER
CHG Hospital Beds Inc., London, Canada on 3/15/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
1892<p>
DISTRIBUTION
Nationwide and Canada<p>

3/23/2016 Accu-Chek Inform II Base Unit, Cl II
Company:Roche Diagnostics Operations, Inc.
Date of Enforcement Report 3/23/2016
Class II:<p>
PRODUCT
Inform II Blood Glucose Monitoring System Accu-Chek inform II Blood Glucose Monitoring System is intended for testing outside the body (in vitro diagnostic use) and is intended for multiple-patient use in professional healthcare settings. This system should only be use with single-use, auto-disabling lancing devices. Recall Number Z-1172-2016<p>
REASON
Accu-Chek Inform II Base Unit might produce physical transmission errors in the form of data loss in the communication between the meter and the Data Management Systems (DMS). The issue can lead to the data loss or in the worst case to an erroneous assignment of the patient data (patient mismatch). The issue will only occur at sites using POTCT1-A communication via USB.<p>
RECALLING FIRM/MANUFACTURER
Roche Diagnostics Operations, Inc. Indianapolis, IN on 3/14/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
US 5,604 devices, OUS 91,925<p>
DISTRIBUTION
Nationwide <p>

3/23/2016 Puritan Bennett 980 Ventilator System Cl II
Company: Covidien LP (formerly Nellcor Puritan Bennett Inc.)
Date of Enforcement Report 3/23/2016
Class II:<p>
PRODUCT
Puritan Bennett 980 Ventilator System, PB980 Ventilator (980xxxxxxxx). Intended to provide continuous ventilation for pediatric and adult patients who require either invasive ventilation or non-invasive ventilation.. Recall Number Puritan Bennett 980 Ventilator System, PB980 Ventilator (980xxxxxxxx). Intended to provide continuous ventilation for pediatric and adult patients who require either invasive ventilation or non-invasive ventilation. Recall Number: Z-1181-2016 <p>
REASON
Graphical user interface (GUI) unresponsive to touch and Loss of primary ventilation under certain circumstances. Covidien Respiratory and Monitoring Solutions, now a part of Medtronic, issued a field corrective action notice for two issues on all models of Puritan Bennett 980 (PB980) ventilator.<p>
RECALLING FIRM/MANUFACTURER
Covidien LP (formerly Nellcor Puritan Bennett Inc.) Boulder, CO on 3/16/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
1,864 units<p>
DISTRIBUTION
Nationwide and Internationally<p>

3/16/2016 Spacelab Healthcare Xhibit Central Station, Cl II
Company: Spacelab Healthcare, Inc.
Date of Enforcement Report 3/16/2016
Class II:<p>
PRODUCT
Spacelabs Healthcare Xhibit Central Station, Model 96102 is used to provide clinicians with central monitoring of patient data for those patients connected to networked Spacelabs Healthcare patient monitors and telemetry transmitters. Recall Number Z-1092-2016<p>
REASON
The firm has received one report of values for patient height and weight being switched when input at the Xhibit Central Station, Model 96102, causing a bedside monitor Body Surface Area (BSA) calculation to be in error.<p>
RECALLING FIRM/MANUFACTURER
Spacelab Healthcare, Inc., Snoqualmie, WA on 3/10/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
1075<p>
DISTRIBUTION
Nationwide and Internationally<p>

3/16/2016 Philips Trilogy, Cl II
Company: Philips Respironics.
Date of Enforcement Report 3/46/2016
Class II:<p>
PRODUCT
Trilogy 100, Trilogy 200, Trilogy O2, Trilogy 202, Trilogy EC, Garbin, Garbin Plus Trilogy 100, Trilogy 200, Garbin, Garbin plus provides continuous or intermittent ventilatory support for the care of individuals who require mechanical ventilation.. Recall Number Z-1065-2016<p>
REASON

Software issue.<p>
RECALLING FIRM/MANUFACTURER
Philips Respironics, Monroeville, PA on 3/7/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
104,508 units<p>
DISTRIBUTION
Worldwide<p>

3/16/2016 Ortho VITROS 5,1 FS Chemistry System, Cl II
Company: Ortho-Clinical Diagnostics
Date of Enforcement Report 3/16/2016
Class II:<p>
PRODUCT
VITROS VITROS 5,1 FS Chemistry System, Catalog Number 6801375, Unique Device Identifier Number 10758750001132; and VITROS 5,1 FS Chemistry System (Refurbished), Catalog Number 6801890, Unique Device Identifier Number 10758750001644; IVD. The VITROS 5.1, FS Chemistry System performs discrete clinical tests on serum, urine, and cerebral spinal fluid specimens. Methodologies include colorimetric (CM), potentiometric (PM), rate (RT), and immuno-rate (IR) tests using multi-layered VITROS Slides. Recall Number Z-1075-2016<p>
REASON
ncreased U90-382 or 6LU condition codes generated by VITROS 250, 350, 5,1 FS, 4600 and 5600 Chemistry Systems when using Calibrator Kit 9, Lot 954. A trend of complaints regarding customers actions following U90-382 or 6LU condition codes was noted (See RES 72289 - VITROS Calibrator Kit 9, lot 954 recall).<p>
RECALLING FIRM/MANUFACTURER
Ortho-Clinical Diagnostics, Rochester, NY on 3/8/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
US = 994; Foreign = 1405<p>
DISTRIBUTION
Nationwide and Internationally.<p>

3/16/2016 Ortho VITROS 5600 Chemistry Systems, Cl II
Company: Ortho-Clinical Diagnostics
Date of Enforcement Report 3/16/2016
Class II:<p>
PRODUCT
VITROS 5600 Chemistry System, Catalog Number 6802413, Unique Device Identifier Number 10758750002740; IVD. Product Usage: For use in the in vitro quantitative, semi-quantitative, and qualitative measurement of a variety of analytes of clinical interest, using VITROS Chemistry Products Slides, VITROS Chemistry Products MicroTip Reagents and VITROS Immunodiagnostic Products Reagents.. Recall Number Z-1074-2016<p>
REASON
ncreased U90-382 or 6LU condition codes generated by VITROS 250, 350, 5,1 FS, 4600 and 5600 Chemistry Systems when using Calibrator Kit 9, Lot 954. A trend of complaints regarding customers actions following U90-382 or 6LU condition codes was noted (See RES 72289 - VITROS Calibrator Kit 9, lot 954 recall).<p>
RECALLING FIRM/MANUFACTURER
Ortho-Clinical Diagnostics, Rochester, NY on 3/8/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
US = 1009; Foreign = 1003<p>
DISTRIBUTION
Nationwide and Internationally.<p>

3/16/2016 Ortho VITROS 4600 Chemistry System, Cl II
Company: Ortho-Clinical Diagnostics
Date of Enforcement Report 3/16/2016
Class II:<p>
PRODUCT
VITROS 4600 Chemistry System, Catalog Number 6802445, Unique Device Identifier Number 10758750012343; IVD. Product Usage: For in vitro diagnostic use. The VITROS 4600 Chemistry System is intended for use in the in vitro quantitative measurement of a variety of analytes of clinical interest, using both VITROS Chemistry Products Slides (colorimetric endpoint, rate, ion-selective electrode, and immunorate methods) and VITROS Chemistry Products MicroTip liquid reagents (spectrophotometric and spectrophotometric immunoassay methods.) Recall Number Z-1073-2016 <p>
REASON
ncreased U90-382 or 6LU condition codes generated by VITROS 250, 350, 5,1 FS, 4600 and 5600 Chemistry Systems when using Calibrator Kit 9, Lot 954. A trend of complaints regarding customers actions following U90-382 or 6LU condition codes was noted (See RES 72289 - VITROS Calibrator Kit 9, lot 954 recall).<p>
RECALLING FIRM/MANUFACTURER
Ortho-Clinical Diagnostics, Rochester, NY on 3/8/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
US = 163; Foreign = 286<p>
DISTRIBUTION
Nationwide and Internationally.<p>

3/16/2016 Ortho VITROS 350 Chemistry Systems, Cl II
Company: Ortho-Clinical Diagnostics
Date of Enforcement Report 3/16/2016
Class II:<p>
PRODUCT
VITROS 350 Chemistry System, Catalog Number 6802153, Unique Device Identifier Number 10758750002054; IVD. Product Usage: For in vitro diagnostic use. Product Usage: For in vitro diagnostic use. The VITROS 350 Chemistry System performs discrete clinical tests on serum, urine, and cerebral spinal fluid specimens. Methodologies include colorimetric (CM), potentiometric (PM), rate (RT), and immuno-rate (IR) tests using multi-layered VITROS Slides.. Recall Number Z-1072-2016 <p>
REASON
ncreased U90-382 or 6LU condition codes generated by VITROS 250, 350, 5,1 FS, 4600 and 5600 Chemistry Systems when using Calibrator Kit 9, Lot 954. A trend of complaints regarding customers actions following U90-382 or 6LU condition codes was noted (See RES 72289 - VITROS Calibrator Kit 9, lot 954 recall).<p>
RECALLING FIRM/MANUFACTURER
Ortho-Clinical Diagnostics, Rochester, NY on 3/8/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
US = 885; Foreign: 3221<p>
DISTRIBUTION
Nationwide and Internationally.<p>

3/16/2016 Ortho VITROS 250 Chemistry Systems, Cl II
Company: Ortho-Clinical Diagnostics
Date of Enforcement Report 3/16/2016
Class II:<p>
PRODUCT
VITROS 250 Chemistry Systems, Catalog 8132086, Unique Device Identifier No. 10758750004409,

and VITROS 250 Refurbished, Catalog 6801759, Unique Device Identifier No. 10758750001330; IVD. Product Usage: For in vitro diagnostic use. The VITROS 250 Chemistry System performs discrete clinical tests on serum, urine, and cerebral spinal fluid specimens. Methodologies include colorimetric (CM), potentiometric (PM), rate (RT), and immuno-rate (IR) tests using multi-layered VITROS Slides. Recall Number Z-1071-2016<p>
REASON
ncreased U90-382 or 6LU condition codes generated by VITROS 250, 350, 5,1 FS, 4600 and 5600 Chemistry Systems when using Calibrator Kit 9, Lot 954. A trend of complaints regarding customers actions following U90-382 or 6LU condition codes was noted (See RES 72289 - VITROS Calibrator Kit 9, lot 954 recall).<p>
RECALLING FIRM/MANUFACTURER
Ortho-Clinical Diagnostics, Rochester, NY on 3/8/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
US: 802; Foreign: 2472<p>
DISTRIBUTION
Nationwide and Internationally.<p>

3/16/2016 Philips Allura Xper, Cl II
Company: Philips Medical Systems, Inc.
Date of Enforcement Report 3/16/2016
Class II:<p>
PRODUCT
Philips X-Ray Systems, Allura Xper with R8.2.16 Product Usage: The Allura Xper FD1O and Allura Xper FD1O/10 is intended for use in cardiovascular and vascular X-ray imaging applications, including diagnostic, interventional procedures (such as PTCA, stent placement and atherectomies), pacemaker implantations and Electrophysiology (EP). The Allura Xper FD2O, Allura Xper FD2O/10 and Allura Xper FD2O/20 is intended for: Dedicated vascular and neurovascular imaging applications, including diagnostic and interventional procedures. Recall Number Z-1066-2016<p>
REASON
Upon initiating Fluoroscopy the user may encounter a user message Fluoro failed.<p>
RECALLING FIRM/MANUFACTURER
Philips Medical Systems, Inc., Andover, MA on 3/7/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
196 devices<p>
DISTRIBUTION
Nationwide and Canada<p>

3/2/2016 software for Syngo Dynamics, Cl II
Company: Siemens Medical Solutions USA, Inc.
Date of Enforcement Report 3/2/2016
Class II:<p>
PRODUCT
software for Syngo Dynamics a Picture Archiving and Communication System (PACS) intended for acceptance, transfer, display, storage, archive and manipulation of digital medical images, including quantification and report generation. Syngo Dynamics is not intended to be used for reading of mammography images. Recall Number Z-0826-2016 <p>
REASON
Siemens is releasing a software update that addresses an issue of mixing data from multiple patients. In rare situations, echo trend graphs may mix data from multiple patients.<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Malvern, PA on 2/19/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE

151<p>
DISTRIBUTION
Nationwide <p>

3/2/2016 Delta XRF Analyzer , Cl II
Company: Regulatory Insight, Inc.
Date of Enforcement Report 3/2/2016
Class II:<p>
PRODUCT
Olympus Scientific Solutions Americas Corporation (OSSA) Delta XRF Analyzer . This is a Analytical X-ray system. Recall NumberZ-0803-2016<p>
REASON
The Firm has discovered a Software bug.<p>
RECALLING FIRM/MANUFACTURER
Olympus Scientific Solutions Americas, Waltham,MA on 2/19/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
5000 US<p>
DISTRIBUTION
Nationwide <p>

3/2/2016 Philips IntelliVue Measurement Module X1, Cl II
Company: Philips Medical Systems, Inc.
Date of Enforcement Report 3/2/2016
Class II:<p>
PRODUCT
Philips IntelliVue Measurement Module X1 Model: M3001A. Recall Number Z-0853-2016<p>
REASON
The ST elevation alarm on the Patient Monitor or standalone X2 Measurement Module will not sound when indicated for all chest leads derived using Hexad 12-Lead ECG Monitoring in the Host Monitor.<p>
RECALLING FIRM/MANUFACTURER
Philips Medical Systems, Inc., Andover, MA on 2/23/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
13300<p>
DISTRIBUTION
Worldwide<p>

3/2/2016 Siemens Syngo Plaza , Cl II
Company: Siemens Medical Solutions USA, Inc.
Date of Enforcement Report 3/2/2016
Class II:<p>
PRODUCT
Syngo Plaza Picture archiving and communication system. Software only. PACS intended to display, process, read, report, communicate, distribute, store and archive digital medical images. Stores and archives within DICOM structured reports. Integrates hospital/radiology information systems.. Recall Number Z-0862-2016 <p>
REASON
Siemens is releasing an updated software version to address several software issues including RGB images will show "?" since calculation of HU is not possible; save as option enabled; changes in access for loading studies; breast region is now properly fitted to segment boundary when clicking fit breast to

screen..<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Malvern, PA on 2/23/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
68<p>
DISTRIBUTION
Nationwide <p>

3/2/2016 Philips Healthcare PIIC Classic Upgrade, Cl II
Company: Philips Medical Systems, Inc.
Date of Enforcement Report 3/2/2016
Class II:<p>
PRODUCT
Philips Healthcare PIIC Classic Upgrade, 866117 Physiological, Patient Monitor (With Arrhythmia Detection or Alarm). Recall Number Z-0857-2016<p>
REASON
Reconstructed ECG leads viewed or printed at the Information Center iX may misrepresent the ECG waveform in specific leads..<p>
RECALLING FIRM/MANUFACTURER
Philips Medical Systems, Inc., Andover, MA on 2/23/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
5569<p>
DISTRIBUTION
Worldwide<p>

3/2/2016 Philips IntelliVue Info Center iX, Cl II
Company: Philips Medical Systems, Inc.
Date of Enforcement Report 3/2/2016
Class II:<p>
PRODUCT
Philips Healthcare IntelliVue Info Center iX, A.0 866023 Recall Number Z-0856-2016<p>
REASON
Reconstructed ECG leads viewed or printed at the Information Center iX may misrepresent the ECG waveform in specific leads.<p>
RECALLING FIRM/MANUFACTURER
Philips Medical Systems, Inc., Andover, MA on 2/23/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
5671<p>
DISTRIBUTION
Worldwide<p>

3/2/2016 GE Precision MPi , Cl II
Company: Regulatory Insight, Inc.
Date of Enforcement Report 3/2/2016
Class II:<p>
PRODUCT
GE Precision MPi is an all-digital multipurpose tilt-C x-ray system, intended for a multitude of diagnostic procedures, including radiology, fluoroscopy, interventional procedures, vascular and non-vascular procedures, and specialized applications including angiographic studies. Recall Number Z-0753-2016<p>

REASON
It was discovered that the Remote Touch Panel (RTP) of the GE Precision MPi X-ray system may not always boot up as intended and needs to be updated to properly accomplish its intended purpose.<p>
RECALLING FIRM/MANUFACTURER
Regulatory Insight, Inc., Littleton, CO 2/24/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
43<p>
DISTRIBUTION
Nationwide <p>

2/24/2016 Eclipse Treatment Planning System, Cl II
Company: Varian Medical Systems, Inc.
Date of Enforcement Report 2/24/2016
Class II:<p>
PRODUCT
Eclipse Treatment Planning System versions 11, 13.0, 13.5 and 13.6; Model number: H48; Product Usage: The Eclipse Treatment Planning System (Eclipse TPS) is used to plan radiotherapy treatments for patients with malignant or benign diseases. Eclipse TPS is used to plan external beam irradiation with photon, electron and proton beams, as well as for internal irradiation (brachytherapy) treatments. Recall NumberZ-0805-2016<p>
REASON
When using PBC 11.0.31 to calculate the dose for a conventional arc field with more than 100 segments for Eclipse versions 11.0, 13.0, 13.5 or 13.6, the displayed dose does not correspond to the calculated Monitor Units (MU). Potential for unintended radiation exposure.<p>
RECALLING FIRM/MANUFACTURER
Varian Medical Systems, Inc.,Palo Alto CA on 1/11/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
9499<p>
DISTRIBUTION
Nationwide and Internationally<p>

2/24/2016 EVOLIS Microplate System, Cl II
Company: Bio-Rad Laboratories, Inc.
Date of Enforcement Report 2/24/2016
Class II:<p>
PRODUCT
EVOLIS Microplate System, Catalog # 89601. Part number 89788 for the EVOLIS Operator's Manual. In vitro diagnostic Product Usage: EVOLIS Microplate System is a 4 plate fully integrated microplate processing system designed for use with multiple EIA assays. Recall NumberZ-0807-2016<p>
REASON
The error "Washer Reagent Clean Fluid" level low alarmed, which prompted the customer to open the system drawer. When the system drawer was opened the customer noted the plate transport was still running and as a consequence the plate was pushed off the plate transporter.<p>
RECALLING FIRM/MANUFACTURER
Bio-Rad Laboratories, Inc., Redmond, WA on 12/22/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
278 units<p>
DISTRIBUTION
US Nationwide and Puerto Rico<p>

2/24/2016 Jadak Barcode Scanner, OTS/SOUP problem, Cl II
Company: CareFusion 303, Inc.
Date of Enforcement Report 2/24/2016
Class II:<p>
PRODUCT
An accessory for the Pyxis Anesthesia ES system and Pyxis Anesthesia system 4000 stations. The Jadak Barcode Scanner is used to scan medication labels during refill of the Pyxis Anesthesia ES system and Pyxis Anesthesia system 4000 stations and dispensing medication for patients. Recall NumberZ-0814-2016<p>
REASON
Customers reported issues when scanning medications with the scanners. When a user scans a medication using the affected barcode scanner, information on a different medication could be communicated to the Pyxis product.
<p>
RECALLING FIRM/MANUFACTURER
CareFusion 303, Inc., San Diego CA on 1/15/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
9,345 units<p>
DISTRIBUTION
US Nationwide and the countries of Saudi Arabia, Bahrain, Australia, United Arab Emirates, Qatar, Mexico, Guam and the Bahamas.<p>

2/17/2016 Toshiba INFX-8000V Bi-Plane X-Ray, Cl II
Company: Toshiba American Medical Systems Inc.
Date of Enforcement Report 2/17/2016
Class II:<p>
PRODUCT
INFX-8000V Bi-Plane X-Ray Interventional System X-ray systems
Recall NumberZ-0752-2016<p>
REASON
When a fontal DA (Digital Angiography) acquisition was done, scattered x-ray came into the dose meter on the lateral side. As a result, the dose meter sent a minus value to the software. Consequently, the software defined the data as an "abnormal value" and it stopped displaying dose data and the dose data was lost. The following message was displayed, "Dose meter abnormal, Dose info disabled".<p>
RECALLING FIRM/MANUFACTURER
Toshiba American Medical Systems Inc., Tustin, CA on 8/4/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
4<p>
DISTRIBUTION
US Nationwide Distribution to OH and NY<p>

2/17/2016 Merge Healthcare RadSuite, Cl II
Company: Merge Healthcare Inc.
Date of Enforcement Report 2/10/2016
Class II:<p>
PRODUCT
RadSuite, a picture archive and communications system. Model Numbers Versions 5.30.0, 5.30.1, 5.30.2, 5.30.2 SB0344, 5.30.3, 5.30.4, 5.30.4 HF0418E, 5.30.5, 5.30.5 HF0404E, 5.30.5 HF0413E, 5.30.5 HF390E, 5.30.5 SB0368, 5.30.6, 5.30.6 HF0405E, 5.30.6 HF0406E, 5.30.7, 5.30.7 HF0429E, 5.30.7 HF0441E, 5.30.7 HF0446E, 5.30.7 HF0470E, 5.30.7 HF0473E, 5.30.8, 5.30.8 HF0477E, 5.30.8 HF0490E, 5.30.8 HF0495 SB0508E, 5.30.8 HF0495E, 5.30.8 HF0495E SB504E, 5.30.8 HF0550, 5.30.8

SB0485E, 5.30.8 SB0486E, 5.30.X SB0381E, 5.35.1, 5.35.1 HF0487E, 5.35.1 HF0489E, 5.35.2, 5.35.3, 5.35.4, 5.35.4 HF0513, 5.35.4 HF0518, 5.35.4 HF0528, 5.35.4 HF0531, 5.35.4 HF0535, 5.35.4 HF0546, 5.35.4 HF0555, 5.35.4 HF0555.1, 5.35.4 HF0555.2, 5.35.4 HF0555.3, 5.35.4 HF0560, 5.35.4 Powerscribe Validation, 5.35.5, 5.35.5 From CCS, 5.35.5.1, 8.30.0, 8.30.1, 8.30.3, 8.30.3.1, 8.30.4, 8.30.5, 8.30.6, 8.30.6.1, 8.30.6.2, 8.30.6.3, 8.30.7, 8.30.7.1, 8.30.7.2, 8.30.7.3, 8.30.7.3-Hopkins, 8.30.7.4, 8.30.7.5, 8.30.7.5.b, 8.30.7.6, 8.30.7.7, 8.30.7.8. Recall NumberZ-0794-2016<p>
REASON
Potential incorrect Standardized Uptake Values (SUV) measurements in RadSuite.e that is calculating improperly in some cases. This can result in an incorrect dose calculation.<p>
RECALLING FIRM/MANUFACTURER
Merge Healthcare Inc., Hartland, WI on 12/17/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
164<p>
DISTRIBUTION
Nationwide <p>

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2/11/2016 Dräger Medical Emergency Ventilators, Class I

Company: Drager Medical Inc.
Date of Enforcement Report 2/11/2016
Class I:<p>
PRODUCT
Dräger Medical Inc. Recalls Emergency Transport Ventilators Due to a System Error that may lead to a Halt in Ventilation Therapy. The Dräger Oxylog Emergency Transport Ventilators provide constant breathing support for adults and children. These ventilators are used in hospitals or during patient transport. <p>
REASON
Dräger is recalling the Oxylog Emergency Transport Ventilators because an electrical issue may cause the device to stop working if the control knobs (adjustment potentiometers) are not regularly used.
If the device operator does not intervene, the patient may not receive enough oxygen and could suffer serious adverse health consequences, including injury or death..<p>
RECALLING FIRM/MANUFACTURER
Dräger Medical Inc., 12/22/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
1117<p>
DISTRIBUTION
Nationwide <p>

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2/10/2016 Philips DS/US Proton Feature, Cl II

Company: Philips Medical Systems
Date of Enforcement Report 2/10/2016
Class II:<p>
PRODUCT
DS/US Proton Feature with Pinnacle3 Software Version 10.0.0 and 14.0.0 Radiation Therapy Planning System Model #459800200621
Recall NumberZ-0745-2016<p>
REASON
In DS/US proton planning, there is a correction factor used internally to the dose engine that is calculating improperly in some cases. This can result in an incorrect dose calculation.<p>
RECALLING FIRM/MANUFACTURER
Philips Medical Systems, Andover, MA on 1/8/2016. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
3<p>

DISTRIBUTION
US: Nationwide Distribution in the states of FL, OH, and MO.<p>

2/10/2016 Radiometer AQURE System, Cl II
Company: Radiometer America Inc
Date of Enforcement Report 2/10/2016
Class II:<p>
PRODUCT
AQURE System; Model Number: 933-599. The AQURE System manages blood gas and immunoassay analyzers.
Recall NumberZ-0748-2016<p>
REASON
The AQURE System has a design error regarding sample type in which sample type may be specified for some results and left blank for other results. The fact that the sample type field is left blank in some cases could lead to misinterpretation of results..<p>
RECALLING FIRM/MANUFACTURER
Radiometer America Inc, Brea, CA on 12/29/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
375<p>
DISTRIBUTION
Nationwide and Internationally<p>

2/10/2016 Mindray Panorama Patient Monitoring Network, Cl II
Company: Mindray DS USA, Inc. dba Mindray North America
Date of Enforcement Report 2/10/2016
Class II:<p>
PRODUCT
Panorama Patient Monitoring Network. Software Kit 0020-00-0205-19A, View Station Software Kit 0020-00-0206-16A, Work Station Software Kit 0020-00-0207-16A, Software Kit Upgrade TECH-00-910. The Panaroma Patient Monitoring Network is intended for use in a fixed location in the healthcare facility setting as a central viewing station. It is not intended to be directly connected to patient at any time or installed in a patient's vicinity.
Recall NumberZ-0701-2016<p>
REASON
An issue with the Panorama Central Station may cause the system to spontaneously restart. This may occur after about 49 days of continuous operation. On restart, monitoring will be lost for about 2.5 minutes. Settings and configurations are maintained..<p>
RECALLING FIRM/MANUFACTURER
Mindray DS USA, Inc. dba Mindray North America, Mahwah, NJ on 12/15/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
63 products<p>
DISTRIBUTION
Nationwide <p>

2/10/2016 Philips INTEGRIS BV3000 MONO, Cl II
Company: Philips Electronics North America Corporation
Date of Enforcement Report 2/10/2016
Class II:<p>
PRODUCT
INTEGRIS BV3000 MONO; Model Number: 72241 The Philips INTEGRIS 3000 I 5000 system is intended for interventional and diagnostic vascular and neurovascular procedures. The Philips

INTEGRIS Allura 9 Biplane system is intended for diagnostic cardiovascular, vascular and interventional procedures. The Philips INTEGRIS Allura 12 & 15 system is intended for peripheral, abdominal, cerebral diagnostic and interventional angiography, neuro applications, cardiac applications and non-vascular interventions
Recall NumberZ-0730-2016<p>
REASON
The use of Allura Xper, Allura Clarity, Allura CV, Allura Centron and UNIQ systems regarding live images and still images can lead to still images being interpreted as live Images.<p>
RECALLING FIRM/MANUFACTURER
Philips Electronics North America Corporation, Andover, MA on 11/3/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
13297 in total<p>
DISTRIBUTION
Nationwide and Internationally<p>

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2/10/2016 Philips INTEGRIS CV, Cl II
Company: Philips Electronics North America Corporation
Date of Enforcement Report 2/10/2016
Class II:<p>
PRODUCT
INTEGRIS CV; Model Number: 722030 The Philips INTEGRIS 3000 I 5000 system is intended for interventional and diagnostic vascular and neurovascular procedures. The Philips INTEGRIS Allura 9 Biplane system is intended for diagnostic cardiovascular, vascular and interventional procedures. The Philips INTEGRIS Allura 12 & 15 system is intended for peripheral, abdominal, cerebral diagnostic and interventional angiography, neuro applications, cardiac applications and non-vascular interventions
Recall NumberZ-0729-2016<p>
REASON
The use of Allura Xper, Allura Clarity, Allura CV, Allura Centron and UNIQ systems regarding live images and still images can lead to still images being interpreted as live Images.<p>
RECALLING FIRM/MANUFACTURER
Philips Electronics North America Corporation, Andover, MA on 11/3/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
13297 in total<p>
DISTRIBUTION
Nationwide and Internationally<p>

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2/10/2016 Philips INTEGRIS Allura 15-12 (biplane), Cl II
Company: Philips Electronics North America Corporation
Date of Enforcement Report 2/10/2016
Class II:<p>
PRODUCT
INTEGRIS Allura 15-12 (biplane); Product Code: 722044 The Philips INTEGRIS 3000 I 5000 system is intended for interventional and diagnostic vascular and neurovascular procedures. The Philips INTEGRIS Allura 9 Biplane system is intended for diagnostic cardiovascular, vascular and interventional procedures. The Philips INTEGRIS Allura 12 & 15 system is intended for peripheral, abdominal, cerebral diagnostic and interventional angiography, neuro applications, cardiac applications and non-vascular interventions
Recall NumberZ-0728-2016<p>
REASON
The use of Allura Xper, Allura Clarity, Allura CV, Allura Centron and UNIQ systems regarding live images and still images can lead to still images being interpreted as live Images.<p>

RECALLING FIRM/MANUFACTURER
Philips Electronics North America Corporation, Andover, MA on 11/3/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
13297 in total<p>
DISTRIBUTION
Nationwide and Internationally<p>

2/10/2016 Philips INTEGRIS Allura 15-12 (mono), Cl II
Company: Philips Electronics North America Corporation
Date of Enforcement Report 2/10/2016
Class II:<p>
PRODUCT
INTEGRIS Allura 15-12 (mono); Model Number: 722043 The Philips INTEGRIS 3000 I 5000 system is intended for interventional and diagnostic vascular and neurovascular procedures. The Philips INTEGRIS Allura 9 Biplane system is intended for diagnostic cardiovascular, vascular and interventional procedures. The Philips INTEGRIS Allura 12 & 15 system is intended for peripheral, abdominal, cerebral diagnostic and interventional angiography, neuro applications, cardiac applications and non-vascular interventions
Recall NumberZ-0727-2016<p>
REASON
The use of Allura Xper, Allura Clarity, Allura CV, Allura Centron and UNIQ systems regarding live images and still images can lead to still images being interpreted as live Images.<p>
RECALLING FIRM/MANUFACTURER
Philips Electronics North America Corporation, Andover, MA on 11/3/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
13297 in total<p>
DISTRIBUTION
Nationwide and Internationally<p>

2/10/2016 Philips INTEGRIS Allura 9 (biplane), Cl II
Company: Philips Electronics North America Corporation
Date of Enforcement Report 2/10/2016
Class II:<p>
PRODUCT
INTEGRIS Allura 9 (biplane); Model Number: 722021 The Philips INTEGRIS 3000 I 5000 system is intended for interventional and diagnostic vascular and neurovascular procedures. The Philips INTEGRIS Allura 9 Biplane system is intended for diagnostic cardiovascular, vascular and interventional procedures. The Philips INTEGRIS Allura 12 & 15 system is intended for peripheral, abdominal, cerebral diagnostic and interventional angiography, neuro applications, cardiac applications and non-vascular interventions
Recall NumberZ-0726-2016<p>
REASON
The use of Allura Xper, Allura Clarity, Allura CV, Allura Centron and UNIQ systems regarding live images and still images can lead to still images being interpreted as live Images.<p>
RECALLING FIRM/MANUFACTURER
Philips Electronics North America Corporation, Andover, MA on 11/3/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
13297 in total<p>
DISTRIBUTION
Nationwide and Internationally<p>

2/10/2016 Philips INTEGRIS BV5000, Cl II
Company: Philips Electronics North America Corporation
Date of Enforcement Report 2/10/2016
Class II:<p>
PRODUCT
INTEGRIS BV5000: Model Number: 72249 The Philips INTEGRIS 3000 I 5000 system is intended for interventional and diagnostic vascular and neurovascular procedures. The Philips INTEGRIS Allura 9 Biplane system is intended for diagnostic cardiovascular, vascular and interventional procedures. The Philips INTEGRIS Allura 12 & 15 system is intended for peripheral, abdominal, cerebral diagnostic and interventional angiography, neuro applications, cardiac applications and non-vascular interventions
Recall NumberZ-0725-2016<p>
REASON
The use of Allura Xper, Allura Clarity, Allura CV, Allura Centron and UNIQ systems regarding live images and still images can lead to still images being interpreted as live Images.<p>
RECALLING FIRM/MANUFACTURER
Philips Electronics North America Corporation, Andover, MA on 11/3/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
13297 in total<p>
DISTRIBUTION
Nationwide and Internationally<p>

2/10/2016 Philips INTEGRIS V5000, Cl II
Company: Philips Electronics North America Corporation
Date of Enforcement Report 2/10/2016
Class II:<p>
PRODUCT
INTEGRIS V5000: Model Number: 72248 The Philips INTEGRIS 3000 I 5000 system is intended for interventional and diagnostic vascular and neurovascular procedures. The Philips INTEGRIS Allura 9 Biplane system is intended for diagnostic cardiovascular, vascular and interventional procedures. The Philips INTEGRIS Allura 12 & 15 system is intended for peripheral, abdominal, cerebral diagnostic and interventional angiography, neuro applications, cardiac applications and non-vascular interventions
Recall NumberZ-0724-2016<p>
REASON
The use of Allura Xper, Allura Clarity, Allura CV, Allura Centron and UNIQ systems regarding live images and still images can lead to still images being interpreted as live Images.<p>
RECALLING FIRM/MANUFACTURER
Philips Electronics North America Corporation, Andover, MA on 11/3/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
13297 in total<p>
DISTRIBUTION
Nationwide and Internationally<p>

2/10/2016 Philips INTEGRIS BH5000, Cl II
Company: Philips Electronics North America Corporation
Date of Enforcement Report 2/10/2016
Class II:<p>
PRODUCT
INTEGRIS BH5000; Model Number: 72246 The Philips INTEGRIS 3000 I 5000 system is intended for interventional and diagnostic vascular and neurovascular procedures. The Philips INTEGRIS Allura 9 Biplane system is intended for diagnostic cardiovascular, vascular and interventional procedures. The

Philips INTEGRIS Allura 12 & 15 system is intended for peripheral, abdominal, cerebral diagnostic and interventional angiography, neuro applications, cardiac applications and non-vascular interventions
Recall NumberZ-0723-2016<p>
REASON
The use of Allura Xper, Allura Clarity, Allura CV, Allura Centron and UNIQ systems regarding live images and still images can lead to still images being interpreted as live Images.<p>
RECALLING FIRM/MANUFACTURER
Philips Electronics North America Corporation, Andover, MA on 11/3/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
13297 in total<p>
DISTRIBUTION
Nationwide and Internationally<p>

2/10/2016 Philips INTEGRIS H5000, Cl II
Company: Philips Electronics North America Corporation
Date of Enforcement Report 2/10/2016
Class II:<p>
PRODUCT
INTEGRIS H5000; Model Number: 72246 The Philips INTEGRIS 3000 I 5000 system is intended for interventional and diagnostic vascular and neurovascular procedures. The Philips INTEGRIS Allura 9 Biplane system is intended for diagnostic cardiovascular, vascular and interventional procedures. The Philips INTEGRIS Allura 12 & 15 system is intended for peripheral, abdominal, cerebral diagnostic and interventional angiography, neuro applications, cardiac applications and non-vascular interventions
Recall NumberZ-0722-2016<p>
REASON
The use of Allura Xper, Allura Clarity, Allura CV, Allura Centron and UNIQ systems regarding live images and still images can lead to still images being interpreted as live Images.<p>
RECALLING FIRM/MANUFACTURER
Philips Electronics North America Corporation, Andover, MA on 11/3/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
13297 in total<p>
DISTRIBUTION
Nationwide and Internationally<p>

2/10/2016 Philips INTEGRIS V3000, Cl II
Company: Philips Electronics North America Corporation
Date of Enforcement Report 2/10/2016
Class II:<p>
PRODUCT
INTEGRIS V3000; Model Number: 72243, 72244, 72245 The Philips INTEGRIS 3000 I 5000 system is intended for interventional and diagnostic vascular and neurovascular procedures. The Philips INTEGRIS Allura 9 Biplane system is intended for diagnostic cardiovascular, vascular and interventional procedures. The Philips INTEGRIS Allura 12 & 15 system is intended for peripheral, abdominal, cerebral diagnostic and interventional angiography, neuro applications, cardiac applications and non-vascular interventions
Recall NumberZ-0721-2016<p>
REASON
The use of Allura Xper, Allura Clarity, Allura CV, Allura Centron and UNIQ systems regarding live images and still images can lead to still images being interpreted as live Images.<p>
RECALLING FIRM/MANUFACTURER
Philips Electronics North America Corporation, Andover, MA on 11/3/2015. Voluntary: Firm Initiated

recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
13297 in total<p>
DISTRIBUTION
Nationwide and Internationally<p>

2/10/2016 Philips INTEGRIS BH3000, Cl II
Company: Philips Electronics North America Corporation
Date of Enforcement Report 2/10/2016
Class II:<p>
PRODUCT
INTEGRIS BH3000; Model Number: 72242 The Philips INTEGRIS 3000 I 5000 system is intended for interventional and diagnostic vascular and neurovascular procedures. The Philips INTEGRIS Allura 9 Biplane system is intended for diagnostic cardiovascular, vascular and interventional procedures. The Philips INTEGRIS Allura 12 & 15 system is intended for peripheral, abdominal, cerebral diagnostic and interventional angiography, neuro applications, cardiac applications and non-vascular interventions
Recall NumberZ-0720-2016<p>
REASON
The use of Allura Xper, Allura Clarity, Allura CV, Allura Centron and UNIQ systems regarding live images and still images can lead to still images being interpreted as live Images.<p>
RECALLING FIRM/MANUFACTURER
Philips Electronics North America Corporation, Andover, MA on 11/3/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
13297 in total<p>
DISTRIBUTION
Nationwide and Internationally<p>

2/10/2016 Philips INTEGRIS BN/BV3000, Cl II
Company: Philips Electronics North America Corporation
Date of Enforcement Report 2/10/2016
Class II:<p>
PRODUCT
INTEGRIS BN/BV3000; Model Number: 72240 The Philips INTEGRIS 3000 I 5000 system is intended for interventional and diagnostic vascular and neurovascular procedures. The Philips INTEGRIS Allura 9 Biplane system is intended for diagnostic cardiovascular, vascular and interventional procedures. The Philips INTEGRIS Allura 12 & 15 system is intended for peripheral, abdominal, cerebral diagnostic and interventional angiography, neuro applications, cardiac applications and non-vascular interventions
Recall NumberZ-0719-2016<p>
REASON
The use of Allura Xper, Allura Clarity, Allura CV, Allura Centron and UNIQ systems regarding live images and still images can lead to still images being interpreted as live Images.<p>
RECALLING FIRM/MANUFACTURER
Philips Electronics North America Corporation, Andover, MA on 11/3/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
13297 in total<p>
DISTRIBUTION
Nationwide and Internationally<p>

2/10/2016 Philips INTEGRIS HM3000, Cl II
Company: Philips Electronics North America Corporation
Date of Enforcement Report 2/10/2016
Class II:<p>
PRODUCT
INTEGRIS HM3000; Model Number: 72239 The Philips INTEGRIS 3000 I 5000 system is intended for interventional and diagnostic vascular and neurovascular procedures. The Philips INTEGRIS Allura 9 Biplane system is intended for diagnostic cardiovascular, vascular and interventional procedures. The Philips INTEGRIS Allura 12 & 15 system is intended for peripheral, abdominal, cerebral diagnostic and interventional angiography, neuro applications, cardiac applications and non-vascular interventions
Recall NumberZ-0718-2016<p>
REASON
The use of Allura Xper, Allura Clarity, Allura CV, Allura Centron and UNIQ systems regarding live images and still images can lead to still images being interpreted as live Images.<p>
RECALLING FIRM/MANUFACTURER
Philips Electronics North America Corporation, Andover, MA on 11/3/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
13297 in total<p>
DISTRIBUTION
Nationwide and Internationally<p>

2/10/2016 Philips INTEGRIS H3000, Cl II
Company: Philips Electronics North America Corporation
Date of Enforcement Report 2/10/2016
Class II:<p>
PRODUCT
INTEGRIS H3000; Model Number: 72238 The Philips INTEGRIS 3000 I 5000 system is intended for interventional and diagnostic vascular and neurovascular procedures. The Philips INTEGRIS Allura 9 Biplane system is intended for diagnostic cardiovascular, vascular and interventional procedures. The Philips INTEGRIS Allura 12 & 15 system is intended for peripheral, abdominal, cerebral diagnostic and interventional angiography, neuro applications, cardiac applications and non-vascular interventions
Recall NumberZ-0717-2016<p>
REASON
The use of Allura Xper, Allura Clarity, Allura CV, Allura Centron and UNIQ systems regarding live images and still images can lead to still images being interpreted as live Images.<p>
RECALLING FIRM/MANUFACTURER
Philips Electronics North America Corporation, Andover, MA on 11/3/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
13297 in total<p>
DISTRIBUTION
Nationwide and Internationally<p>

2/10/2016 Philips Cardiovascular Allura Centron, Cl II
Company: Philips Electronics North America Corporation
Date of Enforcement Report 2/10/2016
Class II:<p>
PRODUCT
Cardiovascular Allura Centron; Model Number: 722400 The Allura CV2O is intended for physicians (e.g. cardiologists and radiologists), assisted by trained hospital staff (e.g. nurses and lab technicians), who are qualified to perform medical procedures on humans (having a maximum weight of 250 kg.) with probable internal diseases or injuries for: " Dedicated vascular and carotid imaging applications,

including diagnostic and interventional procedures. " Cardiac imaging applications including diagnostics, interventional rocedures, pacemaker implantations and electrophysiology (EP). " Non-vascular interventions such as drainages, biopsies and vertebroplasties procedures.
Recall NumberZ-0716-2016<p>
REASON
The use of Allura Xper, Allura Clarity, Allura CV, Allura Centron and UNIQ systems regarding live images and still images can lead to still images being interpreted as live Images.<p>
RECALLING FIRM/MANUFACTURER
Philips Electronics North America Corporation, Andover, MA on 11/3/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
13297 in total<p>
DISTRIBUTION
Nationwide and Internationally<p>

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2/10/2016 Philips Allura CV20, Cl II
Company: Philips Electronics North America Corporation
Date of Enforcement Report 2/10/2016
Class II:<p>
PRODUCT
Allura CV20; Model Number: 722031 The Allura CV2O is intended for physicians (e.g. cardiologists and radiologists), assisted by trained hospital staff (e.g. nurses and lab technicians), who are qualified to perform medical procedures on humans (having a maximum weight of 250 kg.) with probable internal diseases or injuries for: " Dedicated vascular and carotid imaging applications, including diagnostic and interventional procedures. " Cardiac imaging applications including diagnostics, interventional rocedures, pacemaker implantations and electrophysiology (EP). " Non-vascular interventions such as drainages, biopsies and vertebroplasties procedures.
Recall NumberZ-0715-2016<p>
REASON
The use of Allura Xper, Allura Clarity, Allura CV, Allura Centron and UNIQ systems regarding live images and still images can lead to still images being interpreted as live Images.<p>
RECALLING FIRM/MANUFACTURER
Philips Electronics North America Corporation, Andover, MA on 11/3/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
13297 in total<p>
DISTRIBUTION
Nationwide and Internationally<p>

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2/10/2016 Philips Xper FD20/20 OR Table, Cl II
Company: Philips Electronics North America Corporation
Date of Enforcement Report 2/10/2016
Class II:<p>
PRODUCT
Allura Xper FD20/20 OR Table; Model Number: 722039 Dedicated vascular and neurovascular imaging applications, including diagnostic and interventional procedures. This includes, e.g. peripheral, cerebral, thoracic and abdominal angiography, as well as PTCAs, stent placements, embolisations and thrombolysis. " Cardiac imaging applications including diagnostics, interventional procedures (such as PTCA, stent placing, atherectomies), pacemaker implantations and ElectroPhysiology " Non-vascular interventions such as drainages, biopsies and vertebroplasties procedures.
Recall NumberZ-0714-2016<p>
REASON
The use of Allura Xper, Allura Clarity, Allura CV, Allura Centron and UNIQ systems regarding live

images and still images can lead to still images being interpreted as live Images.<p>
RECALLING FIRM/MANUFACTURER
Philips Electronics North America Corporation, Andover, MA on 11/3/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
13297 in total<p>
DISTRIBUTION
Nationwide and Internationally<p>

2/10/2016 Philips Allura Xper FD20/20, Cl II

Company: Philips Electronics North America Corporation
Date of Enforcement Report 2/10/2016
Class II:<p>
PRODUCT
Allura Xper FD20/20; Model Number: 722038 Dedicated vascular and neurovascular imaging applications, including diagnostic and interventional procedures. This includes, e.g. peripheral, cerebral, thoracic and abdominal angiography, as well as PTCAs, stent placements, embolisations and thrombolysis. " Cardiac imaging applications including diagnostics, interventional procedures (such as PTCA, stent placing, atherectomies), pacemaker implantations and ElectroPhysiology " Non-vascular interventions such as drainages, biopsies and vertebroplasties procedures.
Recall NumberZ-0713-2016<p>
REASON
The use of Allura Xper, Allura Clarity, Allura CV, Allura Centron and UNIQ systems regarding live images and still images can lead to still images being interpreted as live Images.<p>
RECALLING FIRM/MANUFACTURER
Philips Electronics North America Corporation, Andover, MA on 11/3/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
13297 in total<p>
DISTRIBUTION
Nationwide and Internationally<p>

2/10/2016 Philips Allura Xper FD20 Biplane OR Table, Cl II

Company: Philips Electronics North America Corporation
Date of Enforcement Report 2/10/2016
Class II:<p>
PRODUCT
Allura Xper FD20 Biplane OR Table; Model Numbers: 722025 722020 Dedicated vascular and neurovascular imaging applications, including diagnostic and interventional procedures. This includes, e.g. peripheral, cerebral, thoracic and abdominal angiography, as well as PTCAs, stent placements, embolisations and thrombolysis. " Cardiac imaging applications including diagnostics, interventional procedures (such as PTCA, stent placing, atherectomies), pacemaker implantations and ElectroPhysiology " Non-vascular interventions such as drainages, biopsies and vertebroplasties procedures.
Recall NumberZ-0712-2016<p>
REASON
The use of Allura Xper, Allura Clarity, Allura CV, Allura Centron and UNIQ systems regarding live images and still images can lead to still images being interpreted as live Images.<p>
RECALLING FIRM/MANUFACTURER
Philips Electronics North America Corporation, Andover, MA on 11/3/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE

13297 in total<p>
DISTRIBUTION
Nationwide and Internationally<p>

2/10/2016 Philips Allura Xper FD20 Biplane Cl II
Company: Philips Electronics North America Corporation
Date of Enforcement Report 2/10/2016
Class II:<p>
PRODUCT
Allura Xper FD20 Biplane; Model Numbers: 722013 722008 722015 Dedicated vascular and neurovascular imaging applications, including diagnostic and interventional procedures. This includes, e.g. peripheral, cerebral, thoracic and abdominal angiography, as well as PTCAs, stent placements, embolisations and thrombolysis. " Cardiac imaging applications including diagnostics, interventional procedures (such as PTCA, stent placing, atherectomies), pacemaker implantations and ElectroPhysiology " Non-vascular interventions such as drainages, biopsies and vertebroplasties procedures.
Recall NumberZ-0711-2016<p>
REASON
The use of Allura Xper, Allura Clarity, Allura CV, Allura Centron and UNIQ systems regarding live images and still images can lead to still images being interpreted as live Images.<p>
RECALLING FIRM/MANUFACTURER
Philips Electronics North America Corporation, Andover, MA on 11/3/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
13297 in total<p>
DISTRIBUTION
Nationwide and Internationally<p>

2/10/2016 Philips UNIQ FD OR table, Cl II
Company: Philips Electronics North America Corporation
Date of Enforcement Report 2/10/2016
Class II:<p>
PRODUCT
UNIQ FD OR table; Model Number 722035 The Philips UNIQ is intended for use on human patients to perform: " Vascular, cardiovascular and neurovascular imaging applications, including diagnostic, interventional and minimally invasive procedures. This includes, e.g., peripheral, cerebral, thoracic and abdominal angiography, as well as PTAs, stent placements, embolisations and thrombolysis. " Cardiac imaging applications including diagnostics, interventional and minimally invasive procedures (such as PTCA, stent placing, atherectomies), pacemaker implantations, and electrophysiology (EP). "
Non-vascular interventions such as drainages, biopsies and vertebroplasties procedures
Recall NumberZ-0709-2016<p>
REASON
The use of Allura Xper, Allura Clarity, Allura CV, Allura Centron and UNIQ systems regarding live images and still images can lead to still images being interpreted as live Images.<p>
RECALLING FIRM/MANUFACTURER
Philips Electronics North America Corporation, Andover, MA on 11/3/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
13297 in total<p>
DISTRIBUTION
Nationwide and Internationally<p>

2/10/2016 PhilipsUNIQ FD, CI II
Company: Philips Electronics North America Corporation
Date of Enforcement Report 2/10/2016
Class II:<p>
PRODUCT
UNIQ FD; Model Numbers: 722028 The Philips UNIQ is intended for use on human patients to perform: " Vascular, cardiovascular and neurovascular imaging applications, including diagnostic, interventional and minimally invasive procedures. This includes, e.g., peripheral, cerebral, thoracic and abdominal angiography, as well as PTAs, stent placements, embolisations and thrombolysis. " Cardiac imaging applications including diagnostics, interventional and minimally invasive procedures (such as PTCA, stent placing, atherectomies), pacemaker implantations, and electrophysiology (EP). " Non-vascular interventions such as drainages, biopsies and vertebroplasties procedures
Recall NumberZ-0708-2016<p>
REASON
The use of Allura Xper, Allura Clarity, Allura CV, Allura Centron and UNIQ systems regarding live images and still images can lead to still images being interpreted as live Images.<p>
RECALLING FIRM/MANUFACTURER
Philips Electronics North America Corporation, Andover, MA on 11/3/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
13297 in total<p>
DISTRIBUTION
Nationwide and Internationally<p>

2/10/2016 Philips Xper FD20, CI II
Company: Philips Electronics North America Corporation
Date of Enforcement Report 2/10/2016
Class II:<p>
PRODUCT
Allura Xper FD20; Model Numbers: 722028 722012 722006 Dedicated vascular and neurovascular imaging applications, including diagnostic and interventional procedures. This includes, e.g. peripheral, cerebral, thoracic and abdominal angiography, as well as PTCAs, stent placements, embolisations and thrombolysis. " Cardiac imaging applications including diagnostics, interventional procedures (such as PTCA, stent placing, atherectomies), pacemaker implantations and ElectroPhysiology " Non-vascular interventions such as drainages, biopsies and vertebroplasties procedures
Recall NumberZ-0707-2016<p>
REASON
The use of Allura Xper, Allura Clarity, Allura CV, Allura Centron and UNIQ systems regarding live images and still images can lead to still images being interpreted as live Images.<p>
RECALLING FIRM/MANUFACTURER
Philips Electronics North America Corporation, Andover, MA on 11/3/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
13297 in total<p>
DISTRIBUTION
Nationwide and Internationally<p>

2/10/2016 Philips Allura Xper FD20/15, CI II
Company: Philips Electronics North America Corporation
Date of Enforcement Report 2/10/2016
Class II:<p>
PRODUCT
Allura Xper FD20/15; Model Numbers: 722058 Dedicated vascular and neurovascular imaging

applications, including diagnostic and interventional procedures. This includes, e.g. peripheral, cerebral, thoracic and abdominal angiography, as well as PTCAs, stent placements, embolisations and thrombolysis. " Cardiac imaging applications including diagnostics, interventional procedures (such as PTCA, stent placing, atherectomies), pacemaker implantations and ElectroPhysiology " Non-vascular interventions such as drainages, biopsies and vertebroplasties procedures
Recall NumberZ-0706-2016<p>
REASON
The use of Allura Xper, Allura Clarity, Allura CV, Allura Centron and UNIQ systems regarding live images and still images can lead to still images being interpreted as live Images.<p>
RECALLING FIRM/MANUFACTURER
Philips Electronics North America Corporation, Andover, MA on 11/3/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
13297 in total<p>
DISTRIBUTION
Nationwide and Internationally<p>

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2/10/2016 Philips Allura Xper FD20/10 Cl II
Company: Philips Electronics North America Corporation
Date of Enforcement Report 2/10/2016
Class II:<p>
PRODUCT
Allura Xper FD20/10; Model Numbers: 722029 Dedicated vascular and neurovascular imaging applications, including diagnostic and interventional procedures. This includes, e.g. peripheral, cerebral, thoracic and abdominal angiography, as well as PTCAs, stent placements, embolisations and thrombolysis. " Cardiac imaging applications including diagnostics, interventional procedures (such as PTCA, stent placing, atherectomies), pacemaker implantations and ElectroPhysiology " Non-vascular interventions such as drainages, biopsies and vertebroplasties procedures
Recall NumberZ-0705-2016<p>
REASON
The use of Allura Xper, Allura Clarity, Allura CV, Allura Centron and UNIQ systems regarding live images and still images can lead to still images being interpreted as live Images.<p>
RECALLING FIRM/MANUFACTURER
Philips Electronics North America Corporation, Andover, MA on 11/3/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
13297 in total<p>
DISTRIBUTION
Nationwide and Internationally<p>

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2/10/2016 Philips Allura Xper FD10/10 Cl II
Company: Philips Electronics North America Corporation
Date of Enforcement Report 2/10/2016
Class II:<p>
PRODUCT
Allura Xper FD10/10; Model Numbers: 722027 722011 722005 Intended for Cardiovascular and vascular X-ray imaging applications, including diagnostic, interventional procedures (such as PTCA, stent placement and atherectomies), pacemaker implantations and ElectroPhysiology (EP). Recall NumberZ-0703-2016<p>
REASON
The use of Allura Xper, Allura Clarity, Allura CV, Allura Centron and UNIQ systems regarding live images and still images can lead to still images being interpreted as live Images.<p>
RECALLING FIRM/MANUFACTURER

Philips Electronics North America Corporation, Andover, MA on 11/3/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
13297 in total<p>
DISTRIBUTION
Nationwide and Internationally<p>

2/10/2016 Philips Allura Xper FD10, FD10 C, FD10 F, Cl II

Company: Philips Electronics North America Corporation
Date of Enforcement Report 2/102016
Class II:<p>
PRODUCT
Allura Xper FD10, FD10 C, and FD10 F; Model Numbers: 722026 722010 722003 722002 722001 Intended for Cardiovascular and vascular X-ray imaging applications, including diagnostic, interventional procedures (such as PTCA, stent placement and atherectomies), pacemaker implantations and ElectroPhysiology (EP).
Recall NumberZ-0702-2016<p>
REASON
The use of Allura Xper, Allura Clarity, Allura CV, Allura Centron and UNIQ systems regarding live images and still images can lead to still images being interpreted as live Images.<p>
RECALLING FIRM/MANUFACTURER
Philips Electronics North America Corporation, Andover, MA on 11/3/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
13297 in total<p>
DISTRIBUTION
Nationwide and Internationally<p>

2/10/2016 Siemens ADVIA Chemistry XPT Systems, Cl II

Company: Siemens Healthcare Diagnostics, Inc..
Date of Enforcement Report 2/10/2016
Class II:<p>
PRODUCT
ADVIA Chemistry XPT Systems, Software Version 1.0.3, SMN 11127538 Clinical chemistry analyzer that runs tests on serum, plasma, urine, or cerebral spinal fluid in random access and batch modes at a throughput rate of both 1800 photometric tests per hour and 600 electrolyte (ISE) tests per hour.
Recall NumberZ-0755-2016<p>
REASON
Multiple Software issues. Auto Start-UP Fail, Calibration Interval Resets when a Reagent Blank is run, Control Definition screen assumes range defined is 2 SD, Laboratory Information System (LIS) communication/Laboratory Automation (LAS) issue, Printer Driver Resets, ISE Calibration Ranges are too conservative for Urine Sodium, Archiving and deletion may fail and Workstation services may restart.<p>
RECALLING FIRM/MANUFACTURER
Siemens Healthcare Diagnostics, Inc., Tarrytown, NY on 10/7/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
87 units<p>
DISTRIBUTION
Nationwide and Internationally <p>

2/3/2016 Bio-Rad D-10 Rack Loader, Cl II
Company: Bio-Rad Laboratories Inc.
Date of Enforcement Report 2/3/2016
Class II:<p>
PRODUCT
D-10 Rack Loader; Model Number 220-0600; Hematology: The D-10 is a fully integrated system for sample dilution, processing and analysis of hemoglobin, designed for use with specific Bio-Rad reagent kits. The D-10 incorporates the use of a dedicated software system for instrument control, data collection, and analysis.
Recall NumberZ-0695-2016<p>
REASON
On a rare occasion, there is a potential to assign a patient result to an incorrect sample ID when running in D10 Rack Loader configuration..<p>
RECALLING FIRM/MANUFACTURER
Bio-Rad Laboratories, Inc., Hercules, CA on 12/15/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
165 in US, 200 Internationally<p>
DISTRIBUTION
Nationwide and Internationally.<p>

1/20/2016 Ortho VITROS 5,1 FS Chemistry System Cl II
Company: Ortho-Clinical Diagnostics
Date of Enforcement Report 1/20/2016
Class II:<p>
PRODUCT
VITROS 5,1 FS Chemistry System, Catalog Number 6801375, Unique Device Identifier Number 10758750001132, and VITROS 5,1 FS Chemistry System Refurbished, Catalog Number 6801890, Unique Device Identifier Number 10758750001644, Software Version 2.8 and below, IVD. Product Usage: The VITROS 5,1 FS Chemistry System is intended for use in the in vitro quantitative measurement of a variety of analytes of clinical interest, using both VITROS Chemistry Products Slides (colorimetric endpoint, rate, ion-selective electrode, and immunorate methods) and VITROS Chemistry Products MicroTip liquid reagents (spectrophotometric and spectrophotometric immunoassay methods.).
Recall NumberZ-0643-2016<p>
REASON
Software anomaly may allow VITROS Systems to sample and process assays while the fluids and reagent temperatures are not in the required temperature range for optimal processing. When this intermittent issue occurs, the VITROS Systems continue to operate and process results without notification to the User, possibly producing erroneous results.<p>
RECALLING FIRM/MANUFACTURER
Ortho-Clinical Diagnostics, Rochester, NY on 11/3/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
VITROS 5,1: Domestic - 932, Foreign - 1245; 5,1 Refurbished: Domestic - 63; Foreign - 153<p>
DISTRIBUTION
Nationwide and Internationally.<p>

1/20/2016 Ortho VITROS 4600 Chemistry System, Cl II
Company: Ortho-Clinical Diagnostics
Date of Enforcement Report 1/20/2016
Class II:<p>
PRODUCT
VITROS 4600 Chemistry System, Catalog Number 6802445, Unique Device Identifier Number 10758750012343, Software Version 3.2 and below; IVD. Product Usage: The VITROS 4600 Chemistry

System is intended for use in the in vitro quantitative measurement of a variety of analytes of clinical interest, using both VITROS Chemistry Products Slides (colorimetric endpoint, rate, ion-selective electrode, and immunorate methods) and VITROS Chemistry Products MicroTip liquid reagents (spectrophotometric and spectrophotometric immunoassay methods.)
Recall NumberZ-0642-2016<p>
REASON
Software anomaly may allow VITROS Systems to sample and process assays while the fluids and reagent temperatures are not in the required temperature range for optimal processing. When this intermittent issue occurs, the VITROS Systems continue to operate and process results without notification to the User, possibly producing erroneous results.<p>
RECALLING FIRM/MANUFACTURER
Ortho-Clinical Diagnostics, Rochester, NY on 11/3/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
Domestic: 157, Foreign: 270<p>
DISTRIBUTION
Nationwide and Internationally.<p>

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1/20/2016 Ortho VITROS 5000 Chemistry System, Cl II
Company: Ortho-Clinical Diagnostics
Date of Enforcement Report 1/20/2016
Class II:<p>
PRODUCT
VITROS 5600 Chemistry System, Catalog Number 6802413, Unique Device Identifier Number 10758750009916, Software Product Code 6802864, Software Version 3.2 and below; IVD. Product Usage: For use in the in vitro quantitative, semi-quantitative, and qualitative measurement of a variety of analytes of clinical interest, using VITROS Chemistry Products Slides, VITROS Chemistry Products MicroTip Reagents and VITROS Immunodiagnostic Products Reagents.
Recall NumberZ-0641-2016<p>
REASON
Software anomaly may allow VITROS Systems to sample and process assays while the fluids and reagent temperatures are not in the required temperature range for optimal processing. When this intermittent issue occurs, the VITROS Systems continue to operate and process results without notification to the User, possibly producing erroneous results.<p>
RECALLING FIRM/MANUFACTURER
Ortho-Clinical Diagnostics, rochester, NY on 11/3/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
Domestic: 1083, Foreign: 999<p>
DISTRIBUTION
Nationwide and Internationally.<p>

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1/20/2016 Ortho VITROS 3600 Chemistry System, Cl II
Company: Ortho-Clinical Diagnostics
Date of Enforcement Report 1/20/2016
Class II:<p>
PRODUCT
VITROS 3600 Chemistry System, Catalog Number 6802783, Unique Device Identifier Number 10758750009930, Software Product Code 6802866, Software Version 3.2 and below; IVD. Product Usage: For use in the in vitro quantitative, semi-quantitative, and qualitative measurement of a variety of analytes of clinical interest, using VITROS Immunodiagnostic Products Reagents.
Recall NumberZ-0640-2016<p>
REASON
Software anomaly may allow VITROS Systems to sample and process assays while the fluids and reagent temperatures are not in the required temperature range for optimal processing. When this

intermittent issue occurs, the VITROS Systems continue to operate and process results without notification to the User, possibly producing erroneous results.<p>
RECALLING FIRM/MANUFACTURER
Ortho-Clinical Diagnostics, rochester, NY on 11/3/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
Domestic: 200, Foreign: 554<p>
DISTRIBUTION
Nationwide and Internationally.<p>

1/15/2016 Brainlab Cranial Image-Guided Surgery Sys,
Class I
Company: Brainlab AG
Date of Enforcement Report 8/26/2015
Class I:<p>
PRODUCT
Brainlab Cranial IGS System
Brainlab Cranial Navigation Systems (all existing versions before Cranial 3.0)
Distribution Dates: May 1996 to May 2015
Devices Recalled in the U.S.: 1021units Nationwide
Device Use: Brainlab Cranial IGS System shows the area of interest and the position of an instrument relative to the patient’s anatomy to enable minimally invasive surgical procedures.<p>
REASON
Brainlab is recalling the Cranial IGS System due to potential inaccuracies in the display by the navigation system compared to the patient anatomy. This could lead to inaccurate, ineffective medical procedures, and serious life-threatening injuries including death..<p>
RECALLING FIRM/MANUFACTURER
Brainlab AG, Recall initiated 4/22/2013: <p>
VOLUME OF PRODUCT IN COMMERCE
102 units<p>
DISTRIBUTION
Arkansas (AR)
California (CA)
Colorado (CO)
Maryland (MD)
North Carolina (NC)
Ohio (OH)
Pennsylvania (PA)
Texas (TX)
FDA District: Los Angeles<p>

1/13/2016 Philips Lumify Diagnostic Ultrasound Cl II
Company: Philips Ultrasound Inc
Date of Enforcement Report 1/13/2016
Class II:<p>
PRODUCT
Philips Lumify Diagnostic Ultrasound, Catalogue Number: 795216 Part Number: 989605449841 with 453561845331 (software version 1.0)
Recall NumberZ-0596-2016<p>
REASON
Color Flow direction is displayed incorrectly in Lumify 1.0. The system displayed Color Flow direction does not correctly represent the annotated Color Bar or Velocity Markers. (e.g.) When the Color Bar conveys that Red is to be displayed for color flow toward the Transducer, the system displays Blue for color flow toward the Transducer. This could result in misdiagnosis in some studies.<p>

RECALLING FIRM/MANUFACTURER
Philips Ultrasound Inc, Bothell WA on 12/9/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
21 units<p>
DISTRIBUTION
distributed in CA, CT, ND, NV, OR, RI, TN, and WA<p>

1/13/2016 Elekta Oncentra Radiation Therapy Planning
Cl II
Company: Elekta, Inc.
Date of Enforcement Report 1/13/2016
Class II:<p>
PRODUCT
Oncentra External Beam - VMAT - Radiation therapy planning system Product Usage: The Oncentra system is a radiation treatment planning software designed to analyze and plan radiation treatments in three dimensions for the purpose of treating patients with cancer.
Recall NumberZ-0604-2016<p>
REASON
When using the option "Tumor Overlap Fraction" in VMAT planning it has been observed that in rare cases the system does include an organ at risk as target volume. This could result in open MLC, and open jaws in areas away from the target volume.<p>
RECALLING FIRM/MANUFACTURER
Elekta Inc., Altanta, GA on 12/18/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
154<p>
DISTRIBUTION
Worldwide<p>

1/13/2016 Vidco Remote Patient Monitoring System, Cl
II
Company: Vidco Inc.
Date of Enforcement Report 1/13/2016
Class II:<p>
PRODUCT
Remote Patient Monitoring System, MDP 2000 Series, Part Numbers: MDP2040-0100, PGM340R3, or PGM340R4. The MDP2000 is intended for use in conjunction with patient monitoring equipment. The MDP2000 is not patient connected Examples of areas where the MDP200 is used include ICU, CCU, PACU, Emergency, Telemetry Step-down and other areas where patient's physiological information are to be observed at one or more locations. Typical information displayed includes ECG and blood pressure waveforms and numeric values which as heart rate and systolic, mean and diastolic pressure. This device acts as the Central Monitor Station, it permits from one (1) to sixteen (16) bedside monitor(s) to be connected simultaneously. Recall NumberZ-0582-2016<p>
REASON
Testing at customer site showed unit Remote Patient Monitoring System MDP2040-0100 in a continuous trap condition, not allowing system to reset and reboot. Two customers recently complained of the system freezing and it could only be restarted if the user re-applied power.<p>
RECALLING FIRM/MANUFACTURER
Vidco Inc., on 11/18/2015. Beaverton, OR on 11/8/2015 Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
59 units<p>
DISTRIBUTION
US Nationwide distribution in the states of AZ, CA, MD, NM, NJ, and OH.<p>

1/13/2016 Natus Quantum with NeuroWorks Software, CL II
Company:Natus Neurology DBA Excel Tech., Ltd. (XLTEK)
Date of Enforcement Report 1/132016
Class II:<p>
PRODUCT
Natus Quantum System with NeuroWorks Software. Catalog /Part Numbers: 013926. The Natus Quantum Amplifier is intended to be used as an electroencephalograph: to acquire, display, store and archive electrophysiological signals. The amplifier should be used in conjunction with Natus NeuroWorks /SleepWorks software to acquire scalp and intracranial electroencephalographic (EEG) signals as well as polysomnographic (PSG) signals.
Recall NumberZ-0581-2016<p>
REASON
During an internal testing, Natus Medical Incorporated, identified that in Neuro Works 8.1 with Quantum hardware, the incoming signal is displayed with reversed polarity.<p>
RECALLING FIRM/MANUFACTURER
Natus Neurology DBA Excel Tech., Ltd. (XLTEK). Oakville, CA on 11/11/2015.Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
56 (43 US, 13 OUS)<p>
DISTRIBUTION
Nationwide and Internationally<p>

1/13/2016 Software version VD10E for Syngo X, Cl II
Company: Siemens Medical Solutions USA, Inc.
Date of Enforcement Report 1/13/2016
Class II:<p>
PRODUCT
Software version VD10E for Syngo X-Workplace; Picture archiving and communication system. Recall NumberZ-0597-2016<p>
REASON
Potential post-processing software issue when using tabcard "4D" on X-Workplace with software version VD10E. A too small measurement in the MPRs of a volume when images are acquired with a CT scanner with a tilted gantry. In a 2x2 layout, the 4D tabcard will show an incorrect, too small length measurement. This could result in selecting a device of the wrong size, which then needs to be exchanged.an invalid combination of printer and the syngo Imaging XS printer configuration file.<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Malvern, PA on 11/18/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
73 units<p>
DISTRIBUTION
Nationwide <p>

1/6/2016 MOSAIQ Oncology Information System Cl II
Company: Elekta, Inc.
Date of Enforcement Report 1/6/2016
Class II:<p>
PRODUCT
MOSAIQ Oncology Information System MOSAIQ is an oncology information system used to manage workflows for treatment planning and delivery. It supports information flow among healthcare facility personnel and can be used wherever radiotherapy and/or chemotherapy are prescribed. Recall NumberZ-0557-2016<p>

REASON
Incorrect drug dosage due to "Age Limit" and patient weight data item issue..<p>
RECALLING FIRM/MANUFACTURER
Elekta Inc., Altanta, GA on 12/9/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
399<p>
DISTRIBUTION
Worldwide<p>

1/6/2016 Merge Cardio Cl II
Company: Merge Healthcare Inc.
Date of Enforcement Report 1/6/2016
Class II:<p>
PRODUCT
Merge Cardio with software version 10.1 LA.
Recall NumberZ-0555-20166<p>
REASON
The firm, Merge Healthcare, sent out Merge HEMO V10.0 & Merge CARDIO V10.1 software to 3 customers before the product was completely validated in house.<p>
RECALLING FIRM/MANUFACTURER
Merge Healthcare Inc., Hartland, WI on 10/26/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
1<p>
DISTRIBUTION
Distributed in the states of IL, NC, and VT.<p>

1/6/2016 Merge Hemo , Cl II
Company: Merge Healthcare Inc.
Date of Enforcement Report 1/6/2016
Class II:<p>
PRODUCT
Merge Hemo with software versions 10.0 LA. Merge Hemo (formerly named HeartSuite Hemodynamics) monitors, measures, and records physiologic data from a human patient undergoing a cardiac catheterization procedure.
Recall NumberZ-0554-2016<p>
REASON
The firm, Merge Healthcare, sent out Merge HEMO V10.0 & Merge CARDIO V10.1 software to 3 customers before the product was completely validated in house..<p>
RECALLING FIRM/MANUFACTURER
Merge Healthcare Inc., Hartland, WI on 10/26/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
2<p>
DISTRIBUTION
Distributed in the states of IL, NC, and VT.<p>

12/30/2015 Draeger Optional PS500 Power Supply Unit
Cl II
Company: Draeger Medical, Inc.
Date of Enforcement Report 12/30/2015
Class II:<p>
PRODUCT
Optional PS500 Power Supply Unit for the Evita V500 Ventilator and Babylog VN500 Ventilator. Babylog VN500 is a ventilation unit intended for the ventilation of neonatal and pediatric patients. Recall Number

Z-0436-2016<p>
REASON
The firm became aware of cases in which the battery run times of the optional PS 500 power supply unit with the Infinity Workstation Critical Care (Evita Infinity V 500) were unexpectedly short due to the design of the charging algorithm in the current software. Devices used for patient transport will be a priority.<p>
RECALLING FIRM/MANUFACTURER
Draeger Medical, Inc., Telford, PA on 12/1/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
2422<p>
DISTRIBUTION
Nationwide<p>

12/30/2015 Siemens Syngo Imaging XS , Cl II
Company: Siemens Medical Solutions USA, Inc.
Date of Enforcement Report 12/30/2015
Class II:<p>
PRODUCT
Syngo Imaging XS is a Picture Archiving and Communication System (PACS)
Recall NumberZ-0550-2016<p>
REASON
For the Syngo Workflow SLR System with Software Ver: VB10C: Printouts may be printed in incorrect anatomical size when using syngo Imaging XS filming application in conjunction with a printer not released for anatomical print usage. This may happen due to an invalid combination of printer and the syngo Imaging XS printer configuration file.<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Malvern, PA on 11/17/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
42<p>
DISTRIBUTION
US Distribution <p>

12/30/2015 Philips Ingenuity CT Computed Tomography
Cl II
Company: Philips Medical Systems (Cleveland) Inc
Date of Enforcement Report 12/30/2015
Class II:<p>
PRODUCT
Ingenuity CT Computed Tomography X-ray system
Recall NumberZ-0549-2016<p>
REASON
Perfusion scan feature may not be available on machines running software versions 4.1.2, 4.1.3, and 4.1.4. Customers previously using the basic axial perfusion software (versions preceding 4.1.2) without buying the helical perfusion license key could not access the basic axial perfusion feature after upgrading to software version 4.1.2.<p>
RECALLING FIRM/MANUFACTURER
Philips Medical Systems (Cleveland) Inc, Cleveland, OH on 10/29/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
31 units<p>
DISTRIBUTION
Worldwide<p>

12/30/2015 Ingenuity Core 128 Computed Tomography, Cl II
Company: Philips Medical Systems (Cleveland) Inc
Date of Enforcement Report 12/30/2015
Class II:<p>
PRODUCT
Ingenuity Core 128 Computed Tomography X-ray system
Recall NumberZ-0548-2016<p>
REASON
Perfusion scan feature may not be available on machines running software versions 4.1.2, 4.1.3, and 4.1.4. Customers previously using the basic axial perfusion software (versions preceding 4.1.2) without buying the helical perfusion license key could not access the basic axial perfusion feature after upgrading to software version 4.1.2.<p>
RECALLING FIRM/MANUFACTURER
Philips Medical Systems (Cleveland) Inc, Cleveland, OH on 10/29/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
177 units<p>
DISTRIBUTION
Worldwide<p>

12/30/2015 Ingenuity Core Computed Tomography, Cl II
Company: Philips Medical Systems (Cleveland) Inc
Date of Enforcement Report 12/30/2015
Class II:<p>
PRODUCT
Ingenuity Core Computed Tomography X-ray system
Recall NumberZ-0547-2016<p>
REASON
Perfusion scan feature may not be available on machines running software versions 4.1.2, 4.1.3, and 4.1.4. Customers previously using the basic axial perfusion software (versions preceding 4.1.2) without buying the helical perfusion license key could not access the basic axial perfusion feature after upgrading to software version 4.1.2.<p>
RECALLING FIRM/MANUFACTURER
Philips Medical Systems (Cleveland) Inc, Cleveland, OH on 10/29/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
135 units<p>
DISTRIBUTION
Worldwide<p>

12/30/2015 Philips Brilliance iCT SPTomography Cl II
Company: Philips Medical Systems (Cleveland) Inc
Date of Enforcement Report 12/30/2015
Class II:<p>
PRODUCT
Brilliance iCT SP Computed Tomography X-ray system
Recall NumberZ-0546-2016<p>
REASON
Perfusion scan feature may not be available on machines running software versions 4.1.2, 4.1.3, and 4.1.4. Customers previously using the basic axial perfusion software (versions preceding 4.1.2) without buying the helical perfusion license key could not access the basic axial perfusion feature after

upgrading to software version 4.1.2.<p>
RECALLING FIRM/MANUFACTURER
Philips Medical Systems (Cleveland) Inc, Cleveland, OH on 10/29/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
12 units<p>
DISTRIBUTION
Worldwide<p>

12/30/2015 Philips Brilliance iCT Computed Tomography Cl II

Company: Philips Medical Systems (Cleveland) Inc
Date of Enforcement Report 12/30/2015
Class II:<p>
PRODUCT
Brilliance iCT Computed Tomography X-ray system
Recall NumberZ-0545-2016<p>
REASON
Perfusion scan feature may not be available on machines running software versions 4.1.2, 4.1.3, and 4.1.4. Customers previously using the basic axial perfusion software (versions preceding 4.1.2) without buying the helical perfusion license key could not access the basic axial perfusion feature after upgrading to software version 4.1.2.<p>
RECALLING FIRM/MANUFACTURER
Philips Medical Systems (Cleveland) Inc, Cleveland, OH on 10/29/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
51 units<p>
DISTRIBUTION
Worldwide<p>

12/30/2015 Philips Brilliance 64 Computed Tomography, Cl II

Company: Philips Medical Systems (Cleveland) Inc
Date of Enforcement Report 12/30/2015
Class II:<p>
PRODUCT
Brilliance 64 Computed Tomography X-ray system
Recall NumberZ-0544-2016<p>
REASON
Perfusion scan feature may not be available on machines running software versions 4.1.2, 4.1.3, and 4.1.4. Customers previously using the basic axial perfusion software (versions preceding 4.1.2) without buying the helical perfusion license key could not access the basic axial perfusion feature after upgrading to software version 4.1.2.<p>
RECALLING FIRM/MANUFACTURER
PPhilips Medical Systems (Cleveland) Inc, Cleveland, OH on 10/29/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
30 units<p>
DISTRIBUTION
Worldwide<p>

12/30/2015 Shimadzu Mobile x-ray, Cl II
Company: Shimadzu Medical Systems.
Date of Enforcement Report 12/30/2015
Class II:<p>
PRODUCT
Mobile X-ray system MobileDaRt Evolution/FDR Go Software
Recall NumberZ-0451-2016<p>
REASON
Shimadzu Corporation is recalling the Shimadzu Mobile X-ray system because an image may not transfer to image server properly...<p>
RECALLING FIRM/MANUFACTURER
Shimadzu Medical Systems, Torrence, CA on 11/10/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
297 units<p>
DISTRIBUTION
Nationwide and Canada<p>

12/23/2015 UniCel DxH 600 Coulter Cellular Analysis Sy, Cl II
Company: Beckman Coulter Inc..
Date of Enforcement Report 12/23/2015
Class II:<p>
PRODUCT
UniCel DxH 800 Coulter Cellular Analysis System, Software Version 3.0.2.0, Part No. 629029, B24465, B24802 The UniCel DxH 800/DxH 600 analyzers are quantitative, multi-parameter, automated hematology analyzers for in vitro diagnostic use in screening patient populations found in clinical laboratories. The DxH 800 is available as an analyzer for use on a benchtop or with a floor stand. The DxH 600 is available as an analyzer for use on a benchtop only.
Recall NumberZ-0432-2016<p>
REASON
Beckman Coulter is recalling the DxH 800 Slidemaker Stainer Software version 3.0.2.0 and DxH 600 software version 1.1.1.0 because the software for the DxH systems allows the creation of multiple orders with the same Specimen identification (ID) but different Patient identification when manually editing pending orders at the System Manager..<p>
RECALLING FIRM/MANUFACTURER
Beckman Coulter Inc., Brea, CA on 12/1/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
666 units total (327 units in US)<p>
DISTRIBUTION
Worldwide<p>

12/23/2015 UUniCel DxH 600 Coulter Cellular Analysiss, Cl II
Company: Beckman Coulter Inc..
Date of Enforcement Report 12/23/2015
Class II:<p>
PRODUCT
UniCel DxH 600 Coulter Cellular Analysis System, Software Version 3.0.2.0, Part No. 775222 The UniCel DxH 800/DxH 600 analyzers are quantitative, multi-parameter, automated hematology analyzers for in vitro diagnostic use in screening patient populations found in clinical laboratories. The DxH 800 is available as an analyzer for use on a benchtop or with a floor stand. The DxH 600 is available as an analyzer for use on a benchtop only.

Recall NumberZ-0433-2016<p>
REASON
Beckman Coulter is recalling the DxH 800 Slidemaker Stainer Software version 3.0.2.0 and DxH 600 software version 1.1.1.0 because the software for the DxH systems allows the creation of multiple orders with the same Specimen identification (ID) but different Patient identification when manually editing pending orders at the System Manager..<p>
RECALLING FIRM/MANUFACTURER
Beckman Coulter Inc., Brea, CA on 12/1/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
834 units total (594 units in US)<p>
DISTRIBUTION
Worldwide<p>

12/23/2015 UniCel DxH 800 Coulter Cellular Analysis, Cl
II
Company: Beckman Coulter Inc..
Date of Enforcement Report 12/23/2015
Class II:<p>
PRODUCT
UniCel DxH 800 Coulter Cellular Analysis System, Software Version 3.0.2.0, Part No. 629029, B24465, B24802 The UniCel DxH 800/DxH 600 analyzers are quantitative, multi-parameter, automated hematology analyzers for in vitro diagnostic use in screening patient populations found in clinical laboratories. The DxH 800 is available as an analyzer for use on a benchtop or with a floor stand. The DxH 600 is available as an analyzer for use on a benchtop only.
Recall NumberZ-0432-2016<p>
REASON
Beckman Coulter is recalling the DxH 800 Slidemaker Stainer Software version 3.0.2.0 and DxH 600 software version 1.1.1.0 because the software for the DxH systems allows the creation of multiple orders with the same Specimen identification (ID) but different Patient identification when manually editing pending orders at the System Manager..<p>
RECALLING FIRM/MANUFACTURER
Beckman Coulter Inc., Brea, CA on 12/1/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
3,951 units total (1,975 units in US)<p>
DISTRIBUTION
Worldwide<p>

12/23/2015 GE Healthcare Optima IGS 320, Cl II
Company: GE Medical Systems, LLC.
Date of Enforcement Report 12/23/2015
Class II:<p>
PRODUCT
GE Healthcare Optima IGS 320. Product Usage: The angiographic X-ray systems are indicated for use for patients from newborn to geriatric in generating fluoroscopic and rotational images of human anatomy for cardiovascular, vascular and non-vascular, diagnostic and interventional procedures. Additionally, with the OR table, the angiographic X-ray systems are indicated for use in generating fluoroscopic and rotational images of human anatomy for image-guided surgical procedures. The OR table is suitable for interventional and surgical procedures.
Recall NumberZ-0414-2016<p>
REASON
GE Healthcare has recently become aware of a potential safety issue related to a non-recoverable loss of displayed imaging (loss of monitor video) involving Optima CL323i & Optima IGS 320 systems .<p>
RECALLING FIRM/MANUFACTURER

GE Medical Systems, LLC, Waukesha, WI. on 11/13/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
45<p>
DISTRIBUTION
Nationwide and Internationally<p>

12/23/2015 GE Healthcare Optima CL323i, Cl II
Company: GE Medical Systems, LLC.
Date of Enforcement Report 12/23/2015
Class II:<p>
PRODUCT
GE Healthcare Optima CL323i Product Usage: The angiographic X-ray systems are indicated for use for patients from newborn to geriatric in generating fluoroscopic and rotational images of human anatomy for cardiovascular, vascular and non-vascular, diagnostic and interventional procedures. Additionally, with the OR table, the angiographic X-ray systems are indicated for use in generating fluoroscopic and rotational images of human anatomy for image-guided surgical procedures. The OR table is suitable for interventional and surgical procedures.
Recall NumberZ-0413-2016<p>
REASON
GE Healthcare has recently become aware of a potential safety issue related to a non-recoverable loss of displayed imaging (loss of monitor video) involving Optima CL323i & Optima IGS 320 systems .<p>
RECALLING FIRM/MANUFACTURER
GE Medical Systems, LLC, Waukesha, WI. on 11/13/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
108<p>
DISTRIBUTION
Nationwide and Internationally<p>

12/23/2015 MYLA CLI V3.X TO V4.1 ML350 SERVER, Cl II
Company: bioMerieux Inc.
Date of Enforcement Report 12/23/2015
Class II:<p>
PRODUCT
MYLA CLI V3.X TO V4.1 ML350 SERVER Product Usage: MYLA is a computer application (Middleware) based on Web 2.0 technology which: Interfaces between the instruments connected to the application and the LIS(s) (Laboratory Information System(s)).
Recall NumberZ-0431-2016<p>
REASON
MYLA® software connected to a Laboratory Information System (LIS) and a VITEK® 2 system has the potential to link a test result to an incorrect patient record with the same specimen ID..<p>
RECALLING FIRM/MANUFACTURER
bioMerieux Inc. Durham, NC on 11/3/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
626<p>
DISTRIBUTION
Worldwide<p>

12/23/2015 bioMerieuxMYLA CLI V3.X TO V4.1 DL380 SERVER CI II
Company: bioMerieux Inc.
Date of Enforcement Report 12/23/2015
Class II:<p>
PRODUCT
MYLA CLI V3.X TO V4.1 DL380 SERVER Product Usage: MYLA is a computer application (Middleware) based on Web 2.0 technology which: Interfaces between the instruments connected to the application and the LIS(s) (Laboratory Information System(s)).
Recall NumberZ-0430-2016<p>
REASON
MYLA® software connected to a Laboratory Information System (LIS) and a VITEK® 2 system has the potential to link a test result to an incorrect patient record with the same specimen ID..<p>
RECALLING FIRM/MANUFACTURER
bioMerieux Inc. Durham, NC on 11/3/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
626<p>
DISTRIBUTION
Worldwide<p>

12/23/2015 bioMerieux MYLA MASTER DVD V4.1 CLI, CI II
Company: bioMerieux Inc.
Date of Enforcement Report 12/23/2015
Class II:<p>
PRODUCT
MYLA MASTER DVD V4.1 CLI Product Usage: MYLA is a computer application (Middleware) based on Web 2.0 technology which: Interfaces between the instruments connected to the application and the LIS(s) (Laboratory Information System(s)).
Recall NumberZ-0429-2016<p>
REASON
MYLA® software connected to a Laboratory Information System (LIS) and a VITEK® 2 system has the potential to link a test result to an incorrect patient record with the same specimen ID..<p>
RECALLING FIRM/MANUFACTURER
bioMerieux Inc. Durham, NC on 11/3/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
626<p>
DISTRIBUTION
Worldwide<p>

12/23/2015 bioMerieux MYLA MASTER DVD V4.0 CLI, CI II
Company: bioMerieux Inc.
Date of Enforcement Report 12/23/2015
Class II:<p>
PRODUCT
MYLA MASTER DVD V4.0 CLI Product Usage: MYLA is a computer application (Middleware) based on Web 2.0 technology which: Interfaces between the instruments connected to the application and the LIS(s) (Laboratory Information System(s)).
Recall NumberZ-0428-2016<p>
REASON
MYLA® software connected to a Laboratory Information System (LIS) and a VITEK® 2 system has the potential to link a test result to an incorrect patient record with the same specimen ID..<p>

RECALLING FIRM/MANUFACTURER
bioMerieux Inc. Durham, NC on 11/3/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
626<p>
DISTRIBUTION
Worldwide<p>

12/23/2015 bioMerieux MYLA CLINIC PATCH 3.3.0 CD, CI II

Company: bioMerieux Inc.
Date of Enforcement Report 12/23/2015
Class II:<p>
PRODUCT
MYLA CLINIC PATCH 3.3.0 CD Product Usage: MYLA is a computer application (Middleware) based on Web 2.0 technology which: Interfaces between the instruments connected to the application and the LIS(s) (Laboratory Information System(s)).
Recall NumberZ-0427-2016<p>
REASON
MYLA® software connected to a Laboratory Information System (LIS) and a VITEK® 2 system has the potential to link a test result to an incorrect patient record with the same specimen ID..<p>
RECALLING FIRM/MANUFACTURER
bioMerieux Inc. Durham, NC on 11/3/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
626<p>
DISTRIBUTION
Worldwide<p>

12/23/2015 bioMerieux MYLA MASTER DVD 3.2, CI II

Company: bioMerieux Inc.
Date of Enforcement Report 12/23/2015
Class II:<p>
PRODUCT
MYLA MASTER DVD 3.2 CLI DL380 Product Usage: MYLA is a computer application (Middleware) based on Web 2.0 technology which: Interfaces between the instruments connected to the application and the LIS(s) (Laboratory Information System(s)).
Recall NumberZ-0426-2016<p>
REASON
MYLA® software connected to a Laboratory Information System (LIS) and a VITEK® 2 system has the potential to link a test result to an incorrect patient record with the same specimen ID..<p>
RECALLING FIRM/MANUFACTURER
bioMerieux Inc. Durham, NC on 11/3/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
626<p>
DISTRIBUTION
Worldwide<p>

12/23/2015 bioMerieux MYLA CLINIC PATCH 3.2.0 CI II

Company: bioMerieux Inc.
Date of Enforcement Report 12/23/2015
Class II:<p>
PRODUCT
MYLA CLINIC PATCH 3.2.0 CD Product Usage: MYLA is a computer application (Middleware) based on Web 2.0 technology which: Interfaces between the instruments connected to the application

and the LIS(s) (Laboratory Information System(s)).
Recall NumberZ-0425-2016<p>
REASON
MYLA® software connected to a Laboratory Information System (LIS) and a VITEK® 2 system has the potential to link a test result to an incorrect patient record with the same specimen ID..<p>
RECALLING FIRM/MANUFACTURER
bioMerieux Inc. Durham, NC on 11/3/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
626<p>
DISTRIBUTION
Worldwide<p>

12/23/2015 Philips Healthcare Ingenuity CT , Cl II
Company: Philips Electronics North America Corporation
Date of Enforcement Report 12/23/2015
Class II:<p>
PRODUCT
Philips Healthcare Ingenuity CT Computed Tomography X-ray system
Recall NumberZ-0408-2016<p>
REASON
During scans with specific protocol steps, the software unexpectedly sets the Axial (2 axis) scan length to a different length than the user set in the plan.<p>
RECALLING FIRM/MANUFACTURER
Philips Electronics North America Corporation, Andover, MA on 4/4/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
105<p>
DISTRIBUTION
Worldwide<p>

12/23/2015 Philips Healthcare Ingenuity Core 128, Cl II
Company: Philips Electronics North America Corporation
Date of Enforcement Report 12/23/2015
Class II:<p>
PRODUCT
Philips Healthcare Brilliance 64 Computed Tomography X-ray system
Recall NumberZ-0407-2016<p>
REASON
During scans with specific protocol steps, the software unexpectedly sets the Axial (2 axis) scan length to a different length than the user set in the plan.<p>
RECALLING FIRM/MANUFACTURER
Philips Electronics North America Corporation, Andover, MA on 4/4/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
105<p>
DISTRIBUTION
Worldwide<p>

12/23/2015 Philips Healthcare Ingenuity Core, Cl II
Company: Philips Electronics North America Corporation
Date of Enforcement Report 12/23/2015
Class II:<p>
PRODUCT

Philips Healthcare Ingenuity Core Computed Tomography X-ray system
Recall NumberZ-0406-2016<p>
REASON
During scans with specific protocol steps, the software unexpectedly sets the Axial (2 axis) scan length to a different length than the user set in the plan.<p>
RECALLING FIRM/MANUFACTURER
Philips Electronics North America Corporation, Andover, MA on 4/4/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
105<p>
DISTRIBUTION
Worldwide<p>

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12/23/2015 Philips Healthcare Brilliance 64, Cl II
Company: Philips Electronics North America Corporation
Date of Enforcement Report 12/23/2015
Class II:<p>
PRODUCT
Philips Healthcare Brilliance 64 Computed Tomography X-ray system
Recall NumberZ-0405-2016<p>
REASON
During scans with specific protocol steps, the software unexpectedly sets the Axial (2 axis) scan length to a different length than the user set in the plan.<p>
RECALLING FIRM/MANUFACTURER
Philips Electronics North America Corporation, Andover, MA on 4/4/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
7<p>
DISTRIBUTION
Worldwide<p>

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12/16/2015 GE Healthcare, Revolution CT, Cl II
Company: GE Medical Systems, LLC.
Date of Enforcement Report 12/16/2015
Class II:<p>
PRODUCT
GE Healthcare, Revolution CT Scanners. Revolution CT- The system is intended for head, whole body, cardiac and vascular X-ray Computed Tomography applications. The system is intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission projection data from the same axial plane taken at different angles.
Recall NumberZ-0401-2016<p>
REASON
GE Healthcare has recently become aware of a potential issue with routine head scans on your Revolution CT scanner. A potential hazardous situation can occur during a routine head scan with possible artifacts that may emulate pathology between the brain tissue and bone in the head images. No injuries have been reported to date related to this issue.<p>
RECALLING FIRM/MANUFACTURER
GE Medical Systems, LLC, Waukesha, WI. on 10/23/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
125 (US = 37; OUS = 88)<p>
DISTRIBUTION
Nationwide and Internationally<p>

12/16/2015 WalkMed Infusion Triton Infusion Pump, Cl II

Company:.WalkMed Infusion, LLC.
Date of Enforcement Report 12/16/2015
Class II:<p>
PRODUCT
WalkMed Infusion Triton Infusion Pump (model 300000). Packaged in a single pump box. Four pump boxes are place in an over-shipper for distribution.
Recall NumberZ-0369-2016<p>
REASON
WalkMed Infusion is conducting a field action on the Triton Infusion Pumps (model numbers 300000 and 400000) because of the potential for the device to deliver more than 25% over the target infusion rate.<p>
RECALLING FIRM/MANUFACTURER
WalkMed Infusion, LLC, Englewood, CO, on 11/3/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
2567<p>
DISTRIBUTION
Nationwide. No foreign or military/govt/VA consignees. <p>

12/16/2015 Visicu eCareManager system, Cl II

Company:.Visicu, Inc.
Date of Enforcement Report 12/16/2015
Class II:<p>
PRODUCT
The eCareManager system. Software intended for use in data collection, storage and clinical information management with independent bedside devices, and ancillary systems that are connected either directly or through networks. For use in a hospital environment. eCareManager allows clinicians to generate a PDF display of an order (new, change, discontinue), which is printed at the bedside and/or hospital pharmacy. This printed PDF should be reviewed by the clinician and verified by the hospital pharmacist and entered into the hospital pharmacy system. Recall NumberZ-0399-2016<p>
REASON
A software defect may cause incorrect medication order change. If the user decides to edit the order prior to electronic signature AND selects the return to Previous Screen function, the previously selected medication is replaced with whatever medication is in the number one spot on the complete medication list. At the stage where the order is signed, the medication displayed may be incorrect.<p>
RECALLING FIRM/MANUFACTURER
Visicu, Inc., Baltimore, MD, on 3/27/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
43<p>
DISTRIBUTION
Nationwide <p>

12/16/2015 Philips IntelliVue Information Center iX, Cl II

Company: Philips Medical System12/1610/28
Class II:<p>
PRODUCT
Philips IntelliVue Information Center iX (release A.00, A.01, and A.02) are impacted by this issue: 866023 IntelliVue Info Center iX 866024 PIIC iX Upgrade 866117 PIIC Classic Upgrade The intended use of the Information Center Software is to display physiologic waves, parameters, and trends, format data for strip chart recordings and printed reports, and provide the secondary annunciation of alarms from other networked medical devices at a centralized location. An additional intended use of the

Information Center Software is to provide primary annunciation of alarms and configuration and control access for networked telemetry monitors. Recall NumberZ-0374-2016<p>
REASON
Sp02 and/or Non Invasive Blood Pressure (NBP) alarms may become disabled without visual notification<p>
RECALLING FIRM/MANUFACTURER
Philips Medical Systems, Inc., Andover, MA on 12/19/2014. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
10,013 units<p>
DISTRIBUTION
Worldwide<p>

12/9/2015 Carl Zeiss IOL Master 500, Cl II
Company:.Carl Zeiss Meditec AG.
Date of Enforcement Report 12/9/2015
Class II:<p>
PRODUCT
IOL Master 500: Software versions 7.5 and 7.7; Ophthalmic: IOL Master 500 is intended for biometric determination of ocular measurements of axial length, anterior chamber depth, corneal radius, white-to white (WTW), and for the measurement of pupil size and deviation of the visual axis from the center of the pupil.
Recall NumberZ-0358-2016<p>
REASON
IOL Master software versions 7.5 and 7.7 calculation printouts and exported reports can contain the wrong IOL power data.<p>
RECALLING FIRM/MANUFACTURER
Carl Zeiss Meditec AG, Jena, DE on 10/27/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
1882<p>
DISTRIBUTION
Nationwide <p>

12/9/2015 Carl Zeiss IOL Master 5.5, Cl II
Company:.Carl Zeiss Meditec AG.
Date of Enforcement Report 12/9/2015
Class II:<p>
PRODUCT
IOL Master 5.5: Software versions 7.5 and 7.7; Ophthalmic: used to obtain ocular measurements and perform calculations to allow physicians to determine appropriate IOL power and type for implantation.
Recall NumberZ-0357-2016<p>
REASON
IOL Master software versions 7.5 and 7.7 calculation printouts and exported reports can contain the wrong IOL power data.<p>
RECALLING FIRM/MANUFACTURER
Carl Zeiss Meditec AG, Jena, DE on 10/27/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
49<p>
DISTRIBUTION
Nationwide <p>

12/2/2015 Ingenia, Intera, Achieva and Achieve dStream
Cl II
Company: Philips Medical Systems, Inc.
Date of Enforcement Report 12/2/2015
Class II:<p>
PRODUCT
Ingenia, Intera, Achieva and Achieve dStream MR systems on Software versions R5.1.7 and R5.1.8 with the Mobi View software option. Diagnostic imaging system.
Recall NumberZ-0325-2016<p>
REASON
When a fused series of a sagittal, coronal or radial multi station scan is generated in MobiView, the resultant image order is reversed. This occurs with software release R5.1.7/R5.1.8.<p>
RECALLING FIRM/MANUFACTURER
Philips Medical Systems, Inc., Andover, MA on 8/21/2014. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
307<p>
DISTRIBUTION
Worldwide<p>

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12/2/2015 Siemens Syngo Imaging, VB36D_HF02 Cl II
Company: Siemens Medical Solutions USA, Inc.
Date of Enforcement Report 12/2/2015
Class II:<p>
PRODUCT
Syngo Imaging VB36D_HF02. Radiological image processing system.
Recall NumberZ-0319-2016<p>
REASON
To provide supplementary information regarding the release of the syngo Imaging Software Version VB36D_HF02. The software provides improvements for all syngo Imaging installations running on the software Version VB36D.<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Malvern, PA on 10/28/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
3<p>
DISTRIBUTION
US Distribution to the states of : NC, NE and OH.<p>

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12/2/2015 NxStage System One S Cycler NX1000-4, Cl II
Company:.NxStage Medical, Inc.
Date of Enforcement Report 12/2/2015
Class II:<p>
PRODUCT
NxStage System One S Cycler -High Permeability Hemodialysis System Model no. NX1000-4. Recall NumberZ-0337-2016<p>
REASON
Ultrafiltration Volume (UFV) may not decrease during treatment-software error. The UF pump may continue to run and remove fluid even after the target UF volume has been removed<p>
RECALLING FIRM/MANUFACTURER
NxStage Medical, Inc., Lawrence, MA on 10/29/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
7<p>

DISTRIBUTION
Nationwide and Internationally<p>

12/2/2015 NxStage System One S Cycler NX1000-3-A, Cl II

Company:.NxStage Medical, Inc.
Date of Enforcement Report 12/2/2015
Class II:<p>
PRODUCT
NxStage System One S Cycler - Model no. NX1000-3-A. For home hemodialysis.
Recall NumberZ-0336-2016<p>
REASON
Ultrafiltration Volume (UFV) may not decrease during treatment-software error. The UF pump may continue to run and remove fluid even after the target UF volume has been removed<p>
RECALLING FIRM/MANUFACTURER
NxStage Medical, Inc., Lawrence, MA on 10/29/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
133 units<p>
DISTRIBUTION
Nationwide and Internationally<p>

12/2/2015 NxStage System One S Cycler NX1000-3, Cl II

Company:.NxStage Medical, Inc.
Date of Enforcement Report 12/2/2015
Class II:<p>
PRODUCT
NxStage System One S Cycler - Model no. NX1000-3. For home hemodialysis.
Recall NumberZ-0335-2016<p>
REASON
Ultrafiltration Volume (UFV) may not decrease during treatment-software error. The UF pump may continue to run and remove fluid even after the target UF volume has been removed<p>
RECALLING FIRM/MANUFACTURER
NxStage Medical, Inc., Lawrence, MA on 10/29/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
2,134 units<p>
DISTRIBUTION
Nationwide and Internationally<p>

12/2/2015 NxStage System One S Cycler Model NX100-5A Cl II

Company:.NxStage Medical, Inc.
Date of Enforcement Report 12/2/2015
Class II:<p>
PRODUCT
NxStage System One S Cycler (High Permeability Hemodialysis System) Model no. NX1000-5-A
Recall NumberZ-0327-2016<p>
REASON
Ultrafiltration (UF) Volume software error inaccurate fluid removal<p>
RECALLING FIRM/MANUFACTURER
NxStage Medical, Inc., Lawrence, MA on 10/29/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
16 units<p>
DISTRIBUTION

Nationwide and Internationally<p>

12/2/2015 NxStage System One S Cycler 1000-5, Cl II
Company:.NxStage Medical, Inc.
Date of Enforcement Report 12/2/2015
Class II:<p>
PRODUCT
NxStage System One S Cycler (High Permeability Hemodialysis System) Model no. NX1000-5 Recall NumberZ-0326-2016<p>
REASON
Ultrafiltration (UF) Volume software error inaccurate fluid removal<p>
RECALLING FIRM/MANUFACTURER
NxStage Medical, Inc., Lawrence, MA on 10/29/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
323<p>
DISTRIBUTION
Nationwide and Internationally<p>

12/2/2015 HeartStart MRx Monitor/Defibrillator Cl II
Company:Philips Electronics North America Corporation.
Date of Enforcement Report 12/2/2015
Class II:<p>
PRODUCT
Philips HeartStart MRx Monitor/Defibrillator; M3535A, M3536A, M3536J, M3536M, M3536MC, M3536M2, M3536M4, M3536M5, M3536M6. For use for the termination of ventricular tachycardia and ventricular fibrillation.
Recall NumberZ-0320-2016<p>
REASON
The following MRx software issue has been identified: MRx model M3535A with software version F.03.06 and earlier, and model M3536A with version T.00.05 and earlier may stop the automated Ready-For-Use (RFU) test in an abnormal state when the device is turned off.<p>
RECALLING FIRM/MANUFACTURER
Philips Electronics North America Corporation. on 10/14/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
81,161<p>
DISTRIBUTION
Nationwide and Internationally<p>

11/25/2015 AGFA IMPAX, PACS,, Cl II
Company: AGFA Healthcare Corp.
Date of Enforcement Report 11/25/2015
Class II:<p>
PRODUCT
IMPAX, PACS, Picture Archive and Communications System, IMPAX CV 7.8.x and IMPAX CV 12.x. Corrects certain demographic information (Patient Name, Patient Medical Record Number and/or Accession Number in previously signed reports that have since changed.
Recall NumberZ-0283-2016<p>
REASON
Customers have experienced IMPAX CV software, specifically, Demographics Manager (DM), not producing correct pdf reports after the reports, at the time of physician signature, were correct.<p>
RECALLING FIRM/MANUFACTURER
AGFA Healthcare Corp, Greenville, SC on 9/1/2015. Voluntary: Firm Initiated recall is ongoing. <p>

VOLUME OF PRODUCT IN COMMERCE
19<p>
DISTRIBUTION
Distributed in the states of CA, KY, NH, NY, NC, OH, OR, PA, SC, SD, TN, TX, WA and the country of Canada.<p>

11/25/2015 BrainLAB Image Guided Surgery Cl II
Company: Brainlab AG
Date of Enforcement Report 11/25/2015
Class II:<p>
PRODUCT
BrainLAB Image Guided Surgery (IGS) System, Stereotaxic Instrument navigation software, Cranial ENT version 2.1, and Spine and Trauma 3D versions 2.0 and 2.1 An intraoperative image-guided localization system to enable minimally invasive surgery.
Recall NumberZ-0282-2016<p>
REASON
nstances of data sets not being accurately registered to the patient anatomy were observed.<p>
RECALLING FIRM/MANUFACTURER
Brainlab AG Feldkirchen, DE on 5/8/2015 Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
12 systems total (10 in U.S., 2 in Australia)<p>
DISTRIBUTION
US and Australia<p>

11/18/2015 CARESCAPE VC150 Vital Signs Monitor, Cl II
Company: Innokas Medical Oy.
Date of Enforcement Report 11/18/2015
Class II:<p>
PRODUCT
CARESCAPE VC150 Vital Signs Monitor Monitor vital signs in humans
Recall NumberZ-0264-2016<p>
REASON
Monitor may shut down unintentionally without restarting.<p>
RECALLING FIRM/MANUFACTURER
Innokas Medical Oy. Kempele, FI on 10/22/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
756<p>
DISTRIBUTION
Nationwide and Internationally<p>

11/18/2015 Siemens MODULARIS VARIOSTAR Cl II
Company: Siemens Medical Solutions USA, Inc.
Date of Enforcement Report 11/18/2015
Class II:<p>
PRODUCT
MODULARIS VARIOSTAR; Lithotripter device designed to treat urolithiasis.
Recall NumberZ-0265-2016<p>
REASON
Display freeze of MODULARIS hand control results in information not being updated on the display. Current treatment data is not shown to the user.<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Malvern, PA on 9/24/2015. Voluntary: Firm Initiated recall is

ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
15<p>
DISTRIBUTION
Distributed in PR and the states of MO, NC, GA, MS, LA, and KY<p>

11/18/2015 GE Healthcare, SIGNA PET/MR 3.0T Cl II
Company: GE Healthcare.
Date of Enforcement Report 11/18/2015
Class II:<p>
PRODUCT
GE Healthcare, SIGNA PET/MR 3.0T. Product Usage: The SIGNA PET/MR system combines magnetic resonance diagnostic devices (MRDD) and Positron Emission Tomography (PET) scanners that provide registration and fusion of high-resolution physiologic and anatomic information, acquired simultaneously and isocentrically. The combined system maintains independent functionality of the MR and PET devices, allowing for single modality MR and / or PET imaging. These systems are intended to be utilized by appropriately trained health care professionals to aid in the detection, localization, and diagnosis of diseases and disorders. The MR is intended to produce transverse, sagittal, coronal and oblique cross-sectional MR images, spectroscopic images and/or spectra, and displays the internal structure and/or function of the human body. Other physical parameters derived from the images and/or spectra may also be produced. Depending on the region of interest, approved contrast agents may be used, as described in their labeling. This system may also be used for imaging during interventional procedures when performed with MR compatible devices, such as MR safe biopsy needles. The PET images and measures the distribution of PET radiopharmaceuticals in humans to aid the physician in determining various metabolic (molecular) and physiologic functions within the human body for evaluation of diseases and disorders such as, but not limited to, cardiovascular disease, neurological disorders and cancer. The combined system utilizes the MR for radiation-free attenuation correction maps for PET studies. The system provides inherent anatomical reference for the fused PET and MR images due to precisely aligned MR and PET image coordinate systems.
Recall NumberZ-0260-2016<p>
REASON
When performing head or neck scans, the currently displayed SAR values could be lower than the actual SAR in the head as predicted by SAR modeling. The predicted HEAD SAR value from the modeling suggests the actual SAR in the head could exceed IEC60601-2-33 limit of 3.2 W/kg for some scans.<p>
RECALLING FIRM/MANUFACTURER
GE Healthcare, Waukesha, WI. on 8/31/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
17<p>
DISTRIBUTION
Nationwide and Internationally<p>

11/18/2015 GE Healthcare, SIGNA HDxt 3.0T., Cl II
Company: GE Healthcare.
Date of Enforcement Report 11/18/2015
Class II:<p>
PRODUCT
GE Healthcare, SIGNA HDxt 3.0T. Product Usage: The 1.5T Signa HDx family and 3.0T Signa HDx family are a whole body magnetic resonance scanner for use as a diagnostic imaging device.
Recall NumberZ-0259-2016<p>
REASON
When performing head or neck scans, the currently displayed SAR values could be lower than the actual SAR in the head as predicted by SAR modeling. The predicted HEAD SAR value from the

modeling suggests the actual SAR in the head could exceed IEC60601-2-33 limit of 3.2 W/kg for some scans.<p>
RECALLING FIRM/MANUFACTURER
GE Healthcare, Waukesha, WI. on 8/31/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
215<p>
DISTRIBUTION
Nationwide and Internationally<p>

11/18/2015 GE Healthcare, SIGNA HDx 3.0T, Cl II
Company: GE Healthcare.
Date of Enforcement Report 11/18/2015
Class II:<p>
PRODUCT
GE Healthcare, SIGNA HDx 3.0T. Product Usage: The GE Signa HDx MR system is a whole body magnetic resonance scanner for use as a diagnostic imaging device.
Recall NumberZ-0258-2016<p>
REASON
When performing head or neck scans, the currently displayed SAR values could be lower than the actual SAR in the head as predicted by SAR modeling. The predicted HEAD SAR value from the modeling suggests the actual SAR in the head could exceed IEC60601-2-33 limit of 3.2 W/kg for some scans.<p>
RECALLING FIRM/MANUFACTURER
GE Healthcare, Waukesha, WI. on 8/31/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
350<p>
DISTRIBUTION
Nationwide and Internationally<p>

11/18/2015 GE Healthcare, SIGNA HD 3.0T, Cl II
Company: GE Healthcare.
Date of Enforcement Report 11/18/2015
Class II:<p>
PRODUCT
GE Healthcare, SIGNA HD 3.0T. Product Usage: The Signa Profile EXCITE MR system is an open, whole body scanner for use as a diagnostic imaging device. It may be utilized for imaging during interventional procedures when performed with MR compatible devices such as in-room display and MR safe biopsy needles.
Recall NumberZ-0257-2016<p>
REASON
When performing head or neck scans, the currently displayed SAR values could be lower than the actual SAR in the head as predicted by SAR modeling. The predicted HEAD SAR value from the modeling suggests the actual SAR in the head could exceed IEC60601-2-33 limit of 3.2 W/kg for some scans.<p>
RECALLING FIRM/MANUFACTURER
GE Healthcare, Waukesha, WI. on 8/31/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
97<p>
DISTRIBUTION
Nationwide and Internationally<p>

11/18/2015 GE Healthcare, SIGNA Excite 3.0T., Cl II
Company: GE Healthcare.
Date of Enforcement Report 11/18/2015
Class II:<p>
PRODUCT
GE Healthcare, SIGNA Excite 3.0T. MR System for use as a diagnostic imaging device.
Recall NumberZ-0256-2016<p>
REASON
When performing head or neck scans, the currently displayed SAR values could be lower than the actual SAR in the head as predicted by SAR modeling. The predicted HEAD SAR value from the modeling suggests the actual SAR in the head could exceed IEC60601-2-33 limit of 3.2 W/kg for some scans.<p>
RECALLING FIRM/MANUFACTURER
GE Healthcare, Waukesha, WI. on 8/31/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
55<p>
DISTRIBUTION
Nationwide and Internationally<p>

11/18/2015 GE Healthcare, SIGNA 3.0T, Cl II
Company: GE Healthcare.
Date of Enforcement Report 11/18/2015
Class II:<p>
PRODUCT
GE Healthcare, SIGNA 3.0T. Product Usage: Magnetic resonance system for diagnostic imaging. The indications for use for the 3.0T Signa VH/i (Signa 3.0T MR System) Transmit/Receive Body Imaging Coil expands the imaging capability of the 3.0T Signa VH/i MR Imaging System. The Transmit/Receive Body Imaging Coil is intended for imaging of the Neck, Spine, Abdomen/Thorax and the extremities.
Recall NumberZ-0255-2016<p>
REASON
When performing head or neck scans, the currently displayed SAR values could be lower than the actual SAR in the head as predicted by SAR modeling. The predicted HEAD SAR value from the modeling suggests the actual SAR in the head could exceed IEC60601-2-33 limit of 3.2 W/kg for some scans.<p>
RECALLING FIRM/MANUFACTURER
GE Healthcare, Waukesha, WI. on 8/31/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
19<p>
DISTRIBUTION
Nationwide and Internationally<p>

11/18/2015 GE Healthcare, Discovery MR750w, Cl II
Company: GE Healthcare.
Date of Enforcement Report 11/18/2015
Class II:<p>
PRODUCT
GE Healthcare, Discovery MR750w 3.0T. Product Usage: The Discovery MR750 3.0T, Discovery MR450 1.5T, Discovery MR750w 3.0T and the Optima MR450w 1.5T Systems are whole body magnetic resonance scanners for diagnostic imaging.
Recall NumberZ-0254-2016<p>
REASON
When performing head or neck scans, the currently displayed SAR values could be lower than the actual SAR in the head as predicted by SAR modeling. The predicted HEAD SAR value from the

modeling suggests the actual SAR in the head could exceed IEC60601-2-33 limit of 3.2 W/kg for some scans.<p>
RECALLING FIRM/MANUFACTURER
GE Healthcare, Waukesha, WI. on 8/31/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
756<p>
DISTRIBUTION
Nationwide and Internationally<p>

11/16/2015 Hamilton G5 Ventilator, Class I
Company: Hamilton.Medical
Date of Enforcement Report 8/26/2015
Class I:<p>
PRODUCT
The G5 ventilator provides breathing support for adult, children, infant and newborn patients. The device is intended for use in hospital and other health care facilities. It may be used for transport within a hospital or health care facility.<p>
REASON
The ventilator may stop working, without sounding an alarm, when the device operator presses the oxygen enrichment key to attach the ventilator mask to the patient (suctioning maneuver).
This problem can occur during the following conditions:
When pressing the oxygen enrichment key a second time within 50 milliseconds after the disconnection is detected, or,
When disconnection is detected immediately before the oxygen enrichment period automatically ends, so that detection of disconnection and termination of O2-enrichment occur within 50 milliseconds of each other.
If the device operator does not intervene, the patient may not receive enough oxygen and could suffer serious adverse health consequences, including injury or death.
The firm has received a total of 1 report of device malfunction. No injuries or deaths were reported. <p>
RECALLING FIRM/MANUFACTURER
Hamilton Medical., Recall initiated 4/22/2104<p>

11/11/2015 Triton Smart Ankle iOS Galileo applcation,
Cl II
Company: Otto Bock Healthcare GmbHG
Date of Enforcement Report 11/11/2015
Class II:<p>
PRODUCT
iOS Galileo Application Version 1.1.1 or lower that programs the Triton Smart Ankle; 1C66* Triton Smart Ankle. Recall NumberZ-0209-2016<p>
REASON
Otto Bock Healthcare GmbH has identified a software issue where the foot can produce an undesired response (can move into dorsiflexion) unnoticed by the user. This could potentially result in a fall. In addition, when sitting, the prosthetic foot 1C66 Triton smart ankle can go into the so called Relief Function to move the footplate towards the ground. When operating machines with foot pedals (e.g. driving a car) the possibility exists that the foot could get stuck under the foot pedal and block it or, if the foot is on top of the pedal, it could cause the vehicle to accelerate unintentionally, leading to a hazardous situation.<p>
RECALLING FIRM/MANUFACTURER
Otto Bock Healthcare GmbH, Duderstadt, DE on 10/23/2015 Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
273 in US: 48 Foreign<p>

DISTRIBUTION
Worldwide Distribution - US (nationwide) and to the countries of : Austria, Belgium, Germany, Israel, Luxembourg and Sweden.<p>

11/11/2015 GE Centricity Universal Viewer Cl II
Company: GE Healthcare.
Date of Enforcement Report 11/11/2015
Class II:<p>
PRODUCT
The Centricity Universal Viewer Version is a device that displays medical images (including mammograms) and data from various imaging sources. Images and data can be viewed, communicated, processed and displayed within the system or across computer networks at distributed locations. Typical users of this system are trained professionals, including but not limited to radiologists, physicians, nurses, medical technicians, and assistants.
Recall NumberZ-0226-2016<p>
REASON
Inaccurate distance measurements with magnified projection X-ray images.<p>
RECALLING FIRM/MANUFACTURER
GE Healthcare, Barrington, IL on 9/28/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
Centricity Universal Viewer versions 6.0 and higher 5 units<p>
DISTRIBUTION
Nationwide and Internationally<p>

11/11/2015 GE Centricity PACS IW Cl II
Company: GE Healthcare.
Date of Enforcement Report 11/11/2015
Class II:<p>
PRODUCT
The Centricity PACS-IW with Universal Viewer is a device that displays medical images (including mammograms) and data from various imaging sources. Images and data can be viewed, communicated, processed and displayed within the system or across computer networks at distributed locations. Typical users of this system are trained professionals, including but not limited to radiologists, physicians, nurses, medical technicians, and assistants.Recall NumberZ-0225-2016<p>
REASON
Inaccurate distance measurements with magnified projection X-ray images.<p>
RECALLING FIRM/MANUFACTURER
GE Healthcare, Barrington, IL on 9/28/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
Centricity PACS-IW with Universal Viewer Versions 5.0 SP2 and higher 1052 units<p>
DISTRIBUTION
Nationwide and Internationally<p>

11/11/2015 Brainlab Digital Lightbox, Cl II
Company: Brainlab AG
Date of Enforcement Report 11/11/2015
Class II:<p>
PRODUCT
Digital Lightbox, BrainLAB system, image processing, radiological Product Usage: The Patient Data Manager is a system intended for the display of medical images. The software can transfer images to and from picture archiving and communication systems (PACS), file servers, or removable storage media. It includes functions for image manipulation, basic measurements and 3D visualization (reconstructions and volume rendering). Features for navigation planning include multi-modality image

fusion as well as object and trajectory creation. It is not intended for primary image diagnosis or the review of mammographic images. Recall NumberZ-0218-2016<p>
REASON
Potentially incorrectly displayed objects when actively deselecting a fused reference dataset<p>
RECALLING FIRM/MANUFACTURER
Brainlab AG Feldkirchen, DE on 9/21/2015 Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
897<p>
DISTRIBUTION
Worldwide<p>

11/11/2015 Ortho VITROS 5,1 FS Chemistry System Cl II
Company: Ortho-Clinical Diagnostics
Date of Enforcement Report 11/11/2015
Class II:<p>
PRODUCT
VITROS 5,1 FS Chemistry System, Catalog Number/Product Code 6801375, Unique Device Identifier No. 10758750001132, and VITROS 5,1 FS Chemistry System Refurbished, Catalog Number/Product Code 6801890, Unique Device Identifier No. 10758750001644. Intended for use in the in vitro quantitative measurement of a variety of analytes of clinical interest. Recall NumberZ-0231-2016<p>
REASON
Software Anomaly during ADD Installation on VITROS 5,1 FS Chemistry Systems using Software Versions 2.2.1 through 2.8<p>
RECALLING FIRM/MANUFACTURER
Ortho-Clinical Diagnostics, rochester, NY on 9/10/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
Catalog # 6801375: Domestic 919; Foreign 1251; Catalog 6801890: Domestic 63, Foreign 147<p>
DISTRIBUTION
Nationwide and Internationally.<p>

11/11/2015 AMSCO Small Steam Sterilizers, Cl II
Company: Steris Corporation
Date of Enforcement Report 11/11/2015
Class II:<p>
PRODUCT
AMSCO 400 and AMSCO C Small Steam Sterilizers
Recall NumberZ-0210-2016<p>
REASON
In AMSCO Small Steam Sterilizers equipped with the CS-iQ feature, the sterilizer software inadvertently prevents the capability to operate the foot pedal, which allows the Operator to open and close the sterilizer door..<p>
RECALLING FIRM/MANUFACTURER
Steris Corporation, Mentor, OH on 9/3/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
32 units<p>
DISTRIBUTION
Nationwide<p>

11/11/2015 HeartStart MRx monitor/defibrillator Cl II
Company: Philips Medical Systems, Inc.
Date of Enforcement Report 11/11/2015
Class II:<p>
PRODUCT

HeartStart MRx monitor/defibrillator Models M3535A, M3536A, M3536J, M3536M, M3536MC, M3536M2, M3536M4, M3536M5, M3536M6 Product Usage: The HeartStart MRx is for use for the termination of ventricular tachycardia and ventricular fibrillation. The device is for use by qualified medical personnel trained in the operation of the device and qualified by training in basic life support, advanced cardiac support, or defibrillation. It must be used by or on the order of a physician
Recall NumberZ-0219-2016<p>
REASON
MRx monitor/defibrillator could reboot at an indeterminate time, potentially causing therapy to be interrupted or delayed.<p>
RECALLING FIRM/MANUFACTURER
Philips Medical Systems, Inc., Andover, MA on 12/23/2014. Voluntary: Firm Initiated recall is ongoing.
<p>
VOLUME OF PRODUCT IN COMMERCE
75,693 units<p>
DISTRIBUTION
Worldwide<p>

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11/11/2015 Philips HeartStart MRx, Cl II
Company: Philips Medical Systems, Inc.
Date of Enforcement Report 11/11/2015
Class II:<p>
PRODUCT
Philips HeartStart MRx Monitor/Defibrillators Models: M3535A and M3536A
Recall NumberZ-0204-2016<p>
REASON
1. Device will perform the weekly automated tests hourly, which could cause the therapy capacitors to degrade sooner than intended and 2. While connected to AC or DC power and with no battery installed or the battery installed has a charge level of less than 10%, the Ready for Use (RFU) indicator will not provide the expected low battery indication.<p>
RECALLING FIRM/MANUFACTURER
Philips Medical Systems, Inc., Andover, MA on 11/19/2014. Voluntary: Firm Initiated recall is ongoing.
<p>
VOLUME OF PRODUCT IN COMMERCE
1553 units<p>
DISTRIBUTION
Worldwide<p>

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11/4/2015 Elekta Monaco - Radiation Treatment Plannin,
Cl II
Company:Elekta Inc.
Date of Enforcement Report: 11/4/2015
Class II:<p>
PRODUCT
Monaco - Radiation Treatment Planning used to make treatment plans for patients with prescriptions for external beam radiation therapy.
Recall NumberZ-0181-2016<p>
REASON
Unintended update of Dose and MU and Incorrect Assignment of Bolus.<p>
RECALLING FIRM/MANUFACTURER
Elekta Inc., Atlanta, GA on 10/16/2015 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
154<p>
DISTRIBUTION

CA, IN, MI,MO, TX, WI, Australia, Canada, Germany,m Greece, India, Netherlands, New Zealand, Turkey and United Kingdom<p>

11/4/2015 Varian ARIA Radiation Oncology, Cl II
Company:Natus Neurology Inc.
Date of Enforcement Report: 11/4/2015
Class II:<p>
PRODUCT
ARIA Radiation Oncology, versions 10, 11 , 13.0 and 13.5 with Clinical Assessment License. Model number HIT Product Usage: ARIA Radiation Oncology is a treatment plan and image management application. It enables the authorized user to enter, access, modify, store and archive treatment plan and image data from diagnostic studies, treatment planning, simulation, plan verification and treatment. ARIA Radiation Oncology also stores the treatment histories, including dose delivered to defined sites, and provides tools to verify performed treatments.
Recall NumberZ-0170-2016<p>
REASON
An anomaly was identified with the ARIA for Radiation Oncology software with a Clinical Assessment license. Admin Instructions may not print on drug order prescriptions or be transmitted with e-Rx..<p>
RECALLING FIRM/MANUFACTURER
Natus Neurology Inc., Middleton, WI on 9/28/2015 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
1971<p>
DISTRIBUTION
Nationwide and Internationally<p>

11/4/2015 Siemens ACUSON SC2000 Ultrasound Cl II
Company:Siemens Medical Solutions USA, Inc.
Date of Enforcement Report: 11/4/2015
Class II:<p>
PRODUCT
ACUSON SC2000 ultrasound systems model 10433816 Imaging system that provides the ability to measure anatomical structures and calculation packages that provide info for clinical diagnosis purposes.Recall NumberZ-0182-2016<p>
REASON
Siemens will provide all customers a new version of system software (VA35E or VB10C depending on the hardware configuration). Hardware fixes will be implemented to address situations where the metal component used to engage the wheel lock becomes disconnected, and where the system locks up due to misalignment between the bezel and MPI board, in all units that have not already been corrected.<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Mountainview, CA on 10/7/2015 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
2,099 units<p>
DISTRIBUTION
Nationwide and Internationally<p>

11/4/2015 Siemens CIOS ALPHA,Cl II
Company:Siemens Medical Solutions USA, Inc.
Date of Enforcement Report: 11/4/2015
Class II:<p>
PRODUCT
CIOS ALPHA; image intensified fluoroscopic x-ray system
Recall NumberZ-0118-20166<p>

REASON
patient procedure interruption due to a potential system failure<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Malvern, PA on 8/7/2015 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
44<p>
DISTRIBUTION
Nationwide<p>

11/4/2015 Perkin Elmer Specimen Gate, Cl II
Company:Perkin Elmer Life Sciences Inc.
Date of Enforcement Report 11/4/2015
Class II:<p>
PRODUCT
Perkin Elmer Specimen Gate, Screening Center. Data management of neonatal screening test results and demographics by qualified laboratory personnel in newborn screening programs.Recall Number Z-0166-2016<p>
REASON
It would be possible for an abnormal analytical test result value from an affected newborn to be reported with a default result interpretation of normal. The analytical test result value would be correct but the interpretation of the test result value would be incorrect.<p>
RECALLING FIRM/MANUFACTURER
Perkin Elmer Life Sciences Inc., Turku, FL on 8/26/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
6 units<p>
DISTRIBUTION
US distribution to FL, GA, and NV; and Canada<p>

10/28/2015 Philips MR systems using R5.1i & R5.1 .2 SW, Cl II
Company: Philips Medical Systems, Inc.
Date of Enforcement Report 10/28/2015
Class II:<p>
PRODUCT
All Philips Ingenia, Intera, Achieva and Multiva MR systems using R5.1i and R5.1 .2 version of software. Indicated for use as a diagnostic device. It can produce cross-sectional images, spectroscopic images and/or spectra in any orientation of the internal structure of the head, body, or extremities. Recall NumberZ-0135-2016<p>
REASON
In spine clinical workflows, cross reference lines may be used to determine the position of slices. In cases, where MobiView fused Images are used to show the cross reference lines, the cross reference lines may be positioned incorrectly.<p>
RECALLING FIRM/MANUFACTURER
Philips Medical Systems, Inc., Andover, MA on 5/5/2014. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
317<p>
DISTRIBUTION
Worldwide<p>

10/21/2015 Natus NicoletOne Software, Cl II
Company:Natus Neurology Inc.
Date of Enforcement Report: 10/21/2015
Class II:<p>
PRODUCT
NicoletOne Software v5.94, Catalog/Part Number: 482-649600. The NicoletOne data acquisition and review system, either with or without synchronous digital video. The system is intended for medical purposes to record, measure, store and display full band (FbEEG) cerebral EEG and extracerebral activity for Clinical EEG, Electrocorticography (EcOG), Long Term Monitoring (LTM), Intensive Care Unit (ICU) monitoring and Polysomnography (PSG) Sleep studies. While the Nicolet Neurodiagnostic systems are capable of displaying signals, such as Sp02 and EKG, the system is NOT intended for monitoring such signals for the preservation of life, The Nicolet Neurodiagnostic systems are intended to acquire, analyze, and display data. Recall NumberZ-0117-2016<p>
REASON
Natus Neurology has discovered that when using he NicoletOne v5.94 software, after exiting the impedance check function and returning to the EEG screen, the impedance check signal remains active in waveform, obscuring the EEG signals.<p>
RECALLING FIRM/MANUFACTURER
TNatus Neurology Inc., Middleton, WI on 9/11/2015 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
101 (88 US, 13 OUS)<p>
DISTRIBUTION
Nationwide and Internationally<p>

10/21/2015 Toshiba Aquilion CT System TSX-303A, Cl II
Company:Toshiba American Medical Systems Inc.
Date of Enforcement Report: 10/21/2015
Class II:<p>
PRODUCT
Toshiba Aquilion CT System TSX-303A
Recall NumberZ-0018-2016<p>
REASON
it was found that if two specific operations are performed in multi-phase helical scanning, the acquired raw data may not be saved.<p>
RECALLING FIRM/MANUFACTURER
Toshiba American Medical Systems Inc., Tustin, CA on 5/8/2015 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
459<p>
DISTRIBUTION
Nationwide and Puerto Rico<p>

10/21/2015 Toshiba Aquilion CT System TSX-302A, Cl II
Company:Toshiba American Medical Systems Inc.
Date of Enforcement Report: 10/21/2015
Class II:<p>
PRODUCT
Toshiba Aquilion CT System TSX-302A Recall Number Z-0017-2016<p>
REASON
it was found that if two specific operations are performed in multi-phase helical scanning, the acquired raw data may not be saved.<p>
RECALLING FIRM/MANUFACTURER
Toshiba American Medical Systems Inc., Tustin, CA on 5/8/2015 Voluntary: Firm Initiated recall is

ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
459<p>
DISTRIBUTION
Nationwide and Puerto Rico<p>

10/21/2015 Toshiba Aquilion CT System TSX-301C, Cl II
Company:Toshiba American Medical Systems Inc.
Date of Enforcement Report: 10/21/2015
Class II:<p>
PRODUCT
Toshiba Aquilion CT System TSX-301C
Recall NumberZ-0016-2016<p>
REASON
it was found that if two specific operations are performed in multi-phase helical scanning, the acquired raw data may not be saved.<p>
RECALLING FIRM/MANUFACTURER
Toshiba American Medical Systems Inc., Tustin, CA on 5/8/2015 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
459<p>
DISTRIBUTION
Nationwide and Puerto Rico<p>

10/21/2015 Toshiba Aquilion CT System TSX-301B, Cl II
Company:Toshiba American Medical Systems Inc.
Date of Enforcement Report: 10/21/2015
Class II:<p>
PRODUCT
Toshiba Aquilion CT System TSX-301B Recall Number Z-0015-2016<p>
REASON
it was found that if two specific operations are performed in multi-phase helical scanning, the acquired raw data may not be saved.<p>
RECALLING FIRM/MANUFACTURER
Toshiba American Medical Systems Inc., Tustin, CA on 5/8/2015 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
459<p>
DISTRIBUTION
Nationwide and Puerto Rico<p>

10/21/2015 Toshiba Aquilion CT System TSX-301A, Cl II
Company:Toshiba American Medical Systems Inc.
Date of Enforcement Report: 10/21/2015
Class II:<p>
PRODUCT
Toshiba Aquilion CT System TSX-101A Recall Number Z-0013-2016<p>
REASON
it was found that if two specific operations are performed in multi-phase helical scanning, the acquired raw data may not be saved.<p>
RECALLING FIRM/MANUFACTURER
Toshiba American Medical Systems Inc., Tustin, CA on 5/8/2015 Voluntary: Firm Initiated recall is ongoing <p>

VOLUME OF PRODUCT IN COMMERCE
459<p>
DISTRIBUTION
Nationwide and Puerto Rico<p>

10/21/2015 Toshiba Aquilion CT System TSX-101A, Cl II
Company:Toshiba American Medical Systems Inc.
Date of Enforcement Report: 10/21/2015
Class II:<p>
PRODUCT
Toshiba Aquilion CT System TSX-101A Recall Number Z-0013-2016<p>
REASON
it was found that if two specific operations are performed in multi-phase helical scanning, the acquired raw data may not be saved.<p>
RECALLING FIRM/MANUFACTURER
Toshiba American Medical Systems Inc., Tustin, CA on 5/8/2015 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
459<p>
DISTRIBUTION
Nationwide and Puerto Rico<p>

10/14/2015 Monaco Radiation Treatment Planning System, Cl II
Company:Elekta, Inc.
Date of Enforcement Report: 10/14/2015
Class II:<p>
PRODUCT
Monaco Radiation Treatment Planning System. Used to make treatment plans for patients with prescriptions for external beam radiation therapy.
Recall NumberZ-0112-2016<p>
REASON
Dose and MU are incorrect when CT images are viewed from the head, and, when using multiple prescriptions with forced densities..<p>
RECALLING FIRM/MANUFACTURER
Elekta, Inc., Altanta, GA on 9/15/2015 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
154 units<p>
DISTRIBUTION
Nationwide and Internationally.<p>

10/14/2015 GE Centricity PACS IW, Cl II
Company: GE Healthcare.
Date of Enforcement Report 10/14/2015
Class II:<p>
PRODUCT
Centricity PACS IW by GE Healthcare Dynamic Imaging Solutions is a device that receives medical images (including mammograms) and data from various imaging sources. Images and data can be stored, communicated, processed and displayed within the system or across computer networks at distributed locations.
Recall NumberZ-0023-2016<p>
REASON
IImages may be missing when a system parameter MapRoute is set to a value greater than 1.<p>

RECALLING FIRM/MANUFACTURER
GE Healthcare, Barrington, IL on 9/16/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
921 systems are impacted.<p>
DISTRIBUTION
Nationwide and Internationally<p>

10/14/2015 Siemens SOMATOM Force Cl II
Company:Siemens Medical Solutions USA, Inc.
Date of Enforcement Report: 10/14/2015
Class II:<p>
PRODUCT
SOMATOM Force; computed tomography x-ray system. Intended to generate and process cross-sectional images of patients. Recall NumberZ-0107-2016<p>
REASON
Software and firmware bugs<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Malvern, PA on 8/18/2015 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
21<p>
DISTRIBUTION
Nationwide<p>

10/14/2015 Siemens SOMATOM Definition AS, Cl II
Company:Siemens Medical Solutions USA, Inc.
Date of Enforcement Report: 10/14/2015
Class II:<p>
PRODUCT
SOMATOM Definition AS, intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data from either the same axial plane taken at different angles or spiral planes taken at different angles.
Recall NumberZ-0021-2016<p>
REASON
software bug issues for SW-Version VA48A_SP0. The following safety issues were resolved: 1) Correction to improve visual warning and error indication son the gantry display. 2) Correction to improve acquisition data in order to optimize image quality. 3) Correction to improve robustness and general system behavior in some exception handling procedures. 4) Correction to improve auto post processing coupled to Twin Beam examinations. 5) Correction to assure proper communication between system components. 6) Correction to improve robustness of ECG triggering.<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Malvern, PA on 8/14/2015 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
113 total<p>
DISTRIBUTION
Nationwide<p>

10/14/2015 Siemens SOMATOM Definition Flash, Cl II
Company:Siemens Medical Solutions USA, Inc.
Date of Enforcement Report: 10/14/2015
Class II:<p>
PRODUCT

SOMATOM Definition Flash; intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data from either the same axial plane taken at different angles or spiral planes taken at different angles.
Recall NumberZ-0020-2016<p>
REASON
software bug issues for SW-Version VA48A_SP0. The following safety issues were resolved: 1) Correction to improve visual warning and error indication son the gantry display. 2) Correction to improve acquisition data in order to optimize image quality. 3) Correction to improve robustness and general system behavior in some exception handling procedures. 4) Correction to improve auto post processing coupled to Twin Beam examinations. 5) Correction to assure proper communication between system components. 6) Correction to improve robustness of ECG triggering.<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Malvern, PA on 8/14/2015 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
113 total<p>
DISTRIBUTION
Nationwide<p>

10/14/2015 Siemens SOMATOM Definition Edge, Cl II
Company:Siemens Medical Solutions USA, Inc.
Date of Enforcement Report: 10/14/2015
Class II:<p>
PRODUCT
SOMATOM Definition Edge; intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data from either the same axial plane taken at different angles or spiral planes taken at different angles.
Recall NumberZ-0019-2016<p>
REASON
software bug issues for SW-Version VA48A_SP0. The following safety issues were resolved: 1) Correction to improve visual warning and error indication son the gantry display. 2) Correction to improve acquisition data in order to optimize image quality. 3) Correction to improve robustness and general system behavior in some exception handling procedures. 4) Correction to improve auto post processing coupled to Twin Beam examinations. 5) Correction to assure proper communication between system components. 6) Correction to improve robustness of ECG triggering.<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Malvern, PA on 8/14/2015 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
113 total<p>
DISTRIBUTION
Nationwide<p>

10/14/2015 Siemens Syngo RT Oncologist, Cl II
Company:Siemens Medical Solutions USA, Inc.
Date of Enforcement Report: 10/14/2015
Class II:<p>
PRODUCT
Syngo RT Oncologist, an optional accessory to the linear accelerator system and permits localization, contouring, segmentation, image review, and review and approval of treatment plan parameters. In addition, it includes tools and administrative functions to aid in the diagnosis, staging, and prescription of radiation therapy.
Recall NumberZ-0106-2016<p>

REASON
This update is intended to provide a software update for the Syngo RT Oncologist, which is currently running SW version 4.2 or 4.3. The safety-related issues, which were described in the Customer Safety Notice distributed as UFSN-RTT/RTO 4.3 Adaptive Targeting [Auto-registration]. The update contains several important safety and performance fixes.<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Malvern, PA on 8/11/2015 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
14<p>
DISTRIBUTION
US Distribution to states of: MA, MO, OH, PA, UT, and WI.<p>

10/14/2015 Toshiba Celesteion PCA-9000A/2 PET/CT, Cl II

Company: Toshiba American Medical Systems Inc.
Date of Enforcement Report 10/14/2015
Class II:<p>
PRODUCT
Celesteion PCA-9000A/2 PET/CT System
Recall NumberZ-0005-2016<p>
REASON
It was found that if specific operations are performed in multi-phase helical scanning, the acquired raw data may not be saved due to a software problem.<p>
RECALLING FIRM/MANUFACTURER
Toshiba American Medical Systems Inc, Tustin, CA on 5/8/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
1<p>
DISTRIBUTION
Nevada<p>

10/7/2015 Soundstar Diagnostic Ultrasound Catheters, Cl II

Company: Biosense Webster, Inc.
Date of Enforcement Report 10/7/2015
Class II:<p>
PRODUCT
SOUNDSTAR eco 8F and 10F Diagnostic Ultrasound Catheters. For intra-cardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart.
Recall NumberZ-0003-2016<p>
REASON
Image disappeared from the cardiac ultrasound system when the CARTO 3 EP Navigation System needed restarting while the patient was experiencing pericardial effusion. Affects the CARTOSOUND Module of the CARTO 3 EP Navigation System when used with the SOUNDSTAR eco 8F and 10F Diagnostic Ultrasound Catheters. New precautions added.<p>
RECALLING FIRM/MANUFACTURER
Biosense Webster, Inc., Irwindale, CA on 9/10/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
1035 (U.S.)<p>
DISTRIBUTION
Nationwide and Internationally<p>

10/7/2015 Carto 3 EP Navigation System, Cl II
Company: Biosense Webster, Inc.
Date of Enforcement Report 10/7/2015
Class II:<p>
PRODUCT
Carto 3 EP Navigation System. Electro physiology system which views of the electrical activity of the heart through real-time data on 3-D, color-coded cardiac maps.
Recall NumberZ-0002-2016<p>
REASON
Image disappeared from the cardiac ultrasound system when the CARTO 3 EP Navigation System needed restarting while the patient was experiencing pericardial effusion. Affects the CARTOSOUND Module of the CARTO 3 EP Navigation System when used with the SOUNDSTAR eco 8F and 10F Diagnostic Ultrasound Catheters. New precautions added.<p>
RECALLING FIRM/MANUFACTURER
Biosense Webster, Inc., Irwindale, CA on 9/10/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
1035 (U.S.)<p>
DISTRIBUTION
Nationwide and Internationally<p>

9/30/2015 Siemens linear accelerator systems: Cl II
Company:Siemens Medical Solutions USA, Inc.
Date of Enforcement Report: 9/30/2015
Class II:<p>
PRODUCT
ARTISTE, ONCOR Avantgarde, ONCOR Impression Plus, ONCOR Expression, PRIMUS, PRIMUS Plus, Syngo RT Therapist; therapeutic treatment of cancer Product Usage: The intended use of the SIEMENS branded ARTISTE and ONCOR family of linear accelerator systems is to deliver X-Ray photon and electron radiation for the therapeutic treatment of cancer. PRIMUSTM family of linear accelerator systems is to deliver x-ray radiation for therapeutic treatment of cancer. Syngo RT Therapist is a software application whose indication for use includes the viewing, processing, filming, and archiving of medical images. It also permits patient data management, patient selection/setup, patient positioning verification, treatment planning, treatment delivery/verification, and treatment recording.
Recall NumberZ-2812-2015<p>
REASON
A software fix has been released to prevent automatic movement resulting in a collision safety risk for patients.<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Malvern, PA on 8/6/2015 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
26<p>
DISTRIBUTION
Nationwide and Internationally<p>

9/30/2015 Beckman Coulter MicroScan LabPro, Cl II
Company: Beckman Coulter Inc.
Date of Enforcement Report 9/30/2015
Class II:<p>
PRODUCT
MicroScan LabPro Information Manager System, Version 1.0 to Version 4.11, Catalog No. 10714149, 10714150. Intended to manage both microbial identification (ID) and antimicrobial agent susceptibility

testing (AST).
Recall NumberZ-2809-2015<p>
REASON
Beckman Coulter is recalling the MicroScan LabPro Information Manager System because the software incorrectly allows the operator to manually edit the carbohydrate substrates when manually reading dried overnight gram negative panels with an ID Hold status.<p>
RECALLING FIRM/MANUFACTURER
Beckman Coulter Inc., Brea, CA on 7/17/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
2,456 units total (1,034 units total)<p>
DISTRIBUTION
Worldwide<p>

9/23/2015 Medtronic CryoConsole, Cl II
Company: Medtronic Inc. Cardiac Rhythm Disease Management
Date of Enforcement Report 9/23/2015
Class II:<p>
PRODUCT
Medtronic CryoConsole, models 106A3, 106E2, and 106A2-K For use in performing cardiac ablation procedures. Recall NumberZ-2777-2015<p>
REASON
Medtronic has identified an issue with a USB memory component contained within a subset of CryoConsoles. The issue can result in extended procedure time.<p>
RECALLING FIRM/MANUFACTURER
Medtronic Inc. Cardiac Rhythm Disease Management, Saint Paul, MN on 9/1/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
106 units<p>
DISTRIBUTION
Worldwide..<p>

9/23/2015 Siemens ACUSON SC2000 Ultrasound: Cl II
Company:Siemens Medical Solutions USA, Inc.
Date of Enforcement Report: 9/23/2015
Class II:<p>
PRODUCT
ACUSON SC2000 Ultrasound System with software versions VB10B and lower; Model 10433816; Product Usage: The SC2000 ultrasound imaging system is intended for the following applications: Cardiac, Neo-natal and Fetal Cardiac, Pediatric, Transespohageal, Adult Cephalic, Peripheral Vessel, Abdominal, Abdominal Intraoperative, Intraoperative Neurological, Musculo-skeletal Conventional, and Musculo-skeletal Superficial applications. The system also provides the ability to measure anatomical structures and calculation packages that provide information to the clinician that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes.
Recall NumberZ-2783-2015<p>
REASON
The ACUSON SC2000 ultrasound system considers uppercase/lowercase differences in the same patient name as unique patient instances when registered on the same ultrasound system. If these differences are not corrected at the time of registration, the system does not capture images or clips.<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Mountainview, CA on 8/19/2015 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE

2039 devices<p>
DISTRIBUTION
Nationwide and Internationally<p>

9/23/2015 Bayer Injector, Angiographic, Cl II
Company: Bayer Healthcare
Date of Enforcement Report 9/23/2015
Class II:<p>
PRODUCT
Injector, Angiographic; Medrad® Mark 7 Arterion® Injection System; to be used specifically for the purposes of injecting contrast medium and common flushing solutions into humans for angiographic studies. Recall NumberZ-2775-2015<p>
REASON
Certain Medrad® Mark 7 Arterion® Injection Systems, which utilize Software Version SW 005.006_SH, have a potential situation involving the purge enforcement procedure. This recent software revision has resulted in the removal of purge enforcement from traditional New-Case, Power Up and Syringe Change use cases while the injector head is in the upright position. No injuries reported.<p>
RECALLING FIRM/MANUFACTURER
Bayer Healthcare, Indianola, PA on 8/4/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
71<p>
DISTRIBUTION
Nationwide and Internationally.<p>

9/16/2015 Mindray Patient Monitor, Cl II
Company: Mindray DS USA, Inc. dba Mindray North America
Date of Enforcement Report 9/16/2015
Class II:<p>
PRODUCT
Multi Parameter Patient Monitor (with Arrhythmia Detection and Alarms) Intended to be used for monitoring, displaying, reviewing, storing and alarming of multiple physiological parameters including ECG (3-lead or 5-lead selectable), arrhythmia detection, ST Segment analysis, and heart rate.
Recall NumberZ-2737-2015<p>
REASON
Mindray has identified an issue where the DPM 7 Monitor may display a black screen.<p>
RECALLING FIRM/MANUFACTURER
Mindray DS USA, Inc. dba Mindray North America, Mahwah, NJ on 7/27/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
13 units<p>
DISTRIBUTION
Distributed to the states of CT, IA, KY, MS, PA, UT and WA..<p>

9/16/2015 CDI 500 Blood Parameter Monitoring System, Cl II
Company: Terumo Cardiovascular Systems Corporation
Date of Enforcement Report 9/16/2015
Class II:<p>
PRODUCT
CDI 500 Blood Parameter Monitoring System. Provides continuous, on-line monitoring of the extracorporeal partial pressure of oxygen and and carbon dioxide, pH, potassium, oxygen saturation, hematocrit, hemoglobin and temperature.
Recall NumberZ-2742-2015<p>

REASON
Inaccuracies in SvO2, temperature, pH, pCO2, pO2, Hematocrit, and Potassium readings following a software upgrade to version 1.69.<p>
RECALLING FIRM/MANUFACTURER
Terumo Cardiovascular Systems Corporation, Ann Arbor, MI on 8/7/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
4638<p>
DISTRIBUTION
Nationwide and Internationally.<p>

9/10/2015 Insulet Corporation OmniPod, Class I
Company: Insulet Corporation
Date of Enforcement Report: 9/10/2015
Class I:<p>
PRODUCT
The OmnniPod Insulin Management System is an insulin pump used to deliver insulin to people with diabetes. The insulin pump ?Pod? is a small adhesive pump that sticks directly on the body. Insulin is delivered through a small port holding a tube that is inserted into the skin.<p>
REASON
Insulet has identified two issues with these devices.
The tube either fails to fully insert into the skin or completely retracts after insertion. This failure occurs without an alarm and the Pod will continue to pump insulin.
The Pod will provide an audible alarm signal and display a failure. Once the alarm occurs, the Pod will not pump insulin.
Both failures can result in inaccurate dosage of insulin which can lead to high blood sugar (hyperglycemia). If left untreated, hyperglycemia can cause life-threatening conditions or even death. The firm has received nine reports in which the device has malfunctioned, including five injuries and no reports of deaths.<p>
RECALLING FIRM/MANUFACTURER
Insulet Corporationon, Billerica, MA 7/13/2015.Voluntary: Firm Initiated recall is ongoing.<p>
FDA District: Los Angeles<p>

9/9/2015 RayStation Radiation Therapy Treatment SW, Cl II
Company:RAYSEARCH LABORATORIES AB
Date of Enforcement Report: 9/9/2015
Class II:<p>
PRODUCT
Radiation Therapy Treatment Planning System software RayStation is a software system designed for treatment planning and analysis of radiation therapy. The treatment plans provide treatment unit set-up parameters and estimates of dose distributions expected during the proposed treatment, and may be used to administer treatments after review and approval by the intended user. Recall Number Z-2785-2015<p>
REASON
An error caused by a floating point precision problem tends to cause a problem with the display of isodose lines for dose and dose difference and color tables for dose, dose difference and PET images<p>
RECALLING FIRM/MANUFACTURER
RAYSEARCH LABORATORIES AB, Stockholm, SE on 5/29/2015 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
20<p>

DISTRIBUTION
State of WA and intenationally<p>

9/9/2015 SiemensSyngo.plaza: Cl II
Company:Siemens Medical Solutions USA, Inc.
Date of Enforcement Report: 9/9/2015
Class II:<p>
PRODUCT
Syngo.plaza; picture archiving and communications system Product Usage: Syngo.plaza is a Picture Archiving and Communication System (PACS) intended to display, process, read, report, communicate, distribute, store and archive digital medical images. It supports the physician in diagnosis and treatment planning. Syngo.plaza also supports storage and archiving of DICOM Structured reports. In a comprehensive imaging syngo.plaza integrates Hospital/Radiology Information Systems (HIS/RIS) to enable customer specific workflows. Syngo.plaza optionally uses a variety of advanced postprocessing applications.
Recall NumberZ-2719-2015<p>
REASON
Potential issue leading to data loss and patient data mix-up<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Malvern, PA on 7/6/2015 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
37<p>
DISTRIBUTION
Nationwide<p>

9/9/2015 Transonic Flow Probes, Cl II
Company: Transonic Systems Inc
Date of Enforcement Report 9/9/2015
Class II:<p>
PRODUCT
Transonic Flow Probes. Product Usage: to measure flow intra-operatively
Reacll number 2720-2729.<p>
REASON
Inaccuracies in SvO2, temperature, pH, pCO2, pO2, Hematocrit, and Potassium readings following a software upgrade to version 1.69.<p>
RECALLING FIRM/MANUFACTURER
Transonic Systems Inc, ithaca, NY on 7/27/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
<p>
DISTRIBUTION
Nationwide and Internationally.<p>

9/9/2015 Ortho VITROS 5,1 FS Chemistry System, Cl II
Company: Ortho-Clinical Diagnostics
Date of Enforcement Report 9/9/2015
Class II:<p>
PRODUCT
VITROS 5,1 FS Chemistry System, Catalog Number/Product Code 6801375, Unique Device Identifier No. 10758750001132, and VITROS 5,1 FS Chemistry System Refurbished, Catalog Number/Product Code 6801890, Unique Device Identifier No. 10758750001644, IVD --- Ortho Clinical Diagnostics Inc. The VITROS 5,1 FS Chemistry System with enGEN(TM) Laboratory Automation System is intended for use in the in vitro quantitative measurement of a variety of analytes of clinical interest, using both

VITROS Chemistry Products Slides (colorimetric endpoint, rate, ion-selective electrode, and immunorate methods) and VITROS Chemistry Products MicroTip liquid reagents (spectrophotometric and spectrophotometric immunoassay methods.)
Recall NumberZ-2544-2015<p>
REASON
Software anomaly may occur during the installation of an Assay Data Diskette (ADD) using Software Versions 2.2.1 through 2.8. If the user is utilizing User- Configured (Modified) parameters, ALL default settings are restored in the VITROS 5,1 FS Chemistry System from the ADD instead of retaining the user modified parameters<p>
RECALLING FIRM/MANUFACTURER
TOrtho-Clinical Diagnostics, rochester, NY on 6/30/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
Catalog # 6801375: Domestic 919; Foreign 1251; Catalog 6801890: Domestic 63, Foreign 147<p>
DISTRIBUTION
Nationwide and Internationally.<p>

9/2/2015 Philips DigitalDiagnost, Cl II
Company: Philips Electronics North America Corporation
Date of Enforcement Report 9/2/2015
Class II:<p>
PRODUCT
Philips DigitalDiagnost Release 4.0.3, Release 4.1/4.1.1. excluding systems with SP1 Product Usage: The DigitalDiagnost is intended for use in generating radiographic images of human anatomy by qualified/trained doctors or technicians.
Recall NumberZ-2383-2015<p>
REASON
The system is designed to emit a beep upon termination of an exposure. However, if the system has been powered on for over 12 hours, the system will no longer emit this signal due to a defect in the Microsoft Windows 7 operating system.<p>
RECALLING FIRM/MANUFACTURER
Philips Electronics North America Corporation, Andover, MA on 3/23/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
62<p>
DISTRIBUTION
US Nationwide Distribution to the states of : Arizona, Minnesota, State of Washington, Wyoming and Ohio. Internationally to Canada.<p>

9/2/2015 Guardian Real-Time Monitor, Cl II
Company:Medtronic MiniMed Inc..
Date of Enforcement Report: 9/2/2015
Class II:<p>
PRODUCT
Guardian Real-Time Monitor, Model No. CSS7100. Indicated for continuous or periodic monitoring of glucose levels in the fluid under the skin, in adults (18 years and older) with diabetes mellitus, for the purpose of improving diabetes management.
Recall NumberZ-2442-2015<p>
REASON
Medtronic MiniMed is recalling the Guardian Real-Time Continuous Glucose Monitoring System because it has a language translation error that impacts the Finnish language. Specifically, the Monitor has a Finnish translation error in Predictive Alerts setting: the on-screen Finnish translation for LOW/HIGH is reversed as HIGH/LOW.<p>
RECALLING FIRM/MANUFACTURER

Medtronic MiniMed Inc., Northridge, CA on 7/22/2015 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
254 units<p>
DISTRIBUTION
Finland<p>

9/2/2015 GE Centricity Universal Viewer, Cl II
Company:GE Healthcare.
Date of Enforcement Report: 9/2/2015
Class II:<p>
PRODUCT
Centricity Universal Viewer Product Usage: The Centricity Universal Viewer Version 6.0 software is a picture archiving and communications system, a device that provides one or more capabilities relating to the acceptance, transfer, display, storage, and digital processing of medical images. Its hardware components may include workstations, digitizers, communications devices, computers, video monitors, magnetic, optical disk, or other digital data storage devices, and hardcopy devices. The software components may provide functions for performing operations related to image manipulation, enhancement, compression or quantification. Used in Radiology.<p>
REASON
Images from the Centricity PACS-IW with Universal Viewer and Centricity Universal Viewer may be missing when a system parameter MapRoute is set to a value greater than 1.<p>
RECALLING FIRM/MANUFACTURER
GE Healthcare, Barrington, IL on 8/11/2015 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
26 systems<p>
DISTRIBUTION
Nationwide and Internationally<p>

9/2/2015 GE Centricity PACS-IW, Cl II
Company:GE Healthcare.
Date of Enforcement Report: 9/2/2015
Class II:<p>
PRODUCT
Centricity PACS-IW with Universal Viewer Product Usage: The Centricity PACS-IW with Universal Viewer is a picture archiving and communications system, a device that provides one or more capabilities relating to the acceptance, transfer, display, storage, and digital processing of medical images. Its hardware components may include workstations, digitizers, communications devices, computers, video monitors, magnetic, optical disk, or other digital data storage devices, and hardcopy devices. The software components may provide functions for performing operations related to image manipulation, enhancement, compression or quantification. Used in Radiology.
Recall NumberZ-2469-2015<p>
REASON
Images from the Centricity PACS-IW with Universal Viewer and Centricity Universal Viewer may be missing when a system parameter MapRoute is set to a value greater than 1.<p>
RECALLING FIRM/MANUFACTURER
GE Healthcare, Barrington, IL on 8/11/2015 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
82 systems<p>
DISTRIBUTION
Nationwide and Internationally<p>

9/2/2015 Brainlab ExacTrac 6.0.x, Cl II
Company:Brainlab AG
Date of Enforcement Report: 9/2/2015
Class II:<p>
PRODUCT
ExacTrac 6.0.x Patient Positioning System, Radiation therapy. Intended to be used to place patients at an accurately defined point within the treatment beam of a medical accelerator for stereotactic radiosurgery or radiotherapy procedures.
Recall NumberZ-2440-2015<p>
REASON
ExacTrac 6.0 Patient Positioning System: Display of potentially incorrect Digitally Reconstructed Radiograph (DRR) for x-ray correction and verification.<p>
RECALLING FIRM/MANUFACTURER
Brainlab AG on 8/7/2015, Feldkirchen, DE on 8/5/2015. Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
361 systems<p>
DISTRIBUTION
Nationwide and Internationally<p>

9/2/2015 CARESTREAM DRX-EVOLUTION X-Ray system, Cl II
Company:Carestream Health Inc.
Date of Enforcement Report: 9/2/2015
Class II:<p>
PRODUCT
CARESTREAM DRX-EVOLUTION X-Ray System Product Usage: The device is a permanently installed diagnostic X-ray system for general radiographic x-ray imaging including tomography. The tomography feature is not to be used for imaging pediatric patients. Recall NumberZ-2449-2015<p>
REASON
Carestream became aware of an issue with its DRX Evolution System v5.7 DIRECTVIEW Software v5.6 and v5.7. It has been determined that there is a software defect that impacts image alignment when using the automatic stitching option for long length images. The defect could cause stitching inconsistencies which may go undetected on a radiograph.<p>
RECALLING FIRM/MANUFACTURER
Carestream Health Inc, Rochester, NY on 8/7/2015 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
Domestic: 76 units, Foreign: 160 units<p>
DISTRIBUTION
Nationwide and Internationally<p>

9/2/2015 Nidek OPD-Scan III, Cl II
Company:Nidek Inc.
Date of Enforcement Report: 9/2/2015
Class II:<p>
PRODUCT
OPD-Scan III Refractive Power/Corneal Analyzer Opthalmic Software versions 1.00.08 1.05.07 1.10.01, 1.01.02 1.06.02 1.11.02, 1.02.01 1.07.01 1.12.03, 1.03.02 1.08.01 1.13.01, 1.04.03 1.09.01. Opthalmic: The OPD-Scan III is a diagnostic instrument that is indicated for use for Mapping of refractive error distribution of the eye by measurement and analysis of spherical power, cylindrical power, and cylinder axis.
Recall NumberZ-2477-2015<p>
REASON
Software bug was found where there was no difference in Total and Corneal high-order aberrations, but

differences were found in Internal high-order aberrations.<p>
RECALLING FIRM/MANUFACTURER
Nidek Inc, Freeman, CA on 6/15/2015 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
3836<p>
DISTRIBUTION
Nationwide<p>

9/2/2015 RayStation 4.7, version 4.7.1,Cl II
Company:RAYSEARCH LABORATORIES AB
Date of Enforcement Report: 8/26/2015
Class II:<p>
PRODUCT
RayStation 4.7, version 4.7.1, used with Structure Definition or Automatic Breast Planning. Radiation Therapy Treatment Planning System, for treatment planning and analysis of radiation therapy. Recall NumberZ-2457-2015<p>
REASON
Issue with the algorithm for ROI contraction in RayStation 4.7 when non-uniform contraction distances are used. The ROI contraction tool uses six distances as input: right/left, inferior/superior and posterior/anterior. These contraction distances are, in error, pairwise reversed, i.e. right is interpreted as left, inferior is interpreted as superior, and posterior is interpreted as anterior.<p>
RECALLING FIRM/MANUFACTURER
RAYSEARCH LABORATORIES AB, Stockholm, SE on 5/27/2015 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
126 programs<p>
DISTRIBUTION
Distributed in CO, IL, MI, NC, OH,TN, and WA<p>

8/26/2015 Siemens Artis zee/ zeego systems: Cl II
Company:Siemens Medical Solutions USA, Inc.
Date of Enforcement Report: 8/26/2015
Class II:<p>
PRODUCT
Artis zee/ zeego systems; dedicated angiography systems developed for single and biplane diagnostic imaging and interventional procedures including, but not limited to, pediatric and obese patients. Recall NumberZ-2404-2015<p>
REASON
in case a system error occurs and the system enters the "Bypass Fluoro" mode while the X-ray locking function is active, the only way to exit the X-ray locking function, would be to either resolve the root cause of the system being in "Bypass Fluoro" or to restart the system..<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Malvern, PA on 6/30/2015 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
986<p>
DISTRIBUTION
Nationwide<p>

8/26/2015 Alaris Syringe Pump, Model No. 8110, Class I
Company: CareFusion 303, Inc.
Date of Enforcement Report 8/26/2015
Class I:<p>
PRODUCT
Alaris Syringe Pump, Model No. 8110. Delivers fluids.
Recall NumberZ-2362-2015<p>
REASON
Channel Error code is displayed on the PC unit with an audio and visual alarm, and on the syringe module. After the error is cleared on the PCU, the syringe pump is unresponsive to key presses until the next power cycle, or the module is detached and reattached..<p>
RECALLING FIRM/MANUFACTURER
CareFusion 303, Inc., San Diego CA on 7/21/2015.Voluntary: Firm Initiated recall is ongoing.<p>
VOLUME OF PRODUCT IN COMMERCE
7418 units <p>
DISTRIBUTION
Nationwide and Internationally
FDA District: Los Angeles<p>

8/26/2015 Covidien, Puritan Bennett 980 Ventilators, Class I
Company: Covidien LP
Date of Enforcement Report 8/262015
Class I:<p>
PRODUCT
Puritan Bennett 980 Ventilator System, Universal (with neonatal functionality enabled) and Neonatal Models. Designed for use on Neonatal (NICU) through Adult patient populations who require respiratory support or mechanical ventilation and weigh a minimum of 0.3 kg (0.66 lb). Recall Number Z-2329-2015<p>
REASON
Reports in which tidal volumes reaching patients were lower than set tidal volumes in neonatal Volume Control Plus (VC+) Mode with active humidification. This situation may potentially lead to respiratory compromise if not recognized.<p>
RECALLING FIRM/MANUFACTURER
Covidien LP (now part of Medtronic, formerly Nellcor Puritan Bennett, Inc), Boulder, CO on 7/16/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
657 units <p>
DISTRIBUTION
Worldwide <p>

8/19/2015 BIOTRONIK Pacemaker Programmer software, Cl II
Company: BIOTRONIK Inc..
Date of Enforcement Report 8/19/2015
Class II:<p>
PRODUCT
PSW 1203.U/1, PSW 1301.U, PSW 1307.U, PSW 1403.U, and PSW 1501.U Pacemaker Programmer software. Software approved for use with BIOTRONIK device programmers (trade names: Renamic and ICS 3000). Allows physicians to program devices to pace exclusively in the left ventricle. Recall Number Z-2376-2015<p>
REASON
Ventricular packing: LV software programming versions for BIOTRONIK CRT-P and CRT-D devices are

recalled because they are not approved for use in the US.<p>
RECALLING FIRM/MANUFACTURER
BIOTRONIK, Inc., Lake Oswego, OR on 6/30/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
768 units (software) <p>
DISTRIBUTION
Nationwide <p>

8/12/2015 Philips Philips HeartStart XL+ Defibrillator Cl II

Company: Philips Electronics North America Corporation
Date of Enforcement Report 8/12/2015
Class II:<p>
PRODUCT
Philips HeartStart XL+ Defibrillator/Monitor Product Usage: The HeartStart XL+ is intended for use in a hospital setting by qualified medical personnel trained in the operation of the device and qualified by training in basic life support, advanced life support or defibrillation. When operating as a semi-automatic external defibrillator in AED Mode, the HeartStart XL+ is suitable for use by medical personnel trained in basic life support that includes the use of an AED. When operating in Monitor, Manual Defibrillation or Pacing modes, the HeartStart XL+ is suitable for use by healthcare professionals trained in advance life support.
Recall NumberZ-2328-2015<p>
REASON
Multiple software and hardware issues with device that can affect its function..<p>
RECALLING FIRM/MANUFACTURER
hilips Electronics North America Corporation, Andover, MA on 6/5/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
13,168 devices<p>
DISTRIBUTION
Nationwide and Internatonally <p>

8/5/2015 McKesson Paragon Laboratory Management, Cl II

Company: McKesson Technologies, Inc.
Date of Enforcement Report 8/5/2015
Class II:<p>
PRODUCT
Paragon Laboratory Management. Recall Number Z-2263-2015<p>
REASON
For Paragon Laboratory Management 12.1 and 12.1.1 releases, if used with Microsoft SQL Server 2012, the Final Cumulative Report may incorrectly display the data.<p>
RECALLING FIRM/MANUFACTURER
McKesson Technologies, Inc., Charlotte, NC on 6/15/2014. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
128 <p>
DISTRIBUTION
Nationwide <p>

8/5/2015 Philips: Ingenuity CT scanners, Cl II
Company: Philips Medical Systems, Inc.
Date of Enforcement Report 8/5/2015
Class II:<p>
PRODUCT
Computed Tomography X-ray Systems Ingenuity CT scanners. Intended to produce cross-sectional images of the body by computer reconstruction of X-ray transmission data taken at different angles and planes. Recall NumberZ-2259-2015<p>
REASON
The following issues were discovered through internal testing: · Fast Get Ready incorrectly enabled during service procedures. · Contrast annotation incorrectly missing for some images when manual contrast was administered. · Dot artifact present, intermittently, after startup. · Heart Rate measured value incorrectly remains constant for some heart rate change conditions. · Tube heat predictor fails to warn of overheat condition for long scans.<p>
RECALLING FIRM/MANUFACTURER
Philips Medical Systems, Inc.,Cleveland, OH on 2/5/2015. Voluntary: Firm Initiated recall is ongoing.
<p>
VOLUME OF PRODUCT IN COMMERCE
159 units <p>
DISTRIBUTION
Nationwide and Internatonally <p>

8/5/2015 Philips Ingenuity Core 128, Cl II
Company: Philips Medical Systems, Inc.
Date of Enforcement Report 8/5/2015
Class II:<p>
PRODUCT
Computed Tomography X-ray Systems Ingenuity Core 128. Intended to produce cross-sectional images of the body by computer reconstruction of X-ray transmission data taken at different angles and planes. Recall NumberZ-2258-2015<p>
REASON
The following issues were discovered through internal testing: · Fast Get Ready incorrectly enabled during service procedures. · Contrast annotation incorrectly missing for some images when manual contrast was administered. · Dot artifact present, intermittently, after startup. · Heart Rate measured value incorrectly remains constant for some heart rate change conditions. · Tube heat predictor fails to warn of overheat condition for long scans.<p>
RECALLING FIRM/MANUFACTURER
Philips Medical Systems, Inc.,Cleveland, OH on 2/5/2015. Voluntary: Firm Initiated recall is ongoing.
<p>
VOLUME OF PRODUCT IN COMMERCE
139 units <p>
DISTRIBUTION
Nationwide and Internatonally <p>

8/5/2015 Philips Ingenuity Core, Cl II
Company: Philips Medical Systems, Inc.
Date of Enforcement Report 8/5/2015
Class II:<p>
PRODUCT
Computed Tomography X-ray Systems Ingenuity Core. Intended to produce cross-sectional images of the body by computer reconstruction of X-ray transmission data taken at different angles and planes. Recall NumberZ-2257-2015<p>
REASON

The following issues were discovered through internal testing: · Fast Get Ready incorrectly enabled during service procedures. · Contrast annotation incorrectly missing for some images when manual contrast was administered. · Dot artifact present, intermittently, after startup. · Heart Rate measured value incorrectly remains constant for some heart rate change conditions. · Tube heat predictor fails to warn of overheat condition for long scans.<p>
RECALLING FIRM/MANUFACTURER
Philips Medical Systems, Inc.,Cleveland, OH on 2/5/2015. Voluntary: Firm Initiated recall is ongoing.
<p>
VOLUME OF PRODUCT IN COMMERCE
82 units <p>
DISTRIBUTION
Nationwide and Internatonally <p>

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8/5/2015 Philips Brilliance CT Brilliance iCT SP, Cl II
Company: Philips Medical Systems, Inc.
Date of Enforcement Report 8/5/2015
Class II:<p>
PRODUCT
Computed Tomography X-ray Systems Brilliance iCT SP. Intended to produce cross-sectional images of the body by computer reconstruction of X-ray transmission data taken at different angles and planes.
Recall NumberZ-2256-2015<p>
REASON
The following issues were discovered through internal testing: · Fast Get Ready incorrectly enabled during service procedures. · Contrast annotation incorrectly missing for some images when manual contrast was administered. · Dot artifact present, intermittently, after startup. · Heart Rate measured value incorrectly remains constant for some heart rate change conditions. · Tube heat predictor fails to warn of overheat condition for long scans.<p>
RECALLING FIRM/MANUFACTURER
Philips Medical Systems, Inc.,Cleveland, OH on 2/5/2015. Voluntary: Firm Initiated recall is ongoing.
<p>
VOLUME OF PRODUCT IN COMMERCE
2 units <p>
DISTRIBUTION
Nationwide and Internatonally <p>

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8/5/2015 Philips Brilliance Brilliance iCT, Cl II
Company: Philips Medical Systems, Inc.
Date of Enforcement Report 8/5/2015
Class II:<p>
PRODUCT
Computed Tomography X-ray systems Brilliance iCT, Philips Healthcare System. Intended to produce cross-sectional images of the body by computer reconstruction of X-ray transmission data taken at different angles and planes.
Recall NumberZ-2255-2015<p>
REASON
The following issues were discovered through internal testing: · Fast Get Ready incorrectly enabled during service procedures. · Contrast annotation incorrectly missing for some images when manual contrast was administered. · Dot artifact present, intermittently, after startup. · Heart Rate measured value incorrectly remains constant for some heart rate change conditions. · Tube heat predictor fails to warn of overheat condition for long scans.<p>
RECALLING FIRM/MANUFACTURER
Philips Medical Systems, Inc.,Cleveland, OH on 2/5/2015. Voluntary: Firm Initiated recall is ongoing.
<p>

VOLUME OF PRODUCT IN COMMERCE
38 units <p>
DISTRIBUTION
Nationwide and Internatonally <p>

8/5/2015 Philips Brilliance CT 64-channel, Cl II
Company: Philips Medical Systems, Inc.
Date of Enforcement Report 8/5/2015
Class II:<p>
PRODUCT
Computed Tomography X-ray Systems Brilliance CT 64-channel with Essence technology. Intended to produce cross-sectional images of the body by computer reconstruction of X-ray transmission data taken at different angles and planes.
Recall NumberZ-2254-2015<p>
REASON
The following issues were discovered through internal testing: · Fast Get Ready incorrectly enabled during service procedures. · Contrast annotation incorrectly missing for some images when manual contrast was administered. · Dot artifact present, intermittently, after startup. · Heart Rate measured value incorrectly remains constant for some heart rate change conditions. · Tube heat predictor fails to warn of overheat condition for long scans.<p>
RECALLING FIRM/MANUFACTURER
Philips Medical Systems, Inc.,Cleveland, OH on 2/5/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
4 units <p>
DISTRIBUTION
Nationwide and Internatonally <p>

8/5/2015 Medtronic MiniMed NGP 640G, Cl II
Company: Medtronic MiniMed Inc..
Date of Enforcement Report 8/5/2015
Class II:<p>
PRODUCT
MiniMed NGP 640G 1.8ml (mmol/L), Model No. MMT-1511; NGP 640G 1.8ml (mg/dL), Model No. 1512; NGP 640G PLGM 3ml (mmol/L), Model No. MMT-1711; NGP 640G PLGM 3ml (mg/dL), Model No. MMT-1712. Recall NumberZ-2260-2015<p>
REASON
Medtronic MiniMed is recalling the MiniMed 620G and 640G insulin pumps because there are certain scenarios where the set Bolus screen will not timeout, which could cause confusion by showing a bolus amount that is no longer appropriate.<p>
RECALLING FIRM/MANUFACTURER
Medtronic MiniMed Inc., Northridge, CA on 6/19/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
1936 units <p>
DISTRIBUTION
Internationally <p>

8/5/2015 Siemens ACUSON Virtual Touch IQ option, Cl II
Company:Siemens Medical Solutions USA, Inc.
Date of Enforcement Report: 8/52015
Class II:<p>
PRODUCT

ACUSON S2000 and ACUSON S3000 ultrasound systems with the Virtual Touch IQ option; Model numbers: 10041461, 10440017 -S2000 system 10441730 -S3000 system VTIQ Option- 10439521 and 10439522 Radiology: The ultrasound imaging systems are intended for the following applications: Fetal, Abdominal, Intraoperative, Pediatric, Small Parts, Transcranial, OB/GYN, Cardiac, Pelvic, Neonatal/Adult Cephalic, Vascular, Musculoskeletal, Superficial Musculoskeletal, and Peripheral Vascular applications.
Recall NumberZ-2321-2015<p>
REASON
Potential measurement error on your ACUSON S Family ultrasound system when repositioning the Virtual Touch IQ region of interest from the original (default) location, the lateral position of the measurement tool may not align with the lateral position. of the shear velocity data.<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Mountainview, CA on 6/25/2015 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
629 units <p>
DISTRIBUTION
Nationwide and Internationally<p>

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8/5/2015 Siemens ACUSON S 1000, S 2000, or S 3000,
Cl II

Company:Siemens Medical Solutions USA, Inc.
Date of Enforcement Report: 8/52015
Class II:<p>
PRODUCT
ACUSON S 1000, ACUSON S 2000, or ACUSON S 3000 ultrasound systems with software version C3, C3, C3, or C1. Model numbers: 10041461, 10440017 S 2000 system 10441730 S 3000 system 10441701 S 1000 system Radiology: The ultrasound imaging systems are intended for the following applications: Fetal, Abdominal, Intraoperative, Pediatric, Small Parts, Transcranial, OB/GYN, Cardiac, Pelvic, Neonatal/Adult Cephalic, Vascular, Musculoskeletal, Superficial Musculoskeletal, and Peripheral Vascular applications.
Recall NumberZ-2314-2015<p>
REASON
Potential measurement error on ACUSON S Family ultrasound system when using the Doppler manual trace measurement tool in full screen format that has a low probability of misdiagnosis.<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Mountainview, CA on 6/25/2015 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
1789 units <p>
DISTRIBUTION
Nationwide and Internationally<p>

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8/5/2015 Hamilton-G5 Ventilators, Cl II

Company: Hamilton Medical.
Date of Enforcement Report 8/5/2015
Class II:<p>
PRODUCT
Hamilton-G5 Ventilators with software versions V2.40/2.41 Catalog numbers for G5: 159001 and 159002. Software: 159700.. Intensive care ventilation of adult and pediatric patients and optionally infant and neonatal patients. Recall NumberZ-2057-2015<p>
REASON
Customer reports that the ventilator display can freeze. Ventilation continues but the information is no

longer displayed on the screen and the user can no longer operate the device.<p>
RECALLING FIRM/MANUFACTURER
Hamilton Medical Inc., Reno NV 3/24/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
248 <p>
DISTRIBUTION
Nationwide <p>

7/29/2015 Hitachi PROBEAT, Cl II
Company: Hitachi America, Ltd., Power Systems Division
Date of Enforcement Report: 7/29/2015
Class II:<p>
PRODUCT
PROBEAT WITH DISCRETE SPOT SCANNING SYSTEM Product Usage: Hitachi□s PROBEAT with DSSS is a medical device designed to produce and deliver a proton beam for the treatment of patients with localized tumors and other conditions susceptible to treatment by radiation. Recall Number Z-1838-2015<p>
REASON
At a PROBEAT III site installed in Japan, the operator of the system found that the radiation was delivered inconsistent with the treatment plan and stopped the irradiation. As a result of the investigation, the company determined that the irradiation control system may be potentially affected when rebooting a part of the control system.<p>
RECALLING FIRM/MANUFACTURER
Hitachi America, Ltd., Power Systems Division, Houston, TX on 4/21/2015 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
3 <p>
DISTRIBUTION
US NationwideTexas and Japan<p>

7/29/2015 Philips GEMINI TF Big Bore PET/CT, Cl II
Company: Philips Medical Systems, Inc.
Date of Enforcement Report 7/29/2015
Class II:<p>
PRODUCT
GEMINI TF Big Bore CT/PET System. The Philips GEMINI PET/CT Imaging Systems are a family of integrated diagnostic X-ray Computed Tomography (CT) and Positron Emission Tomography (PET) systems suitable for a wide range of diagnostic applications.
Recall NumberZ-2199-2015<p>
REASON
Philips has identified four (4) software defects in the Tumor LOC software application that may potentially result in irradiation of healthy tissue or non-irradiation of diseased tissue. CT imaging displays both high-density tissue, such as bone, and soft tissue. PET uses radiopharmaceuticals to obtain images by measuring the internal distribution of radioactivity within organs of the body. PET technology enables the practitioner to reconstruct high-resolution, three-dimensional, images of biochemical and metabolic processes of organs within the body.<p>
RECALLING FIRM/MANUFACTURER
Philips Medical Systems, Inc.,Cleveland, OH on 7/1/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
44 units <p>
DISTRIBUTION
Nationwide and Internationally <p>

7/29/2015 Philips GEMINI TF Base CT/PET, Cl II
Company: Philips Medical Systems, Inc.
Date of Enforcement Report 7/29/2015
Class II:<p>
PRODUCT
GEMINI TF Base CT/PET System. The Philips GEMINI PET/CT Imaging Systems are a family of integrated diagnostic X-ray Computed Tomography (CT) and Positron Emission Tomography (PET) systems suitable for a wide range of diagnostic applications.
Recall NumberZ-2198-2015<p>
REASON
Philips has identified four (4) software defects in the Tumor LOC software application that may potentially result in irradiation of healthy tissue or non-irradiation of diseased tissue. CT imaging displays both high-density tissue, such as bone, and soft tissue. PET uses radiopharmaceuticals to obtain images by measuring the internal distribution of radioactivity within organs of the body. PET technology enables the practitioner to reconstruct high-resolution, three-dimensional, images of biochemical and metabolic processes of organs within the body.<p>
RECALLING FIRM/MANUFACTURER
Philips Medical Systems, Inc.,Cleveland, OH on 7/1/2015. Voluntary: Firm Initiated recall is ongoing.
<p>
VOLUME OF PRODUCT IN COMMERCE
2 units <p>
DISTRIBUTION
Nationwide and Internationally <p>

7/29/2015 Philips GEMINI TF Ready PET/CT, Cl II
Company: Philips Medical Systems, Inc.
Date of Enforcement Report 7/29/2015
Class II:<p>
PRODUCT
GEMINI TF Ready CT/PET System. The Philips GEMINI PET/CT Imaging Systems are a family of integrated diagnostic X-ray Computed Tomography (CT) and Positron Emission Tomography (PET) systems suitable for a wide range of diagnostic applications.
Recall NumberZ-2197-2015<p>
REASON
Philips has identified four (4) software defects in the Tumor LOC software application that may potentially result in irradiation of healthy tissue or non-irradiation of diseased tissue. CT imaging displays both high-density tissue, such as bone, and soft tissue. PET uses radiopharmaceuticals to obtain images by measuring the internal distribution of radioactivity within organs of the body. PET technology enables the practitioner to reconstruct high-resolution, three-dimensional, images of biochemical and metabolic processes of organs within the body.<p>
RECALLING FIRM/MANUFACTURER
Philips Medical Systems, Inc.,Cleveland, OH on 7/1/2015. Voluntary: Firm Initiated recall is ongoing.
<p>
VOLUME OF PRODUCT IN COMMERCE
1 unit <p>
DISTRIBUTION
Nationwide and Internationally <p>

7/29/2015 Philips GEMINI TF 64 slice PET/CT, Cl II
Company: Philips Medical Systems, Inc.
Date of Enforcement Report 7/29/2015
Class II:<p>
PRODUCT
GEMINI TF 64 Slice CT/PET System. The Philips GEMINI PET/CT Imaging Systems are a family of integrated diagnostic X-ray Computed Tomography (CT) and Positron Emission Tomography (PET) systems suitable for a wide range of diagnostic applications.
Recall NumberZ-2196-2015<p>
REASON
Philips has identified four (4) software defects in the Tumor LOC software application that may potentially result in irradiation of healthy tissue or non-irradiation of diseased tissue. CT imaging displays both high-density tissue, such as bone, and soft tissue. PET uses radiopharmaceuticals to obtain images by measuring the internal distribution of radioactivity within organs of the body. PET technology enables the practitioner to reconstruct high-resolution, three-dimensional, images of biochemical and metabolic processes of organs within the body.<p>
RECALLING FIRM/MANUFACTURER
Philips Medical Systems, Inc.,Cleveland, OH on 7/1/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
22 units <p>
DISTRIBUTION
Nationwide and Internationally <p>

7/29/2015 Philips GEMINI TF 16 slice PET/CT, Cl II
Company: Philips Medical Systems, Inc.
Date of Enforcement Report 7/29/2015
Class II:<p>
PRODUCT
GEMINI TF 16 Slice CT/PET System. The Philips GEMINI PET/CT Imaging Systems are a family of integrated diagnostic X-ray Computed Tomography (CT) and Positron Emission Tomography (PET) systems suitable for a wide range of diagnostic applications.
Recall NumberZ-2195-2015<p>
REASON
Philips has identified four (4) software defects in the Tumor LOC software application that may potentially result in irradiation of healthy tissue or non-irradiation of diseased tissue. CT imaging displays both high-density tissue, such as bone, and soft tissue. PET uses radiopharmaceuticals to obtain images by measuring the internal distribution of radioactivity within organs of the body. PET technology enables the practitioner to reconstruct high-resolution, three-dimensional, images of biochemical and metabolic processes of organs within the body.<p>
RECALLING FIRM/MANUFACTURER
Philips Medical Systems, Inc.,Cleveland, OH on 7/1/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
13 units <p>
DISTRIBUTION
Nationwide and Internationally <p>

7/29/2015 Philips GEMINI LXL CT/PET System, Cl II
Company: Philips Medical Systems, Inc.
Date of Enforcement Report 7/29/2015
Class II:<p>
PRODUCT

GEMINI LXL CT/PET System. The Philips GEMINI PET/CT Imaging Systems are a family of integrated diagnostic X-ray Computed Tomography (CT) and Positron Emission Tomography (PET) systems suitable for a wide range of diagnostic applications.
Recall NumberZ-2194-2015<p>
REASON
Philips has identified four (4) software defects in the Tumor LOC software application that may potentially result in irradiation of healthy tissue or non-irradiation of diseased tissue. CT imaging displays both high-density tissue, such as bone, and soft tissue. PET uses radiopharmaceuticals to obtain images by measuring the internal distribution of radioactivity within organs of the body. PET technology enables the practitioner to reconstruct high-resolution, three-dimensional, images of biochemical and metabolic processes of organs within the body.<p>
RECALLING FIRM/MANUFACTURER
Philips Medical Systems, Inc.,Cleveland, OH on 7/1/2015. Voluntary: Firm Initiated recall is ongoing.
<p>
VOLUME OF PRODUCT IN COMMERCE
2 units <p>
DISTRIBUTION
Nationwide and Internationally <p>

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7/29/2015 Philips GXL GEMINI PET/CT, Cl II
Company: Philips Medical Systems, Inc.
Date of Enforcement Report 7/29/2015
Class II:<p>
PRODUCT
GEMINI GXL 16 Slice CT/PET System. The Philips GEMINI PET/CT Imaging Systems are a family of integrated diagnostic X-ray Computed Tomography (CT) and Positron Emission Tomography (PET) systems suitable for a wide range of diagnostic applications.
Recall NumberZ-2193-2015<p>
REASON
Philips has identified four (4) software defects in the Tumor LOC software application that may potentially result in irradiation of healthy tissue or non-irradiation of diseased tissue. CT imaging displays both high-density tissue, such as bone, and soft tissue. PET uses radiopharmaceuticals to obtain images by measuring the internal distribution of radioactivity within organs of the body. PET technology enables the practitioner to reconstruct high-resolution, three-dimensional, images of biochemical and metabolic processes of organs within the body.<p>
RECALLING FIRM/MANUFACTURER
Philips Medical Systems, Inc.,Cleveland, OH on 7/1/2015. Voluntary: Firm Initiated recall is ongoing.
<p>
VOLUME OF PRODUCT IN COMMERCE
2 units <p>
DISTRIBUTION
Nationwide and Internationally <p>

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7/29/2015 Philips Pinnacle3 Software, Cl II
Company: Philips Medical Systems, Inc.
Date of Enforcement Report 7/29/2015
Class II:<p>
PRODUCT
Pinnacle3 Software Version 9.0, 9.2, 9.4 and 9.6, Model Numbers 453560446041, 459800091001, 459800220161, 459800232931, 459800235871, 459800338451.
Recall NumberZ-2200-2015<p>
REASON
Philips, Pinnacle Radiation Treatment Planning System version 9 0, 9 2 9 4, 9 6 is being recalled

because the dose may be inconsistent with the density of a density-overridden ROI.<p>
RECALLING FIRM/MANUFACTURER
Philips Medical Systems, Inc., Andover, MA 7/31/2014. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
1383 <p>
DISTRIBUTION
Nationwide and Internationally <p>

7/29/2015 Volcano s5/s5i/CORE Ultrasound Systems, Cl
II

Company:Volcano Corporation
Date of Enforcement Report: 7/29/2015
Class II:<p>
PRODUCT
1) Volcano s5/s5i/CORE Intravascular Ultrasound Systems with software versions 3.3 and 3.4 (with and without iFR Scout Technology) and v.3.4 software kits; Model s5. Radiology: The Volcano s5/s5i and CORE Series Intravascular Imaging and Pressure System is used for the qualitative and quantitative evaluation of vascular morphology in the coronary arteries and vessels of the peripheral vasculature.
Recall NumberZ-2131-2015
2)Volcano s5/s5i/CORE Intravascular Ultrasound Systems software versions 3.3 and 3.4 (with and without iFR Scout Technology) and v.3.4 software kits; Model s5x. Radiology: The Volcano s5/s5i and CORE Series Intravascular Imaging and Pressure System is used for the qualitative and quantitative evaluation of vascular morphology in the coronary arteries and vessels of the peripheral vasculature. evaluation of vascular morphology in the coronary arteries and vessels of the peripheral vasculature.
Recall NumberZ-2133-2015
3) Volcano s5/s5i/CORE Intravascular Ultrasound Systems software versions 3.3 and 3.4 (with and without iFR Scout Technology) and v.3.4 software kits; Model CORE Mobile. Radiology: The Volcano s5/s5i and CORE Series Intravascular Imaging and Pressure System is used for the qualitative and quantitative evaluation of vascular morphology in the coronary arteries and vessels of the peripheral vasculature
Recall NumberZ-2133-2015.
4) Volcano s5/s5i/CORE Intravascular Ultrasound Systems software versions 3.3 and 3.4 (with and without iFR Scout Technology) and v.3.4 software kits; Model s5i Radiology: The Volcano s5/s5i and CORE Series Intravascular Imaging and Pressure System is used for the qualitative and quantitative evaluation of vascular morphology in the coronary arteries and vessels of the peripheral vasculature.
Recall NumberZ-2134-2015
5) Volcano s5/s5i/CORE Intravascular Ultrasound Systems software versions 3.3 and 3.4 (with and without iFR Scout Technology) and v.3.4 software kits; Model s5ix/s5iz Radiology: The Volcano s5/s5i and CORE Series Intravascular Imaging and Pressure System is used for the qualitative and quantitative evaluation of vascular morphology in the coronary arteries and vessels of the peripheral vasculature. Recall Number Z-2135-2015
6) Volcano s5/s5i/CORE Intravascular Ultrasound Systems software versions 3.3 and 3.4 (with and without iFR Scout Technology) and v.3.4 software kits; Model CORE Radiology: The Volcano s5/s5i and CORE Series Intravascular Imaging and Pressure System is used for the qualitative and quantitative evaluation of vascular morphology in the coronary arteries and vessels of the peripheral vasculature.
Recall Number Z-2136-2015.<p>
REASON
During routine testing in-house, a software issue was discovered where an inaccurate FFR/iFR value could be calculated under certain circumstances..<p>
RECALLING FIRM/MANUFACTURER
Volcano Corporation, Rancho Cordova, CA on 6/22/2015 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
Total of 4007 devices, all models<p>
DISTRIBUTION

Nationwide and Internationally<p>

7/22/2015 Elekta MOSAIQ Oncology Information System, Cl II

Company:Elekta, Inc.
Date of Enforcement Report: 7/22/2015
Class II:<p>
PRODUCT
MOSAIQ Oncology Information System MOSAIQ is an oncology information system used to manage workflows for treatment planning and delivery. It supports information flow among healthcare facility personnel and can be used wherever radiotherapy and/or chemotherapy are prescribed. Recall NumberZ-2063-2015 <p>
REASON
A problem exists in MOSAIQ resulting in the incorrect field size being sent to the treatment machine for stereotactic plans using cones.<p>
RECALLING FIRM/MANUFACTURER
Elekta Inc., Altanta, GA on 7/1/2015 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
74<p>
DISTRIBUTION
Nationwide and Internationally<p>

7/22/2015 Viewray Patient Handling System software, Cl II

Company:Viewray Incorporated
Date of Enforcement Report: 7/22/2015
Class II:<p>
PRODUCT
Patient Handling System (Motion Control Software), Product Usage: Indicated for stereotactic radiosurgery and precision radiotherapy for lesions, tumors, and conditions anywhere in the body when radiation treatment is indicated.
Recall NumberZ-2085-2015<p>
REASON
ViewRay" received a report that the couch moved unexpectedly into the bore after performing a RTCS reboot.<p>
RECALLING FIRM/MANUFACTURER
Viewray Incorporated, Oakwood Village, OH on 4/1/2015 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
3<p>
DISTRIBUTION
Distributed in the states of CA, MO & WI.<p>

7/15/2015 Siemens Dimension Vista Systems, Cl II

Company:Siemens Healthcare Diagnostics, Inc
Date of Enforcement Report: 7/15/2015
Class II:<p>
PRODUCT
Siemens Healthcare Diagnostics Dimension Vista Systems, used with the Dimension Vista Intelligent Lab System software version 3.6.1. In vitro diagnostic analyzer.
Recall NumberZ-2054-2015 <p>
REASON
there is the potential for two software issues to occur in Vista software versions 3.6.1 Issue #1 :Samples stop processing without notification for Dimension Vista instruments running software version 3.6.1.

Issue#2:The Dimension Vista 1500 causing a series of unflagged, unexpected low results and complaints of results flagged with assay errors.<p>
RECALLING FIRM/MANUFACTURER
Siemens Healthcare Diagnostics, Inc., Newark, DE on 5/21/2015 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
2315<p>
DISTRIBUTION
Nationwide and Internationally <p>

7/8/2015 Siemens EasyLink" Data Management System
Cl II
Company:Siemens Healthcare Diagnostics, Inc
Date of Enforcement Report: 7/8/2015
Class II:<p>
PRODUCT
EasyLink" Data Management System; a clinical data management system that assists medical laboratory professionals with preanalytic and post-analytic functions in conjunction with multiple instruments, the laboratory information system (LIS) and Siemens StreamLAB® Automation Solutions.
Recall NumberZ-1942-2015<p>
REASON
This recall of the EasyLink Data Management System encompasses three separate software defects occurring under three separate sets of conditions. These software defects affect the custom/auto-verification rules (e.g. hold, release, and reorder). With each defect when auto-verification rules are turned on and the software error manifests, a subset of the configured rule(s) is/are not active. The affected analyte(s) include any analyte that can be run on the connected analyzers. The EasyLink defect does not produce erroneous results ---- System Limitations and Software Issues<p>
RECALLING FIRM/MANUFACTURER
Siemens Healthcare Diagnostics, Inc., Newark, DE on 4/29/2015 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
1355<p>
DISTRIBUTION
Nationwide and Internationally <p>

7/8/2015 Siemens SYNGO IMAGING V30 and V31, Cl II
Company:Siemens Medical Solutions USA, Inc.
Date of Enforcement Report: 7/8/2015
Class II:<p>
PRODUCT
SYNGO IMAGING (VERSION V30 and V31); Syngo Imaging is a Picture Archiving and Communication System (PACS) intended to display, process, read, report, communicate, distribute, store and archive digital medical images, including digital mammography images.
Recall NumberZ-1972-2015<p>
REASON
Siemens became aware that during certain clinical workflows minor safety issues may occur. No adverse events reported.<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Malvern, PA on 5/11/2015 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
5<p>
DISTRIBUTION

US in the states of NC and NE<p>

7/8/2015 Viewray Treatment Planning software, Cl II
Company:Viewray Incorporated
Date of Enforcement Report: 7/8/2015
Class II:<p>
PRODUCT
Treatment Planning and Delivery System Software version 3.6. ViewRay" Indicated for stereotactic radiosurgery and precision radiotherapy for lesions, tumors, and conditions anywhere in the body when radiation treatment is indicated.
Recall NumberZ-1954-2015 <p>
REASON
The firm discovered that the software was failing to determine new patient locations if imaging is not enable during treatment.<p>
RECALLING FIRM/MANUFACTURER
Viewray Incorporated, Oakwood Village, OH on 5/7/2015 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
3<p>
DISTRIBUTION
Distributed in the states of CA, MO & WI.<p>

7/8/2015 ACUSON SC2000 Ultrasound, Cl II
Company:Siemens Medical Solutions USA, Inc.
Date of Enforcement Report: 7/8/2015
Class II:<p>
PRODUCT
ACUSON SC2000 Ultrasound Systems between software versions VA16A and VA30A and with the Stress Echo Option. Model number 10433816: The SC2000 ultrasound imaging system is intended for the following applications: Cardiac, Neo-natal and Fetal Cardiac, Pediatric, Transespohageal, Adult Cephalic, Peripheral Vessel, Abdominal, Abdominal Intraoperative, Intraoperative Neurological, Musculo-skeletal Conventional, and Musculo-skeletal Superficial applications. The system also provides the ability to measure anatomical structures and calculation packages that provide information to the clinician that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes.
Recall NumberZ-1959-2015 <p>
REASON
When performing a 2D Stress Echo study, some following keystrokes result in a potential loss of data, where some selected clips may not be saved as part of the study.<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Mountain View, CA on 5/29/2015 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
573 devices<p>
DISTRIBUTION
Nationwide and Internationally <p>

7/8/2015 Varian VariSource iX, Cl II
Company:Varian Medical Systems Inc
Date of Enforcement Report: 7/8/2015
Class II:<p>
PRODUCT
The VariSource iX series afterloader systems are computer controlled remote electro/mechanical systems used for medical purposes, for placing a cable incorporating an irradiated iridium seed

internally or close by a malignant tumor or tumor bed in a practice known as brachytherapy. Recall NumberZ-1849-2015 <p>
REASON
After an application freeze and restart of the VariSource iX series by power cycling, the Partial Fraction generated by the system will not be correct. The application freeze issue affects only the systems equipped with magnetic Hard Disk Drives (HDD).<p>
RECALLING FIRM/MANUFACTURER
Varian Medical Systems Inc., Charlottesville, VA on 5/18/2015 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
55<p>
DISTRIBUTION
Nationwide and Internationally <p>

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7/8/2015 Siemens CentraLink" Data Management System Cl II

Company:Siemens Healthcare Diagnostics, Inc
Date of Enforcement Report: 7/8/2015
Class II:<p>
PRODUCT
CentraLink" Data Management System; software is a network solution provider and multi-system data manager for the instruments and lab automation systems (LAS) within the lab. The CentraLink software consolidates data from all connected instruments so that an operator can review and edit patient and quality control results from a single location.
Recall NumberZ-1957-2015 <p>
REASON
Siemens Healthcare Diagnostics has determined that the sample query function that includes Instrument or Instrument Group as search criteria may not return all samples from the Dimension Vista systems if onboard aliquot support rules are configured in the CentraLink system.<p>
RECALLING FIRM/MANUFACTURER
Siemens Healthcare Diagnostics, Inc., Newark, DE on 5/19/2015 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
1941<p>
DISTRIBUTION
Nationwide and Internationally <p>

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7/8/2015 Siemens Cios Alpha, Cl II

Company:Siemens Medical Solutions USA, Inc.
Date of Enforcement Report: 7/8/2015
Class II:<p>
PRODUCT
Cios Alpha; The Cios Alpha is a mobile X-ray system designed to provide X-ray imaging of the anatomical structures of patient during clinical applications. Clinical applications may include but are not limited to: interventional fluoroscopic, gastro-intestinal, endoscopic, urologic, pain management, orthopedic, neurologic, vascular, cardiac, critical care and emergency room procedures. The patient population may include pediatric patients
Recall NumberZ-1958-2015 <p>
REASON
Under certain circumstances the Cios Alpha system may freeze during a procedure.<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Malvern, PA on 5/5/2015 Voluntary: Firm Initiated recall is ongoing <p>

VOLUME OF PRODUCT IN COMMERCE
37<p>
DISTRIBUTION
Nationwide <p>

7/8/2015 Siemens Rapidlab 1260 and Rapidlab 1265 Cl II
Company:Siemens Healthcare Diagnostics, Inc
Date of Enforcement Report: 7/8/2015
Class II:<p>
PRODUCT
The Rapidlab 1260 and Rapidlab 1265 systems are blood gas analyzers used for laboratory testing of blood gases, electrolytes, metabolites and CO-oximetry in arterial, venous and capillary whole blood samples.
Recall NumberRapid Lab 1260: Z-1961-2015
Rapidlab 1265 Z-1962-2015 <p>
REASON
D50 and D51 Diagnostic error codes are not functional.<p>
RECALLING FIRM/MANUFACTURER
Siemens Healthcare Diagnostics, Inc., Walpole, MA on 5/6/2015 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
Rapidlab 1260: 122 devices
Rapidlab 1265: 2713 devices<p>
DISTRIBUTION
Nationwide and Internationally <p>

7/2/2015 CareFusion Alaris Syringe Pump Alarm, Class I
Company: CareFusion 303, Inc.
Date of Enforcement Report 7/2/2015
Class I:<p>
PRODUCT
A syringe pump is a small infusion pump that delivers fluids, such as nutrients and medications, into a patient?s body in controlled amounts. They are widely used in clinical settings such as hospitals, nursing homes, and in the home..<p>
REASON
An error in the syringe pump triggers a visual and audible alarm and causes the pump to stop supplying the infusion to the patient. Even when the user clears the error code 351.6740, the syringe pump does not respond to key presses until the product is detached and reattached to the PC unit used to program, monitor and provide power to the syringe pump. Failure of syringe module may result in a delay or interruption of therapy and can lead to serious patient injury or death.
CareFusion has received 108 reports of the issue occurring. There have been no reports of permanent injury or death...<p>
RECALLING FIRM/MANUFACTURER
CareFusion 303, Inc., San Diego CA on 7/2/2015.<p>
VOLUME OF PRODUCT IN COMMERCE
6,458 <p>
DISTRIBUTION
US
FDA District: Los Angeles<p>

7/1/2015 Siemens Artis zee/ zeego systems, Cl II
Company:Siemens Medical Solutions USA, Inc.
Date of Enforcement Report: 7/1/2015
Class II:<p>
PRODUCT
Artis zee/ zeego systems; Product Usage: Usage: Artis zee/ zeego systems are dedicated angiography systems developed for single and biplane diagnostic imaging and interventional procedures including, but not limited to, pediatric and obese patients. Procedures that can be performed include cardiac angiography, neuro angiography, general angiography, rotational angiography, multipurpose angiography and whole body radiographic/fluoroscopic procedures. Artis zee/ zeego systems; Product Usage: Usage: Artis zee/ zeego systems are dedicated angiography systems developed for single and biplane diagnostic imaging and interventional procedures including, but not limited to, pediatric and obese patients. Procedures that can be performed include cardiac angiography, neuro angiography, general angiography, rotational angiography, multipurpose angiography and whole body radiographic/fluoroscopic procedures. .Recall NumberZ-1846-2015 <p>
REASON
There exists a possible position sensor fault in the swivel base axis not being detected by the system software. When moving, the system could potentially exceed its usual speed, resulting in a collision. No injuries reported.<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Malvern, PA on 5/22/2015 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
475<p>
DISTRIBUTION
Nationwide <p>

6/26/2015 Software Recall Summary 2004-Mid2015.
Based on our searches and posting of software related recalls there appears to be a significant increase of recalls reported to FDA in 2008 and then some reduction but still higher than prior years in 2009.Then a bit lower in 2010 and significantly higher in 2011-2014. It is unclear if this indicates a decrease in safety, an increase in the number of software based devices or the functionality that software controls, or simply an increase in reporting. Yearly total software recalls to the best of our ability to identify were :<p>
Mid2015 - 107 :
2014 - 228 :
2013 - 197 :
2012 - 173
2011 – 177
2010 – 76
2009 – 98 software related recalls published as of Jan 1, 2010
2008 - 132
2007 - 82
2006 - 81
2005 - 66
2004 - 84

6/24/2015 Philips Philips Ultrasound, Model Q-Station, Cl II
Company: Philips Ultrasound Inc
Date of Enforcement Report 6/24/2015
Class II:<p>
PRODUCT
Philips Ultrasound, Model Q-Station, with software version 3 or higher, Catalog number: 795088; Part

Number: 989605382391 Q-Station is application software intended to manage, view, analyze, and report qualitative and quantitative image data from ultrasound exams. It is designed to host optional advanced analysis applications via QLAB integration and provide integrated tools that allow users to manually assess and score cardiac wall motion and export images and / or exams and reports. Q-Station can view DICOM images of non-ultrasound images such as CT, MR, NM, CR, MG, XA, PET, RT and X-Ray modalities for reference viewing. It support connectivity to ultrasound systems, PACS and other DICOM storage repositories. Recall NumberZ-1807-2015<p>
REASON
Philips Healthcare has discovered a problem in the Philips Ultrasound Q-Station version 3.0 or higher that could result in measurements from a study (Structured Report) to be appended to subsequent studies for other patients.<p>
RECALLING FIRM/MANUFACTURER
Philips Ultrasound Inc.,Bothell, WA on 5/15/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
121 units (30 in US and 91 international) <p>
DISTRIBUTION
Nationwide and Internationally<p>

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6/24/2015 Morate ELI 380 Electrocardiograph, Cl II
Company: Mortara Instrument, Inc
Date of Enforcement Report 6/24/2015
Class II:<p>
PRODUCT
ELI 380 Electrocardiograph. The ELI 380 is intended to be a high-performance, multichannel resting electrocardiograph. As a resting electrocardiograph, the ELI 380 simultaneously acquires data from each lead. Once the data is acquired, it can be analyzed, reviewed, stored, printed or transmitted. It is a device primarily intended for use in hospitals, but may be used in medical clinics and offices of any size. Recall NumberZ-1796-2015<p>
REASON
Mortara Instrument, Inc. has recently become aware of a potential safety hazard involving our ELI 380 electrocardiograph. When used in a particular workflow, acquired ECG waveforms for one patient may become associated with the patient demographics for a different patient when the record is transmitted to a records management system.<p>
RECALLING FIRM/MANUFACTURER
Mortara Instrument, Inc, Milwaukee, WI on 5/29/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
176 <p>
DISTRIBUTION
Nationwide and Internationally<p>

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6/24/2015 Boston Scientific CLEARSIGN II Amplifier, Cl II
Company: Boston Scientific Corporation
Date of Enforcement Report 6/24/2015
Class II:<p>
PRODUCT
CLEARSIGN II Amplifier for LABSYSTEM PRO EP Recording System, 120 channels, using firmware version 2.08. The channel numbers in the amplifier are as follows: Material number: H30120020210 - 40 Channel CLEARSIGN II Amplifier, catalog number 2002021; Material number: H30120020220 80 Channel CLEARSIGN II Amplifier, catalog number 2002022; Material number: H30120020230 120 Channel CLEARSIGN II Amplifier, catalog number 2002023; Material number: H30120020240 160 Channel Clearsign II Amplifier, catalog number 2002014. The CLEARSIGN II Amplifier is intended to amplify and condition electrocardiographic signals of biologic origin and pressure transducer input,

transmitting this information to a host computer (the LABSYSTEM PRO EP Recording System) that can record and display the information
Recall NumberZ-1817-2015<p>
REASON
Boston Scientific has received complaints indicating that, when using the blood pressure (BP) channels on the CLEARSIGN II Amplifier, the surface Electrocardiogram (ECG) channels become over-written to a variable degree, with the result that it appears shifted from baseline on the system's output screen. This may, in turn, manifest as an uninterpretable ECG signal in the affected channel.<p>
RECALLING FIRM/MANUFACTURER
Boston Scientific Corporation, Lowell, MA on 6/2/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
43 units <p>
DISTRIBUTION
internationally, No US distribution <p>

6/24/2015 CareFusion Alaris PC unit model 8015, Cl II
Company: CareFusion 303, Inc.
Date of Enforcement Report 6/24/2015
Class II:<p>
PRODUCT
Alaris PC unit model 8015, software version 9.17 Infusion Pump. Product Usage: The Alaris PC unit is the central programming, monitoring and power supply component for the Alaris System. The software is embedded in the Alaris PC unit.
Recall NumberZ-1811-2015<p>
REASON
CareFusion has identified an issue with the Alaris PC unit model 8015 software version 9.17 related to the cancel functionality that be used during atypical infusion programming to cancel user inputted values.<p>
RECALLING FIRM/MANUFACTURER
CareFusion 303, Inc., San Diego, CA on 5/13/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
63 units <p>
DISTRIBUTION
Nationwide <p>

6/17/2015 Elekta Leksell GammaPlan, Cl II
Company: Elekta Inc.
Date of Enforcement Report 6/17/2015
Class II:<p>
PRODUCT
Leksell GammaPlan, a computer based dose planning system specifically designed for use with Leksell Gamma Knife, radiation therapy treatment.
Recall NumberZ-1719-2015<p>
REASON
Memory can become corrupted when creating a fused study via drag & drop in Leksell GammaPlan 10.2.<p>
RECALLING FIRM/MANUFACTURER
Elekta Inc., Atlanta, GA on 6/1/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
10 <p>
DISTRIBUTION
Nationwide and Internationally <p>

6/17/2015 Ortho-Clinical Assay Data Disk, Cl II
Company:Ortho-Clinical Diagnostics
Date of Enforcement Report: 6/17/2015
Class II:<p>
PRODUCT
Assay Data Disk (ADD), All DRV versions that support product within expiry dating Automates pre-analytical and post-analytical sample and data management for in vitro diagnostic use. VITROS Urine Assays: VITROS Calcium (Ca), Magnesium (Mg), and Phosphorus (Phos) requires acidification pretreatment prior to urine assay testing
Recall NumberZ-1729-2015<p>
REASON
Software anomaly regarding urine samples that require acidified pretreatment. The software has allowed urine samples for assays that require acidified pretreatment to be metered from the same sample container as assays that required no pretreatment when the sample was programmed.<p>
RECALLING FIRM/MANUFACTURER
Ortho-Clinical Diagnostics, Rochester, NY on 4/6/2015 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
2,387 units Total (987 domestically & 1400 internationally)<p>
DISTRIBUTION
Nationwide and Internationally <p>

6/17/2015 VITROS 5,1 FS Chemistry System Software, Cl II
Company:Ortho-Clinical Diagnostics
Date of Enforcement Report: 6/17/2015
Class II:<p>
PRODUCT
VITROS 5,1 FS Chemistry System, Software Version 2.8 & Below Automates pre-analytical and post-analytical sample and data management for in vitro diagnostic use. VITROS Urine Assays: VITROS Calcium (Ca), Magnesium (Mg), and Phosphorus (Phos) requires acidification pretreatment prior to urine assay testing.Recall Z-1728-2015<p>
REASON
Software anomaly regarding urine samples that require acidified pretreatment. The software has allowed urine samples for assays that require acidified pretreatment to be metered from the same sample container as assays that required no pretreatment when the sample was programmed.<p>
RECALLING FIRM/MANUFACTURER
Ortho-Clinical Diagnostics, Rochester, NY on 4/6/2015 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
2,387 units Total (987 domestically & 1400 internationally)<p>
DISTRIBUTION
Nationwide and Internationally <p>

6/17/2015 VITROS 5600 Chemistry System, Software, Cl II
Company:Ortho-Clinical Diagnostics
Date of Enforcement Report: 6/17/2015
Class II:<p>
PRODUCT
VITROS 5600 Chemistry System, Software Version 3.2 & Below. Automates pre-analytical and post-analytical sample and data management for in vitro diagnostic use.
Recall NumberZ-1743-2015<p>
REASON
Software anomaly allows testing of multiple assays using a single urine specimen, regardless of the

pretreatment requirements for each selected assay, potentially leading to biased patient results.<p>
RECALLING FIRM/MANUFACTURER
Ortho-Clinical Diagnostics, Rochester, NY on 4/6/2015 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
895 units total (907 domestically & 988 internationally)<p>
DISTRIBUTION
Nationwide and Internationally <p>

6/17/2015 VITROS 4600 Chemistry SystemSoftware Cl II
Company:Ortho-Clinical Diagnostics
Date of Enforcement Report: 6/17/2015
Class II:<p>
PRODUCT
VITROS 4600 Chemistry System, Software Version 3.2 & Below. Automates pre-analytical and post-analytical sample and data management for in vitro diagnostic use.
Recall NumberZ-1742-2015<p>
REASON
Software anomaly allows testing of multiple assays using a single urine specimen, regardless of the pretreatment requirements for each selected assay, potentially leading to biased patient results.<p>
RECALLING FIRM/MANUFACTURER
Ortho-Clinical Diagnostics, Rochester, NY on 4/6/2015 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
255 units total (131 domestically & 255 internationally)<p>
DISTRIBUTION
Nationwide and Internationally <p>

6/10/2015 Siemens Syngo.via and Syngo.x, Cl II
Company:Siemens Medical Solutions USA, Inc.
Date of Enforcement Report: 6/10/2015
Class II:<p>
PRODUCT
Syngo.via and Syngo.x ; a software solution intended to be used for viewing, manipulation, communication, and storage of medical images.
Recall NumberZ-1705-2015 <p>
REASON
measurements drawn on the 2nd and subsequent images of the series are not visible on printouts when the series is sent to print.<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Malvern, PA on 5/15/2015 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
167<p>
DISTRIBUTION
Nationwide <p>

6/10/2015 Siemens syngo Workflow SLR, Cl II
Company:Siemens Medical Solutions USA, Inc.
Date of Enforcement Report: 6/10/2015
Class II:<p>
PRODUCT
syngo Workflow SLR; The information system syngo® Workflow SLR is a digital radiology information system (RIS) with integrated modules for patient administration, examination, reporting, statistics and system administration. The system electronically displays stores, retrieves, transfers, exchanges, and

prints.
Recall NumberZ-1704-2015<p>
REASON
A potential exists for order transactions from interfaced HIS (Hospital Information System) systems to be lost during a restart of interface processes when using the Order Batching feature, leading to diagnosis delay.<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Malvern, PA on 5/6/2015 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
131<p>
DISTRIBUTION
Nationwide <p>

6/10/2015 Smiths Medical, BCI® Advisor® , Cl II
Company: Smiths Medical ASD Inc.
Date of Enforcement Report 6/10/2015
Class II:<p>
PRODUCT
Smiths Medical, BCI® Advisor® Vital Signs Monitor, Product Reorder No 92M774325A. Recall Number Z-1692-2015<p>
REASON
Smiths Medical has become aware of an issue with specific serial numbers of BCI® Advisor® Vital Signs Monitors (Advisors®). The Auxiliary Serial Input/ Output Modes on the Advisor® do not function as expected, resulting in data formatting issues or incorrect data being transmitted in or out of the serial port into a data collection system. Smiths Medical received no complaints related to this issue.<p>
RECALLING FIRM/MANUFACTURER
Smiths Medical ASD, Inc., Saint Paul, MN on 3/21/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
5 UPDATE 4-20-2015 to include 10 additional devices <p>
DISTRIBUTION
MN <p>

6/3/2015 Elekta Oncentra Brachy Software, Cl II
Company: Elekta Inc.
Date of Enforcement Report 6/3/2015
Class II:<p>
PRODUCT
Oncentra Brachy radiation therapy planning software designed to analyze and plan radiation treatments in three dimensions for the purpose of treating patients with cancer. Recall NumberZ-1712-2015<p>
REASON
Incorrect dose calculation for Regions of Interest (ROIs) defined on a secondary image series.<p>
RECALLING FIRM/MANUFACTURER
Elekta Inc., Atlanta, GA on 5/21/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
351 <p>
DISTRIBUTION
Nationwide and Internationally <p>

6/3/2015 RaySearch RayStation 2.5, 3.0, 3.5 and 4.0 Cl II
Company: RAYSEARCH LABORATORIES AB.
Date of Enforcement Report 6/3/2015
Class II:<p>
PRODUCT
RaySearch RayStation 2.5, 3.0, 3.5 and 4.0; Radiation Therapy Treatment Product Usage: RayStation is a software system designed for treatment planning and analysis of radiation therapy. The treatment plans provide treatment unit set-up parameters and estimates of dose distributions expected during the proposed treatment, and may be used to administer treatments after review and approval by the intended user. The system functionality can be configured based on user needs. The intended users of RayStation shall be clinically qualified radiation therapy staff trained in using the system.
Recall NumberZ-1679-2015<p>
REASON
RaySearch Laboratories AB became aware of an issue with the dose calculation for some imported VMAT plans where controls points are defined with wide gantry angle spacing.<p>
RECALLING FIRM/MANUFACTURER
RAYSEARCH LABORATORIES AB, Stockholm, SE on 5/8/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
539 units <p>
DISTRIBUTION
Nationwide <p>

6/3/2015 Philips Ingenuity CT. Cl II
Company: Philips Medical Systems, Inc.
Date of Enforcement Report 6/3/2015
Class II:<p>
PRODUCT
Ingenuity CT. Computed Tomography X-ray systems intended to produce cross-sectional images of the body by computer reconstruction of X-ray transmission data taken at different angles and planes.
Recall NumberZ-1657-2015<p>
REASON
The firm was informed that while raising the patient couch on the system to perform an exam, the couch unexpectedly descended to the lowest point without being commanded to do so.<p>
RECALLING FIRM/MANUFACTURER
Philips Medical Systems, Inc.,Cleveland, OH on 3/16/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
153 units <p>
DISTRIBUTION
China <p>

6/3/2015 Philips Brilliance iCT. Computed Tomography, Cl II
Company: Philips Medical Systems, Inc.
Date of Enforcement Report 6/3/2015
Class II:<p>
PRODUCT
Brilliance iCT. Computed Tomography X-ray systems intended to produce cross-sectional images of the body by computer reconstruction of X-ray transmission data taken at different angles and planes.
Recall NumberZ-1656-2015<p>
REASON
The firm was informed that while raising the patient couch on the system to perform an exam, the couch

unexpectedly descended to the lowest point without being commanded to do so.<p>
RECALLING FIRM/MANUFACTURER
Philips Medical Systems, Inc.,Cleveland, OH on 3/16/2015. Voluntary: Firm Initiated recall is ongoing.
<p>
VOLUME OF PRODUCT IN COMMERCE
153 units <p>
DISTRIBUTION
China <p>

6/3/2015 Philips Brilliance CT 10 Air, Cl II
Company: Philips Medical Systems, Inc.
Date of Enforcement Report 6/3/2015
Class II:<p>
PRODUCT
Brilliance CT 10 Air. Computed Tomography X-ray systems intended to produce cross-sectional images of the body by computer reconstruction of X-ray transmission data taken at different angles and planes.
Recall NumberZ-1654-2015<p>
REASON
The firm was informed that while raising the patient couch on the system to perform an exam, the couch unexpectedly descended to the lowest point without being commanded to do so.<p>
RECALLING FIRM/MANUFACTURER
Philips Medical Systems, Inc.,Cleveland, OH on 3/16/2015. Voluntary: Firm Initiated recall is ongoing.
<p>
VOLUME OF PRODUCT IN COMMERCE
153 units <p>
DISTRIBUTION
China <p>

6/3/2015 Philips Brilliance CT 6 Air, Cl II
Company: Philips Medical Systems, Inc.
Date of Enforcement Report 6/3/2015
Class II:<p>
PRODUCT
Brilliance CT 6 Air. Computed Tomography X-ray systems intended to produce cross-sectional images of the body by computer reconstruction of X-ray transmission data taken at different angles and planes.
Recall NumberZ-1655-2015<p>
REASON
The firm was informed that while raising the patient couch on the system to perform an exam, the couch unexpectedly descended to the lowest point without being commanded to do so.<p>
RECALLING FIRM/MANUFACTURER
Philips Medical Systems, Inc.,Cleveland, OH on 3/16/2015. Voluntary: Firm Initiated recall is ongoing.
<p>
VOLUME OF PRODUCT IN COMMERCE
153 units <p>
DISTRIBUTION
China <p>

6/3/2015 Philips Brilliance CT 16 Power, Cl II
Company: Philips Medical Systems, Inc.
Date of Enforcement Report 6/3/2015
Class II:<p>
PRODUCT
Brilliance CT 16 Power. Computed Tomography X-ray systems intended to produce cross-sectional

images of the body by computer reconstruction of X-ray transmission data taken at different angles and planes.
Recall NumberZ-1651-2015<p>
REASON
The firm was informed that while raising the patient couch on the system to perform an exam, the couch unexpectedly descended to the lowest point without being commanded to do so.<p>
RECALLING FIRM/MANUFACTURER
Philips Medical Systems, Inc.,Cleveland, OH on 3/16/2015. Voluntary: Firm Initiated recall is ongoing.
<p>
VOLUME OF PRODUCT IN COMMERCE
153 units <p>
DISTRIBUTION
China <p>

6/3/2015 Philips Brilliance CT 40. Computed Tomograp,
Cl II
Company: Philips Medical Systems, Inc.
Date of Enforcement Report 6/3/2015
Class II:<p>
PRODUCT
Brilliance CT 40. Computed Tomography X-ray systems intended to produce cross-sectional images of the body by computer reconstruction of X-ray transmission data taken at different angles and planes.
Recall Number Z-1650-2015<p>
REASON
The firm was informed that while raising the patient couch on the system to perform an exam, the couch unexpectedly descended to the lowest point without being commanded to do so.<p>
RECALLING FIRM/MANUFACTURER
Philips Medical Systems, Inc.,Cleveland, OH on 3/16/2015. Voluntary: Firm Initiated recall is ongoing.
<p>
VOLUME OF PRODUCT IN COMMERCE
153 units <p>
DISTRIBUTION
China <p>

6/3/2015 Philips Brilliance CT 64. Computed Tomograpy
Cl II
Company: Philips Medical Systems, Inc.
Date of Enforcement Report 6/3/2015
Class II:<p>
PRODUCT
Brilliance CT 64. Computed Tomography X-ray systems intended to produce cross-sectional images of the body by computer reconstruction of X-ray transmission data taken at different angles and planes.
Recall NumberZ-1649-2015<p>
REASON
The firm was informed that while raising the patient couch on the system to perform an exam, the couch unexpectedly descended to the lowest point without being commanded to do so.<p>
RECALLING FIRM/MANUFACTURER
Philips Medical Systems, Inc.,Cleveland, OH on 3/16/2015. Voluntary: Firm Initiated recall is ongoing.
<p>
VOLUME OF PRODUCT IN COMMERCE
153 units <p>
DISTRIBUTION
China <p>

6/3/2015 Philips Brilliance CT Big Bore Oncology, Cl II
Company: Philips Medical Systems, Inc.
Date of Enforcement Report 6/3/2015
Class II:<p>
PRODUCT
Brilliance CT Big Bore Oncology. Computed Tomography X-ray systems intended to produce cross-sectional images of the body by computer reconstruction of X-ray transmission data taken at different angles and planes.
Recall NumberZ-1648-2015<p>
REASON
The firm was informed that while raising the patient couch on the system to perform an exam, the couch unexpectedly descended to the lowest point without being commanded to do so.<p>
RECALLING FIRM/MANUFACTURER
Philips Medical Systems, Inc.,Cleveland, OH on 3/16/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
153 units <p>
DISTRIBUTION
China <p>

6/3/2015 Philips MX8000 Dualv. EXP, 728130, Cl II
Company: Philips Medical Systems, Inc.
Date of Enforcement Report 6/3/2015
Class II:<p>
PRODUCT
MX8000 Dualv. EXP, 728130. Computed Tomography X-ray systems intended to produce cross-sectional images of the body by computer reconstruction of X-ray transmission data taken at different angles and planes.
Recall NumberZ-1647-2015<p>
REASON
The firm was informed that while raising the patient couch on the system to perform an exam, the couch unexpectedly descended to the lowest point without being commanded to do so.<p>
RECALLING FIRM/MANUFACTURER
Philips Medical Systems, Inc.,Cleveland, OH on 3/16/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
153 units <p>
DISTRIBUTION
China <p>

6/3/2015 SIEMENS Uroskop Omnia Max, Cl II
Company:Siemens Medical Solutions USA, Inc.
Date of Enforcement Report: 6/3/2015
Class II:<p>
PRODUCT
SIEMENS Uroskop Omnia Max ; a solid state detector fluoroscopic X-Ray system, primarily for urological applications (functional x-ray diagnostic, endourology and minimal invasive urology/surgery). The system,, which includes a radiologic/urologic treatment table, may be used for urological, gastroenterological and gynecological treatment, planning and diagnostic procedures including but not limited to: Querying and retrieving patient history information and/or previous diagnosis and images from other modalities, including X-ray examinations of the urogenital area, Ultrasound examinations, Endourological interventions, Percutaneous interventions, Laparoscopy, Application of fistula, Simple

procedures, Extracorporeal shock wave lithotripsy, Uroflow/urodynamics, Pediatric radiological and therapeutic applications.
Recall NumberZ-1670-2015<p>
REASON
Study and all acquired images deleted when using systems with software version VE10E. Acquisitions have to be repeated. Connection with portable detectors (MAX wi-D, MAX mini) is sporadic in image recovery. Pressing undo button on the RAD subtask card or previous series button on the Image subtask card during image readout. Sporadically, during an automatic or a manual RIS update.<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Malvern, PA on 4/13/2015 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
133<p>
DISTRIBUTION
Nationwide <p>

6/3/2015 SIEMENS Luminos Agile Max, Cl II
Company:Siemens Medical Solutions USA, Inc.
Date of Enforcement Report: 6/3/2015
Class II:<p>
PRODUCT
SIEMENS Luminos Agile Max; a universal imaging system for radiographic and fluoroscopic studies. Using either film cassettes or a digital mobile flat detector, it can perform a range of applications including general R/F, angiography and pediatric examinations. Luminos Agile is applicable to emergency treatment on an outpatient basis, as well as for bedside examinations.
Recall NumberZ-1669-2015<p>
REASON
Study and all acquired images deleted when using systems with software version VE10E. Acquisitions have to be repeated. Connection with portable detectors (MAX wi-D, MAX mini) is sporadic in image recovery. Pressing undo button on the RAD subtask card or previous series button on the Image subtask card during image readout. Sporadically, during an automatic or a manual RIS update.<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Malvern, PA on 4/132015 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
133<p>
DISTRIBUTION
Nationwide <p>

6/3/2015 SIEMENS Axiom Luminos dRF Max, Cl II
Company:Siemens Medical Solutions USA, Inc.
Date of Enforcement Report: 6/3/2015
Class II:<p>
PRODUCT
SIEMENS Axiom Luminos dRF Max, a universal diagnostic imaging system for radiographic and fluoroscopic studies. Using a digital flat detector, it can perform a range of applications including general R/F, angiography and pediatric examinations. The Axiom Luminos dRF is a device intended to visualize anatomical structures by converting a pattern of X-ray into a visible image.
Recall NumberZ-1668-2015<p>
REASON
Study and all acquired images deleted when using systems with software version VE10E. Acquisitions have to be repeated. Connection with portable detectors (MAX wi-D, MAX mini) is sporadic in image recovery. Pressing undo button on the RAD subtask card or previous series button on the Image

subtask card during image readout. Sporadically, during an automatic or a manual RIS update.<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Malvern, PA on 4/13/2015 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
133<p>
DISTRIBUTION
Nationwide <p>

6/3/2015 SIEMENS Ysio Max; Cl II
Company:Siemens Medical Solutions USA, Inc.
Date of Enforcement Report: 6/3/2015
Class II:<p>
PRODUCT
SIEMENS Ysio Max; a radiographic system used in hospitals, clinics, and medical practices. Ysio Max enables radiographic and tomographic exposures of the whole body including: skull, chest, abdomen, and extremities and may be used on pediatric, adult and bariatric patients. It can also be used for intravenous, small interventions (like biopsy, punctures, etc.) and emergency (trauma, critical ill) applications. Exposures may be taken with the patient sitting, standing, or in the prone position. The Ysio Max system is not meant for mammography. The Ysio Max uses integrated or portable digital detectors for generating diagnostic images by converting x-rays into electronic signals. Ysio Max is also designed to be used with conventional film/screen or Computed Radiography (CR) cassettes.
Recall NumberZ-1667-2015<p>
REASON
Study and all acquired images deleted when using systems with software version VE10E. Acquisitions have to be repeated. Connection with portable detectors (MAX wi-D, MAX mini) is sporadic in image recovery. Pressing undo button on the RAD subtask card or previous series button on the Image subtask card during image readout. Sporadically, during an automatic or a manual RIS update<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Malvern, PA on 4/132015 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
133<p>
DISTRIBUTION
Nationwide <p>

6/3/2015 Siemens SOMATOM Emotion 16; Cl II
Company:Siemens Medical Solutions USA, Inc.
Date of Enforcement Report: 6/3/2015
Class II:<p>
PRODUCT
SOMATOM Emotion 16, the intended use of computed tomography is to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data from either the same axial plane taken at different angels or spiral planes taken at different angles.
Recall NumberZ-1645-2015<p>
REASON
Software bugs in VC20B SP0a or SP1 software versions may cause issues that could make it necessary to rescan patients. Syngo Main UI may crash if the Patient Browser is scrolled with arrow keys of the keyboard. Tomo images may freeze on the screen when zoomed in or out under the mode of CAREVision. Sporadic displaying error in WorkStream4D application. DB may lock under heavy and multitasks..<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Malvern, PA on 4/202015 Voluntary: Firm Initiated recall is

ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
75<p>
DISTRIBUTION
Nationwide and Puerto Rico <p>

6/3/2015 Siemens SOMATOM Emotion 6; Cl II
Company:Siemens Medical Solutions USA, Inc.
Date of Enforcement Report: 6/3/2015
Class II:<p>
PRODUCT
SOMATOM Emotion 6; the intended use of computed tomography is to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data from either the same axial plane taken at different angels or spiral planes taken at different angles. Recall NumberZ-1644-2015<p>
REASON
Software bugs in VC20B SP0a or SP1 software versions may cause issues that could make it necessary to rescan patients. Syngo Main UI may crash if the Patient Browser is scrolled with arrow keys of the keyboard. Tomo images may freeze on the screen when zoomed in or out under the mode of CAREVision. Sporadic displaying error in WorkStream4D application. DB may lock under heavy and multitasks..<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Malvern, PA on 4/202015 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
75<p>
DISTRIBUTION
Nationwide and Puerto Rico <p>

6/3/2015 Medtronic SynchroMed II Implantable Infusion
Cl II
Company: Medtronic Neuromodulation
Date of Enforcement Report: 6/3/2015
Class II:<p>
PRODUCT
Medtronic SynchroMed II Implantable Infusion Pumps, models 8637-20 and 8637-40. Sterile. Product Usage: The implantable Medtronic SynchroMed II programmable pumps are part of an infusion system that stores and delivers a prescribed drug to a specific site. The implanted infusion system consists of a SynchroMed II pump and a catheter Recall NumberZ-1681-2015<p>
REASON
Medtronic is conducting a recall of a specific subset of Model 8637-20 and 8637-40 SynchroMed II implantable drug pumps because the audible alarm could cease to function.<p>
RECALLING FIRM/MANUFACTURER
Medtronic Neuromodulation, Minneapolis, MN on 4/10/2015 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
1901 (1576 US, 325 OUS) <p>
DISTRIBUTION
Nationwide and Internationally <p>

6/3/2015 Panorama Patient Monitoring Network, Cl II
Company: Mindray DS USA, Inc. dba Mindray North America
Date of Enforcement Report: 6/3/2015
Class II:<p>
PRODUCT
Panorama Patient Monitoring Network, Multi- Parameter Patient Monitor (with Arrhythmia Detection and Alarm. Part number 0998-00-0708-01. The Panorama Network includes the Panorama Telemetry System, which acquires and monitors physiological data for ambulating patients within a defined coverage area.
Recall NumberZ-1675-2015<p>
REASON
Software anomaly in the Panorama System software version 8.9 that manifests when the Panorama is in use with Mindray Passport V Monitor. Arrhythmia alarms which were previously displayed on both the Passport V and Panorama will not be displayed on the Panorama following a restart of either system (due to communication loss, restart, etc.).<p>
RECALLING FIRM/MANUFACTURER
Mindray DS USA, Inc. dba Mindray North America, Mahwah, NJ on 3/12/2015 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
4 units<p>
DISTRIBUTION
Texas <p>

6/3/2015 Philips Pinnacle3 Software Version 10.0 Cl II
Company: Philips Medical Systems, Inc.
Date of Enforcement Report 6/3/2015
Class II:<p>
PRODUCT
Pinnacle3 Software Version 10.0, Model 459800200841. Product Usage: The Pinnacle 3 RTP software allows qualified medical professionals to enter patient data into the system, use that data to construct a plan for radiation therapy and evaluate the plan. Optionally, the qualified medical personnel may output the plan in an electronic or printed form for use by other systems in the delivery of treatment to a patient. Recall NumberZ-1643-2015<p>
REASON
A problem (the dose computed in planning mode is calculated incorrectly) has been detected in the Philips Pinnacle3 software version 10.0 that, if it were to re-occur, could pose a risk for patients or users. Specifically, the dose engine is being passed the wrong snout position. The snout position is used to determine the penumbra of the beam which includes the calculation of the source size and the calculation of the compensator scatter. The actual snout position is shown in the planning window as X, but the value passed to the dose engine is Y, where Y=X + (unmilled compensator thickness physical thickness of compensator). The unmilled compensator thickness is defined in physics mode and is usually around 20-30 cm. In rare situations, this translates into an error in the calculation of the penumbra that in some cases, goes beyond the limits of our specification. The issue only exists in planning mode. In physics mode we do not have this issue because the mechanism for sending the snout position to the dose engine is different in physics than in planning mode. Thus the dose computed in planning mode is different than the dose computed in physics mode. The issue is most pronounced for beams that do not have compensators or where the milled compensator is relatively thin compared to the unmilled compensator.<p>
RECALLING FIRM/MANUFACTURER
Philips Medical Systems, Inc., Andover, MA 4/23/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
4 <p>
DISTRIBUTION
US Nationwide Distribution in the states of MO, FL, OH <p>

5/27/2015 EPIQ 7 Ultrasound Systems, Cl II
Company: Philips Ultrasound, Inc..
Date of Enforcement Report: 5/27/2015
Class II:<p>
PRODUCT
EPIQ 7 Ultrasound System versions 1.3.2 or lower, WITHOUT the Pediatric Cardiology option, Model: EPIQ 7G, EPIC 7C, EPIQ 7W. Catalog Number: 795200 / 795201 Part Number: 989605386721 With: 453561726491 (1.0) 453561728121 (1.0.1) 453561736781 (1.1) 453561750021 (1.1.1) 453561753631 (1.1.2) 453561772251 (1.2) 453561772631 (1.2.1) 453561786591 (1.2.2) 453561785101 (1.3) 453561800601 (1.3.1) 453561805211 (1.3.2) Diagnostic ultrasound imaging and fluid flow analysis
Recall NumberZ-1632-2015<p>
REASON
When EPIQ 7 Ultrasound System, WITHOUT the Pediatric Cardiology option, is set up to "Metric" and weight and/or height is entered, a unit conversion error may result in the incorrect display of their values and incorrect calculation of the patients Body Surface Area (BSA).<p>
RECALLING FIRM/MANUFACTURER
Philips Ultrasound, Inc., Bothell, WA on 4/14/2015 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
1692 units total (902 units in the US and 790 units outside the US <p>
DISTRIBUTION
Nationwide and Internationally<p>

5/27/2015 EPIQ 5 Ultrasound System Cl II
Company: Philips Ultrasound, Inc..
Date of Enforcement Report: 5/27/2015
Class II:<p>
PRODUCT
EPIQ 5 Ultrasound System versions 1.3.2 or lower, WITHOUT the Pediatric Cardiology option, Model: EPIQ 5G, EPIC 5C, EPIQ 5W.Catalog Number: 795204 / 795205. Part Number: 989605408541 With 453561736761 (1.1) 453561750041 (1.1.1) 453561753651 (1.1.2) 453561772231 (1.2) 453561772611 (1.2.1) 453561786571 (1.2.2) 453561785081 (1.3) 453561800581 (1.3.1) 453561805181 (1.3.2) Diagnostic ultrasound imaging and fluid flow analysis.
Recall NumberZ-1631-2015<p>
REASON
When EPIQ 5 Ultrasound System, WITHOUT the Pediatric Cardiology option, is set up to "Metric" and weight and/or height is entered, a unit conversion error may result in the incorrect display of their values and incorrect calculation of the patients Body Surface Area (BSA).<p>
RECALLING FIRM/MANUFACTURER
Philips Ultrasound, Inc., Bothell, WA on 4/14/2015 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
Total 1108 units (490 units in US and 618 units outside the US)<p>
DISTRIBUTION
Nationwide and Internationally<p>

5/27/2015 bioMerieux MYLA server HP Proliant, Cl II
Company: bioMerieux Inc.
Date of Enforcement Report: 5/27/2015
Class II:<p>
PRODUCT
MYLA server HP Proliant: DL380-G8 and ML350-G6 version 3.xx computer application software. MYLA V3 is a computer application ("Middleware") based on Web 2.0 technology which: Interfaces between the instruments connected to the application and the LIS(s) (Laboratory Information System(s).

Recall NumberZ-1621-2015<p>
REASON
The MYLA® server could slow down due to the volume (weight) of the data to manage and it could also stop processing, impacting the server start-up phase. The problem occurs in high volume settings. The MYLA server slows down and will stop processing completely if any task requires more than 5 minutes to complete. The server then fails to reboot and requires service, provided remotely or on-site, from the manufacturer to restart the computer. When the MYLA server does not reboot, results are not uploaded to MYLA or transferred to LIS; the results already transferred to MYLA but not yet uploaded into LIS are not accessible. It also means new test requests are not transferred from LIS to MYLA or from MYLA to the systems. In this circumstance the VITEK 2 and BacT/Alert systems can be used as stand-alone systems however the VITEK MS system connected to MYLA would be unusable as MYLA is the user interface for this system.<p>
RECALLING FIRM/MANUFACTURER
bioMerieux Inc., Durham, NC on 4/14/2015 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
730 units<p>
DISTRIBUTION
Nationwide and Internationally <p>

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5/27/2015 Baxter ABACUS SE, Cl II
Company: Baxter Corporation Englewood
Date of Enforcement Report: 5/27/2015
Class II:<p>
PRODUCT
ABACUS SE (Single-Workstation Edition) and ABACUS ME (Multi-Workstation Edition) Product Usage: The ABACUS Software is a Windows-based order entry software application for comprehensive total parenteral nutrition (TPN) calculations and label printing. Recall NumberZ-1628-2015<p>
REASON
Baxter Corporation is conducting a field action for the ABACUS SE and ME models due to the possibility that the compounder will load the incorrect formula upon scanning the bag label when two or more different formula files have been created with the same order number.<p>
RECALLING FIRM/MANUFACTURER
Baxter Corporation Englewood, Englewood, CO on 4/8/2015 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
882 <p>
DISTRIBUTION
Nationwide <p>

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5/27/2015 Philips Healthcare DuraDiagnost X- Ray Cl II
Company: Philips Medical Systems, Inc.
Date of Enforcement Report 5/27/2015
Class II:<p>
PRODUCT
Philips Healthcare DuraDiagnost X- Ray
Recall NumberZ-1555-2015<p>
REASON
The system is designed to emit a beep upon termination of an exposure. However, if the system has been powered on for over 12 hours, the system will no longer emit this signal. This is a failure to comply with 21CFR 1020.31(j).<p>
RECALLING FIRM/MANUFACTURER
Philips Medical Systems, Inc., Andover, MA 2/9/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE

3 DuraDiagnost <p>
DISTRIBUTION
Worldwide <p>

5/27/2015 Philips Healthcare DigitalDiagnost Xray Cl II
Company: Philips Medical Systems, Inc.
Date of Enforcement Report 5/27/2015
Class II:<p>
PRODUCT
Philips Healthcare DigitalDiagnost System X-Ray
Recall NumberZ-1554-2015<p>
REASON
The system is designed to emit a beep upon termination of an exposure. However, if the system has been powered on for over 12 hours, the system will no longer emit this signal. This is a failure to comply with 21CFR 1020.31(j).<p>
RECALLING FIRM/MANUFACTURER
Philips Medical Systems, Inc., Andover, MA 2/9/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
54 DigitalDiagnost<p>
DISTRIBUTION
Worldwide <p>

5/20/2015 GE Healthcare, CARESCAPE Monitors, Cl II
Company:GE Healthcare
Date of Enforcement Report: 5/20/2015
Class II:<p>
PRODUCT
GE Healthcare, CARESCAPE Monitor B850, B650 and B450 (Bx50).
Recall NumberZ-1606-2015<p>
REASON
The heart rate could be calculated from pacer pulses without indication that pacemaker detection is OFF in some combinations of Bx50 monitors, a PDM, and CIC/CSCS. Then the monitor does not show the Pacer Off message and there may not be an alarm for asystole. Undetected asystole could result in irreversible changes in the patient´s condition and delayed or missed life sustaining patient treatment.<p>
RECALLING FIRM/MANUFACTURER
GE Healthcare, Waukesha, WI on 5/4/2015 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
110 (83 units US, 27 units OUS)<p>
DISTRIBUTION
Nationwide and Internationally. <p>

5/20/2015 Fujifilm Synapse® Cl II
Company: Fujifilm Medical Systems U.S.A., Inc.
Date of Enforcement Report: 5/20/2015
Class II:<p>
PRODUCT
FujiMedical Synapse® Cardiovascular I ProSolv® CardioVascular. A picture Archiving and Communication System Software versions: Synapse® Cardiovascular v4.0.8 Synapse® Cardiovascular v4.0.8 SR1 Recall NumberZ-1611-2015<p>
REASON
Modules resetting. This failure mode happens when the Spacelabs Command Module is configured with the Masimo SpO2 option (-M), the Spacelabs Respiration option (-R) and the Masimo SpO2 PCBA,

PN: 010-1136-02. With these two options and the Masimo SpO2 PCBA present, the module may experience random resets.<p>
RECALLING FIRM/MANUFACTURER
Fujifilm Medical Systems U.S.A., Inc., Stamford, CT on 2/4/2015 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
30 units<p>
DISTRIBUTION
Nationwide and Internationally <p>

5/13/2015 Spacelabs- Ultraview SL Command Modules, CI II

Company: Spacelabs Healthcare Inc
Date of Enforcement Report: 5/13/2015
Class II:<p>
PRODUCT
Ultraview SL Command Modules, Model 91496, with the Masimo SpO2 PCBA, PN: 010-1636-02. The Spacelabs Multi-parameter Module is intended for use with the Patient Care Management System (PCMS) to acquire, monitor, and process various clinical parameters from an adult or neonate/infant populations in any type of clinical environment other than home use. Recall NumberZ-1577-2015<p>
REASON
Modules resetting. This failure mode happens when the Spacelabs Command Module is configured with the Masimo SpO2 option (-M), the Spacelabs Respiration option (-R) and the Masimo SpO2 PCBA, PN: 010-1136-02. With these two options and the Masimo SpO2 PCBA present, the module may experience random resets.<p>
RECALLING FIRM/MANUFACTURER
Spacelabs Healthcare Inc,. Snoqualmie, WA on 4/21/2015 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
1944 units<p>
DISTRIBUTION
Nationwide and Internationally <p>

5/13/2015 Siemens ACUSON SC2000, CI II

Company:Siemens Medical Solutions USA, Inc.
Date of Enforcement Report: 5/13/2015
Class II:<p>
PRODUCT
ACUSON SC2000 volume imaging ultrasound systems at software versions VA16C, VA16D and VA16E. Model 10433816. Product Usage: The SC2000 ultrasound imaging system is intended for the following applications: Cardiac, Neo-natal and Fetal Cardiac, Pediatric, Transespohageal, Adult Cephalic, Peripheral Vessel, Abdominal, Abdominal Intraoperative, Intraoperative Neurological, Musculo-skeletal Conventional, and Musculo-skeletal Superficial applications. The system also provides the ability to measure anatomical structures and calculation packages that provide information to the clinician that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes. Typical examination performed using the SC2000 Ultrasound System are: Cardiac Imaging Applications and Analysis; Vascular Imaging Applications and Analysis; Superficial Imaging Applications; Intraoperative Imaging Applications; Transcranial Imaging Applications;
Recall NumberZ-1581-2015<p>
REASON
In some cases, the system is unable to capture a clip or image during a routine scan.<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Mountain View, CA on 5/11/2012 Voluntary: Firm Initiated recall

has been termindated <p>
VOLUME OF PRODUCT IN COMMERCE
186 units<p>
DISTRIBUTION
Nationwide and Internationally<p>

5/13/2015 EPIQ 7 Ultrasound-Pediatric Cardio Option,
Cl II

Company: Philips Ultrasound, Inc..
Date of Enforcement Report: 5/13/2015
Class II:<p>
PRODUCT
EPIQ 7 Ultrasound System with Pediatric Cardiology option, Model: EPIQ 7G, EPIC 7C, EPIQ 7W. Catalog Number: 795200 / 795201. Part Number: 989605386721 With: 453561726491 (1.0) 453561728121 (1.0.1) 453561736781 (1.1) 453561750021 (1.1.1) 453561753631 (1.1.2) 453561772251 (1.2) 453561772631 (1.2.1) 453561786591 (1.2.2) 453561785101 (1.3) 453561800601 (1.3.1) 453561805211 (1.3.2)
Recall NumberZ-1579-2015<p>
REASON
When Epiq 7 Ultrasound System, WITH the Pediatric Cardiology option, is set up to Metric and weight and/or height is entered, a unit conversion error may result in the incorrect calculation of the patients Body Surface Area (BSA).<p>
RECALLING FIRM/MANUFACTURER
Philips Ultrasound, Inc., Bothell, WA on 4/10/2015 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
2472 units total<p>
DISTRIBUTION
Nationwide and Internationally<p>

5/13/2015 EPIQ 5 Ultrasound-Pediatric Cardio Option,
Cl II

Company: Philips Ultrasound, Inc..
Date of Enforcement Report: 5/13/2015
Class II:<p>
PRODUCT
EPIQ 5 Ultrasound System with Pediatric Cardiology option, Model: EPIQ 5G, EPIC 5C, EPIQ 5W. Catalog Number: 795204 / 795205. Part Number: 989605408541 With 453561736761 (1.1) 453561750041 (1.1.1) 453561753651 (1.1.2) 453561772231 (1.2) 453561772611 (1.2.1) 453561786571 (1.2.2) 453561785081 (1.3) 453561800581 (1.3.1) 453561805181 (1.3.2) Recall NumberZ-1578-2015<p>
REASON
When Epiq 5 Ultrasound System, WITH the Pediatric Cardiology option, is set up to Metric and weight and/or height is entered, a unit conversion error may result in the incorrect calculation of the patients Body Surface Area (BSA).<p>
RECALLING FIRM/MANUFACTURER
Philips Ultrasound, Inc., Bothell, WA on 4/10/2015 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
751 units total<p>
DISTRIBUTION
Nationwide and Internationally<p>

5/13/2015 ViewRay Radiation Therapy System, Cl II
Company: ViewRay Inc.
Date of Enforcement Report: 5/13/2015
Class II:<p>
PRODUCT
ViewRay System, Radiation Therapy System
Recall NumberZ-1580-2015<p>
REASON
The software was not correctly using the RT (Radiation Therapy) to MR (Magnetic Resonance image) coordinate correction for non HFS (Head First Supine) patient orientations, resulting in slice mismatch error.<p>
RECALLING FIRM/MANUFACTURER
ViewRay Inc, Oakwood Village, OH on 1/15/2015 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
1<p>
DISTRIBUTION
US distribution to MO.. <p>

5/13/2015 BrainLabExacTrac 6.x Cl II
Company:Brainlab AG
Date of Enforcement Report: 5/13/2015
Class II:<p>
PRODUCT
ExacTrac 6.x. is software used to place patients at an accurately defined point within the treatment beam of a medical accelerator for stereotactic radiosurgery or radiotherapy procedures. Recall Number Z-1582-2015<p>
REASON
ExacTrac 6.x Patient Positioning System: Potentially incorrect patient positioning when using the ExacTrac Cone Beam CT (CBCT) with a CBCT acquired at a couch angle other than 0.0 degrees.<p>
RECALLING FIRM/MANUFACTURER
Brainlab AG, Feldkirchen, DE on 3/6/2015 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
26 systems<p>
DISTRIBUTION
Nationwide and Internationally <p>

5/13/2015 Stryker Universal Battery Charger, Cl III
Company:Stryker Instruments Div. of Stryker Corporation.
Date of Enforcement Report: 5/13/2015
Class III:<p>
PRODUCT
Universal Charger Product Usage: The Stryker Universal Battery Charger is designed to be used in conjunction with and provide power to non-sterile and sterile batteries. The Stryker Universal Battery Charger is a four station, modular battery charger intended to charge Stryker handpiece battery packs only. The battery charger has the optional functionality to track device usage data. Usage data is accumulated by Stryker and reports are able to be provided to the customer. Recall Number Z-1587-2015<p>
REASON
The Stryker Universal Battery Charger is not transmitting usage data to the Stryker Cloud as designed. The firm is initiating a software correction to address the issue..<p>
RECALLING FIRM/MANUFACTURER
Stryker Instruments Div. of Stryker Corporation, Portage, MI on 3/25/2015 Voluntary: Firm Initiated recall is ongoing <p>

VOLUME OF PRODUCT IN COMMERCE
223 chargers<p>
DISTRIBUTION
Nationwide <p>

5/13/2015 EOS, Digital radiography system, Cl II
Company: Eos Imaging Inc.
Date of Enforcement Report: 5/13/2015
Class II:<p>
PRODUCT
EOS, Digital radiography system used in general radiographic examinations.
Recall NumberZ-1460-2015<p>
REASON
When performing calibration, an alert message on the spectral filtration of the X-ray beam may be suppressed. Improper filtration of the X-ray Beam can then occur in exams set up with copper filtration.<p>
RECALLING FIRM/MANUFACTURER
Eos Imaging Inc, Cambridge, MA on 2/17/2015 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
13<p>
DISTRIBUTION
US Distribution to the states of: CA, DE, PA, MN, FL, MO, OH, IN and IL. <p>

5/13/2015 MHI-TM2000 Linear Accelerator System, Cl II
Company: MITSUBISHI HEAVY INDUSTRIES, LTD., HIROSHIMA MACHINERY WORK.
Date of Enforcement Report: 5/13/2015
Class II:<p>
PRODUCT
MHI-TM2000 Linear Accelerator System (Software Version 3.5.0 and 3.5.1)
Recall NumberZ-1574-2015<p>
REASON
The operator console allows users to deliver therapeutic radiation to patients even though a specific communication error relevant to imaging conditions has occurred. In addition, the treatment record (the delivered radiation record) cannot be saved.<p>
RECALLING FIRM/MANUFACTURER
MITSUBISHI HEAVY INDUSTRIES, LTD., HIROSHIMA MACHINERY WORK, HIROSHIMA, JP on 4/17/2015 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
11<p>
DISTRIBUTION
Nationwide and Internationally <p>

5/13/2015 FDA MedWatch Infusion Pump Cybersecurity Alert
FDA issued a medwatch alert May 13, 2015 regarding security vulnerabilities in Hospira's LifeCare PCA3 and PCA5 Infusion Pump Systems.A researcher has shown that exploiting the vulnerabilies could allow an unauthorized user to remotely modify the dosage delivered. Homeland security was previously working with Hospira about this vulnerability. The full MedWatch noice is at the link provided.

5/6/2015 Spacelabs Ultraview SL Command Modules, Cl II

Company: Spacelabs Healthcare Inc
Date of Enforcement Report: 5/6/2015
Class II:<p>
PRODUCT
Ultraview SL Command Modules, Model 91496-M, upgraded with the Masimo SpO2 Option. Product Usage: The Spacelabs Multi-parameter Module is intended for use with the Patient Care Management System (PCMS) to acquire, monitor, and process various clinical parameters from an adult or neonate/infant populations in any type of clinical environment other than home use. Physiological parameters that may be monitored include ECG with arrhythmia detection, respiration, invasive and noninvasive blood pressure, temperature, oxygen saturation (Sp02) and cardiac output. Acquired data may then be communicated to all information network for display, recording, editing and analysis.
Recall NumberZ-1542-2015<p>
REASON
Ultraview SL Command Modules which were upgraded with the Masimo SpO2 Option, Model 91496-M was affected. Customer reported that during the time that the module is resetting (~10 seconds), monitoring of all parameters will be suspended. Upon completion of this sequence, alarms will be reset to their default values.<p>
RECALLING FIRM/MANUFACTURER
Spacelabs Healthcare Inc,. Snoqualmie, WA on 4/17/2015 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
1999 units total (1932 in the US and 67 international) <p>
DISTRIBUTION
Nationwide and Internationally <p>

5/6/2015 Nihon Kohden Remote Network Station, Cl II

Company: Nihon Kohden America Inc.
Date of Enforcement Report: 5/6/2015
Class II:<p>
PRODUCT
Remote Network Station, Catalog RNS-9703, Model No. RNS-9703-19, RNS-9703-24, Software version 02.40. The RNS 9703 is intended for use by medical professionals to provide secondary cardiac and vital signs monitoring for multiple patients within a medical facility. The device will display physiological data from up to 16 telemetry receiver/transmitters or bedside monitors and generate an alarm when a measured parameter falls outside a pre-set limit or when life threatening arrhythmias are detected.
Recall NumberZ-1543-2015<p>
REASON
Nihon Kohden America (NKA) is recalling the Remote Network Station (RNS) 9703 because it may fail to sound.<p>
RECALLING FIRM/MANUFACTURER
Nihon Kohden America Inc, Irvine, CA on 4/14/2015. Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
208 units <p>
DISTRIBUTION
Nationwide<p>

5/6/2015 AMSCO C and AMSCO 400 Steam Sterilizers, Cl II

Company: Steris Corporation
Date of Enforcement Report: 5/6/2015
Class II:<p>

PRODUCT
AMSCO C and AMSCO 400 Steam Sterilizers, STERIS Corporation. AMSCO C Small Sterilizer, AMSCO 400 Small Sterilizer, AMSCO 400 Medium Sterilizer. Designed for sterilization of heat and moisture-stable materials used in healthcare facilities.
Recall NumberZ-1561-2015<p>
REASON
STERIS has identified that the control board software in select AMSCO 400 and AMSCO C units will interrupt and cancel a processing cycle should the selected sterilizer shutdown time coincide with a processing cycle. This may result in a procedure delay.<p>
RECALLING FIRM/MANUFACTURER
Steris Corporation, Mentor, OH on 2/19/2015 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
701 units<p>
DISTRIBUTION
Nationwide and Internationally <p>

5/6/2015 Dako Test Request Distributor , Cl II
Company: Dako North America Inc.
Date of Enforcement Report: 5/6/2015
Class II:<p>
PRODUCT
Test Request Distributor (TRD 1.3 and TRD 1.4), a software module used on the Dako Omnis System, an automated slide stainer for in vitro diagnostic use. The TRD is intended to distribute patient case, appropriate parts information, track changes, and transform test requests from LIS or manual entries to connected Dako systems.
Recall NumberZ-1548-2015<p>
REASON
If a user requests slides from the LIS or TPID, then updates a request by changing the test, the TRD software will reject the update. The LIS and printed slide label will display the updated test with the requested change, but the Omnis system will execute the initial test, not reflecting the change. The system will not warn the user that the test request was rejected.<p>
RECALLING FIRM/MANUFACTURER
Dako North America Inc.,Carpinteria, CA on 4/1/2015 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
37<p>
DISTRIBUTION
Nationwide and Internationally <p>

5/6/2015 Lumenis Light Sheer Desire Diode Laser, Cl II
Company: Lumenis Limited.
Date of Enforcement Report: 5/6/2015
Class II:<p>
PRODUCT
Light Sheer Desire Diode Laser System with XC Handpiece Accessory options.
Recall NumberZ-1519-2015<p>
REASON
Device software treatment preset parameters for the XC treatment handpiece do not match the Operator Manual, and exceed recommended settings. Operator Manual parameters are lower than indicated for specific hair color and Fitzpatrick skin type resulting in insufficient treatment effect. May result in patient burns and hypopigmentation.<p>
RECALLING FIRM/MANUFACTURER
Lumenis Limited, , IL on 3/25/2015 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE

117 units <p>
DISTRIBUTION
Nationwide and Internationally <p>

5/6/2015 VITROS 5,1 Software Version 2.8 & Below, Cl II
Company:Ortho-Clinical Diagnostics
Date of Enforcement Report: 5/6/2015
Class II:<p>
PRODUCT
Software Version 2.8 & Below on VITROS 5,1 FS Chemistry Systems, Catalog Number 6801375, Global Trade Item Number 10758750001132, and VITROS 5,1 FS Chemistry System Refurbished, Catalog Number 6801890, Global Trade Item Number 10758750001644; IVD. Intended for use in the in vitro quantitative, semi quantitative, and qualitative measurement of a variety of analytes of clinical interest, using VITROS Chemistry Products MicroSlides and VITROS Chemistry Products MicroTip Reagents.
Recall NumberZ-1521-2015<p>
REASON
Software Anomaly; It is possible for the device to process samples with a cartridge other than the intended cartridge, potentially leading to erroneous patient results. If this anomaly occurred previously, an indication would be a series of results that were similar across multiple samples (i.e., results could be believable or outside of the Reportable Range for the intended assay).<p>
RECALLING FIRM/MANUFACTURER
Ortho-Clinical Diagnostics, Rochester, NY on 3/10/2015 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
VITROS 5.1 System: Domestic - 909; Foreign - 1250; 5,1 Refurbished: Domestic - 66 units, Foreign - 152<p>
DISTRIBUTION
Nationwide and Internationally <p>

5/3/2015 Catalys Precision Laser System, Cl II
Company: Optimedica Corporation
Date of Enforcement Report: 5/27/2015
Class II:<p>
PRODUCT
Catalys Precision Laser System-Catalys - U - US product; Catalys-1 - International product; software version 3.00.05 The OptiMedica Catalys Precision Laser System is indicated for use in patients undergoing cataract surgery for removal of the crystalline lens. Recall NumberZ-1683-2015<p>
REASON
Software anomaly on OptiMedica CATALYS System version 3.00.05 that may result in incorrect parameters provided for cataract incision surgeon templates and both eyes have the same parameters.<p>
RECALLING FIRM/MANUFACTURER
BOptimedica Corporation, Sunnyvale, CA on 2/20/2015 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
171 <p>
DISTRIBUTION
Nationwide and Internationally<p>

4/29/2015 Spacelabs Pediatric Flow Sensor Kit, Cl II
Company: Del Mar Reynolds Medical, Ltd.
Date of Enforcement Report: 4/29/2015
Class II:<p>
PRODUCT

Spacelabs Pediatric Flow Sensor Kit, PN: 376-0561-00. This kit is for Spacelabs Healthcare Blease 700/900 Series Ventilators. Designed specifically for the mechanical ventilation of adult and pediatric patients under general anesthesia.
Recall NumberZ-1458-2015<p>
REASON
Reports of inaccurate low flow readings. Monitored inspiratory tidal volume (VTi) and expiratory tidal volume (Vte) measurements from the pediatric flow sensor are reporting out of specification low compared to the actual delivered volumes being administered to the patient.<p>
RECALLING FIRM/MANUFACTURER
Del Mar Reynolds Medical, Ltd., Hertford GB on 3/5/2015 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
1040 units total (398 in the US and 642 international)<p>
DISTRIBUTION
Nationwide and Internationally <p>

4/29/2015 Thermedx Fluid Management System P4000, Cl II

Company:Thermedx LLC
Date of Enforcement Report: 4/29/2015
Class II:<p>
PRODUCT
Fluid Management System P4000; for irrigation and fluid warming in laparoscopic procedures, and distention, fluid warming, and volume/deficit measurements in endoscopic procedures within gynecology, urology, and orthopedic procedures.
Recall NumberZ-1463-2015<p>
REASON
To correct software bugs that could affect the ability to accurately measure fluid deficit..<p>
RECALLING FIRM/MANUFACTURER
Thermedx LLC, Solon, OH on 9/1/2014 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
127 units<p>
DISTRIBUTION
US Distribution to the states of : OH, MS, MA, WA, MI, NC, NY, WV, LA, TX and IL. <p>

4/22/2015 Baxter Master Drug Library Software, Cl II

Company:Baxter Healthcare Corp
Date of Enforcement Report: 4/22/2015
Class II:<p>
PRODUCT
Master Drug Library Software version 8.0, Product Code 35723V080, to be used with SIGMA Spectrum Infusion System (Pump) version 8.0, Product Code 35700BAX2 The SIGMA Spectrum Infusion Pump with Master Drug Library (MDL) is intended to be used for the controlled administration of fluids. Recall NumberZ-1451-2015<p>
REASON
Loading/Bolus default dose settings in the Master Drug Library and the values shown on the pump during programming may differ. MDL drug dose time in seconds will round to the nearest integer in minutes on the pump dose setup screen (20 sec may show as 1 min on the pump display). The pump will administer drugs as configured. The discrepancy may cause therapy delay or unintended rate of delivery.<p>
RECALLING FIRM/MANUFACTURER
Baxter Healthcare Corp, Deerfield, IL on 3/2/2015 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
58 MDLs<p>

DISTRIBUTION
Nationwide and Internationally <p>

4/15/2015 Siemens ADVIA Chemistry XPT System, Cl II
Company:Siemens Medical Solutions USA, Inc.
Date of Enforcement Report: 4/15/2015
Class II:<p>
PRODUCT
ADVIA Chemistry XPT System, Siemens Material Number 10723034, Software Version 1.0.2, Siemens Material Number 11219493, IVD. The ADVIA XPT Chemistry System is an automated, clinical chemistry analyzer that runs tests on serum, plasma, urine, or cerebral spinal fluid in random access and batch modes at a throughput rate of both 1800 photometric tests per hour and 600 electrolyte (ISE) tests per hour.
Recall NumberZ-1399-2015<p>
REASON
Siemens Healthcare Diagnostics has confirmed an issue with ADVIA Chemistry XPT software version 1.0.2. The system may cause samples to remain in an Inprocess state. Test results on a sample that is held Inprocess will not transmit to the LIS. Manual intervention is necessary to complete the processing of the samples that are held Inprocess.<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc,Tarrytown, NY on 2/11/2015 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
16 units<p>
DISTRIBUTION
Distributed in the states of AZ, CA, and WA, and the countries of Germany, Italy, Spain, and UK. <p>

4/8/2015 ACCU-CHEK Connect Diabetes Management App, Cl II
Company:Roche Diabetes Care, Inc.
Date of Enforcement Report: 4/8/2015
Class II:<p>
PRODUCT
ACCU-CHEK Connect Diabetes Management App; Instruction Manual Designed to transfer data for diabetes management. Recall NumberZ-1369-2015<p>
REASON
Roche Diabetes Care has become aware of an issue with the Accu-Chek Connect diabetes management app that could potentially lead to inaccurate bolus advice being provided to the user. A thorough investigation of the situation revealed that this issue may occur if the user changes the screen orientation of the phone from portrait to landscape or vise versa while looking at the Bolus Advisor or Carbohydrate Entry screens.<p>
RECALLING FIRM/MANUFACTURER
Roche Diabetes Care, Inc.Indianapolis, IN on 10/30/2014 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
The application has been downloaded total of 644 times (Italy-219, South Africa-24, Germany-401) and there are 113 bolus advice activations.<p>
DISTRIBUTION
There are no US distributors as the affected device is not marketed in the US. The affected device was distributed in Germany, Italy and South Africa. The application has been downloaded total of 644 times (Italy-219, South Africa-24, Germany-401) and there are 113 bolus advice activations.<p>

4/8/2015 SiemensSyngo.plazma, Cl II
Company:Siemens Medical Solutions USA, Inc.
Date of Enforcement Report: 4/8/2015
Class II:<p>
PRODUCT
Syngo.plaza. A Picture Archiving and Communication System (PACS) intended to display, process, read, report, communicate, distribute, store and archive digital medical images. It supports the physician in diagnosis and treatment planning.
Recall NumberZ-1354-2015<p>
REASON
Possibly incomplete archived studies during pre-fetch. In a server farm setup, when pre-fetch/retrieve operation is performed for partially archived studies, the series that have not yet been archived, will remain unarchived.<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Malvern, PA on 2/18/2015 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
4<p>
DISTRIBUTION
US Distribution: MA, WI, FL <p>

4/8/2015 Philips Computed Tomography X-ray Systems
Cl II
Company: Philips Medical Systems, Inc.
Date of Enforcement Report 4/8/2015
Class II:<p>
PRODUCT
Computed Tomography X-ray Systems (Brilliance CT 64-channel w/Essence technology, Brilliance iCT, Brilliance iCT SP, Ingenuity Core, Ingenuity Core128 & Ingenuity CT), Philips Medical Systems, Cleveland, OH Recall NumberZ-1359-2015<p>
REASON
Philips discovered that a software defect exists in marketed product wherein the sign indication of the longitudinal position of some types of scan is inverted.<p>
RECALLING FIRM/MANUFACTURER
Philips Medical Systems, Inc., Cleveland, OH 2/5/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
424<p>
DISTRIBUTION
Worldwide <p>

4/1/2015 BrainLab ExacTrac versions 6.x , Cl II
Company:Brainlab AG
Date of Enforcement Report: 4/1/2015
Class II:<p>
PRODUCT
ExacTrac versions 6.x patient positioning systems are used to position patients during radiosurgery or radiotherapy procedures..
Recall NumberZ-1316-2015<p>
REASON
The ExacTrac 6.x Patient Positioning System may incorrectly position the patient when using the ExacTrac Cone Beam CT (CBCT) with a TrueBeam-specific optional subvolume-CBCT..<p>
RECALLING FIRM/MANUFACTURER
Brainlab AG, Feldkirchen, DE on 2/16/2015 Voluntary: Firm Initiated recall is ongoing <p>

VOLUME OF PRODUCT IN COMMERCE
24 systems (US); 36 systems (Foreign)<p>
DISTRIBUTION
Nationwide and Internationally <p>

4/1/2015 Siemens MAGNETOM systems, CI II
Company:Siemens Medical Solutions USA, Inc.
Date of Enforcement Report: 4/1/2015
Class II:<p>
PRODUCT
MAGNETOM systems Aera/Skyra/Avanto/Verio with software syngo MR D13A ; indicated for use as magnetic resonance diagnostic devices (MRDD) that produce transverse, sagittal, coronal and oblique cross-sectional images, spectroscopic images and/or spectra, and that display the internal structure and/or function of the head, body, or extremities. Other physical parameters derived from the images and/or spectra may also be produced. Depending on the region of interest, contrast agents may be used. These images and/or spectra and the physical parameters derived from the images and/or spectra, when interpreted by a trained physician, yield information that may assist in diagnosis. The MAGNETOM systems may also be used for imaging during interventional procedures when performed with MR compatible devices such as in-room display and MR-safe biopsy needles.
Recall NumberZ-1308-2015<p>
REASON
The gradient output supervision was permanently turned off on the MAGNETOM system, meaning that gradient outputs could exceed IEC60601-2-33 limits and peripheral nerve stimulation could occur.<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Malvern, PA on 3/9/2015 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
132<p>
DISTRIBUTION
Nationwide <p>

4/1/2015 GE Healthcare, SIGNA Systems , CI II
Company:GE Healthcare
Date of Enforcement Report: 4/1/2015
Class II:<p>
PRODUCT
GE Healthcare, SIGNA 1.5T TWINSPEED, SIGNA INFINITY MRISYSTEM, SIGNA 3.0T INFINITY WITH EXCITE, SIGNA 3.0T WITH EXCITE, SIGNA EXCITE 1.5T, SIGNA EXCITE 3.0T, GE 1.5T AND 3.0T SIGNA HDX MR SYSTEM, Discovery MR750 3.0T, Discovery MR450 1.5T, Discovery MR750w 3.0T, Optima MR450w 1.5T, SIGNA Contour, Brivo MR355, Optima MR360, GE 1.5T SIGNA HDE MR SYSTEM, Signa Openspeed 0.7T MR SYSTEM, Vectra, SIGNA 0.35T OVATION WITH EXCITE, SIGNA 0.2T PROFILE With EXCITE MRI Systems. Recall NumberZ-1305-2015<p>
REASON
GE Healthcare has become aware of a potential safety issue involving MRI systems due to software versions not being maintained properly at some sites.<p>
RECALLING FIRM/MANUFACTURER
GE Healthcare, Waukesha, WI on 3/9/2015 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
9,369 (2,937 US, 6,432 OUS).<p>
DISTRIBUTION
Nationwide and Internationally. <p>

4/1/2015 RayStation Radiation Treatment Plan System
Cl II
Company:RAYSEARCH LABORATORIES AB
Date of Enforcement Report: 4/1/2015
Class II:<p>
PRODUCT
RayStation Radiation Therapy Treatment Planning System; -- RayStation 3.5, RayStation 4.0, RayStation 4.5 and RayStation 4.7. For RayStation 4.7, the issue applies also to machines with fixed jaws, regardless of MLC/jaw position. RayStation is a software system designed for treatment planning and analysis of radiation therapy.
Recall NumberZ-1310-2015<p>
REASON
RaySearch Laboratories AB became aware of an issue found with photon dose calculation for DMLC (Dynamic MLC) plans for machines where the MLC is positioned above the jaws, e.g. some Elekta linacs. The magnitude of the error depends on the beam model output factor corrections and on the individual DMLC plan characteristics.<p>
RECALLING FIRM/MANUFACTURER
RAYSEARCH LABORATORIES AB, Stockholm, SE on 3/4/2015 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
Domestic: 245 units<p>
DISTRIBUTION
Nationwide. <p>

4/1/2015 Alaris PC units infusion pumps, Cl II
Company:CareFusion 303, Inc.
Date of Enforcement Report: 4/1/2015
Class II:<p>
PRODUCT
Alaris PC units, Model No. 8015. Infusion pump.
Recall NumberZ-1311-2015<p>
REASON
CareFusion is recalling the Alaris PC unit because of an error code. The error code may occur upon power on during the "Power-On Self Test" due to a keypad issue.<p>
RECALLING FIRM/MANUFACTURER
CareFusion 303, Inc., San Diego, CA on 3/12/2015 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
56,015 units<p>
DISTRIBUTION
Nationwide and Internationally. <p>

3/25/2015 Passport V Monitor, Cl II
Company:Mindray DS USA, Inc. dba Mindray North America
Date of Enforcement Report: 3/25/2015
Class II:<p>
PRODUCT
VITROS Hand-held Barcode Scanner, Catalog Number 6844210, for use with the following Passport V Monitor, Multiparameter Patient Monitor(with Arrhythmia Detection and Alarms) Intended for intra hospital use under the direct supervision of a licensed healthcare practitioner. Recall Number Z-1280-2015<p>
REASON
An issue has been identified with Passport V Monitors invasive blood pressure function (IBP) which may provide an incorrect IBP measurement<p>

RECALLING FIRM/MANUFACTURER
Mindray DS USA, Inc. dba Mindray North America, Mahwah, NJ on 1/23/2015 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
519<p>
DISTRIBUTION
Nationwide. <p>

3/25/2015 St. Jude TactiSys Quartz Pack, Cl II
Company:St Jude Medical.
Date of Enforcement Report: 3/25/2015
Class II:<p>
PRODUCT
TactiSys Quartz Pack, PN-004 400. For percutaneous catheter radiofrequency (RF) ablation of atrial cardiac arrhythmias that allows visualization of the contact force between TactiCath quartz catheter tip and the heart wall. Product Usage: This device is indicated for use in cardiac electrophysiological mapping and for the treatment of drug refractory recurrent symptomatic paroxysmal atrial fibrillation, when used in conjunction with a compatible radiofrequency generator and three-dimensional mapping system.
Recall NumberZ-1284-2015<p>
REASON
A configuration update needs to be done on TactiSys to appropriately recognize all TactiCath catheters.<p>
RECALLING FIRM/MANUFACTURER
St Jude Medical, Saint Paul, MN on 11/25/2014 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
89<p>
DISTRIBUTION
Nationwide <p>

3/25/2015 Siemens LANTIS Oncology Information System, Cl II
Company:Siemens Medical Solutions USA, Inc.
Date of Enforcement Report: 3/25/2015
Class II:<p>
PRODUCT
Siemens LANTIS Oncology Information System Servers; allows the radiation therapist to deliver treatment to patient using the MEVATRON and all available accessories
Recall NumberZ-1282-2015<p>
REASON
There is a potential safety risk when using LANTIS server software with operating systems with which it has not been validated or released which can lead to an incorrect treatment to the patient..<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Malvern, PA on 1/21/2015 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
87<p>
DISTRIBUTION
Nationwide <p>

3/25/2015 SIEMENS ARTISTE MV System, Cl II
Company:Siemens Medical Solutions USA, Inc.
Date of Enforcement Report: 3/25/2015
Class II:<p>
PRODUCT
ARTISTE MV System, Linear Accelerator (LINAC) with SysVC10A software. The intended use of the ARTISTE MV System linear accelerator system is to deliver x-ray radiation for therapeutic treatment of cancer. Recall NumberZ-0984-2015<p>
REASON
There may be an existing dark current phenomenon on ARTISTE LINAC in combination with IMRT or mARC treatments using unflat beams. Software issue..<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Malvern, PA on 11/19/2014 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
3<p>
DISTRIBUTION
US Distribution to the states of UT, WI, and NY. <p>

3/18/2015 VITROS Hand-held Barcode Scanner, Cl II
Company:Ortho-Clinical Diagnostics
Date of Enforcement Report: 3/18/2015
Class II:<p>
PRODUCT
VITROS Hand-held Barcode Scanner, Catalog Number 6844210, for use with the following VITROS Systems: VITROS 5,1 FS Chemistry System, VITROS 3600 Immunodiagnostics System, VITROS 4600 Chemistry System, VITROS 5600 Integrated System. This product is an accessory for use with VITROS Analyzer Systems.
Recall NumberZ-1263-2015<p>
REASON
n combination with the Batch Programming option (only) for programming samples, the hand-held barcode scanner unexpectedly skips sample cup positions within a sample tray. This issue only occurs when using the Batch Programming option; all other sample programming options function as intended..<p>
RECALLING FIRM/MANUFACTURER
Ortho-Clinical Diagnostics, Rochester, NY on 12/29/2014 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
Domestic: 62 units; Foreign: 10 units<p>
DISTRIBUTION
Nationwide and the countries of Canada, Australia and England. <p>

3/18/2015 Juno DFR x-ray system Cl II
Company: Villa Radiology Systems LLC.
Date of Enforcement Report 3/18/2015
Class II:<p>
PRODUCT
Juno DFR x-ray system
Recall NumberZ-1079-2015<p>
REASON
It has been discovered that the system - does not provide the appropriate audible signal, permanent activation, and manual override, although the system is in high-level control functionality<p>
RECALLING FIRM/MANUFACTURER
Villa Radiology Systems LLC, Oxford, CT. 12/14/2014. Voluntary: Firm Initiated recall is ongoing. <p>

VOLUME OF PRODUCT IN COMMERCE
30<p>
DISTRIBUTION
Nationwide <p>

3/18/2015 SIEMENS SOMATOM Force, Cl II
Company:Siemens Medical Solutions USA, Inc.
Date of Enforcement Report: 3/18/2015
Class II:<p>
PRODUCT
SIEMENS SOMATOM Force with software version VA50A and /or VA50A_FP1 and/or VA50A_SP0; Product Usage: The intended use of computed tomography is to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data from either the same axial plane taken at different angels or spiral planes taken at different angles. Recall NumberZ-1267-2015<p>
REASON
Possibility of image artifacts during data acquisition when using Adaptive Cardio Sequence, Turbo Flash, and Head modes. The update improves system start-up behavior and resuming, ECG handling with visual feedback of correct placement of ECG leads and contact quality, and other safety related issues.<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Malvern, PA on 2/6/2015 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
12<p>
DISTRIBUTION
Nationwide <p>

3/11/2015 Medtronic CareLink Pro MMT-7335 Cl III
Company: Medtronic MiniMed Inc.
Date of Enforcement Report 3/11/2015
Class III:<p>
PRODUCT
CareLink Pro Medtronic CareLink Pro MMT-7335 is a personal computer software application designed to enhance Health Care Provider management of diabetic patients using Medtronic insulin pumps and blood glucose meters. MMT-7335 is intended for use by Health Care Providers/Physicians as a therapy management accessory to: - read and store history and settings data supported insulin pump models and supported blood glucose meters - read and report user-programmable settings on supported pump models - read device data from the CareLink Online system - write new device data to the CareLink system - generate reports from the patient records for use in managing the patient's therapy. CareLink Clinical Medtronic CareLink MMT-7334 is a network based software system residing on a computer server platform connected to the Internet. The system is designed to upload patient data from Medtronic MiniMed insulin pumps and supported third-party blood glucose meters to the MMT-7334 central database via a client PC (Personal Computer), which connects to supported devices. The data contained in MMT-7334 is accessible to users using a standard browser, i.e. Microsoft Internet Explorer, on a PC that is connected to the Internet. The user may view and print various reports generated from the device data uploaded to MMT-7334, plus additional information provided by the user. The product does not provide any medical advice to patients or physicians. This is currently only intended to be used in Clinical Trials. Both products are CD ROMs.
Recall NumberZ-1228-2015<p>
REASON
The firm is informing customers of a software error that might result in an inaccurate display of the Temp Basal time and duration in CareLink Clinical reports with data uploaded from the MiniMed 620G or 640G insulin pump.<p>

RECALLING FIRM/MANUFACTURER
Medtronic MiniMed Inc, Northridge, CA. 11/10/2014. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
5 CareLink Pro 4.0 CD ROMs<p>
DISTRIBUTION
Worldwide Distribution to Japan only. CareLink Clinical is for clinical trials only (US and International)
<p>

3/11/2015 Ikaria, INOmax DSIR, Cl II
Company:INO Therapeutics (dba Ikaria).
Date of Enforcement Report: 3/11/2015
Class II:<p>
PRODUCT
Ikaria, INOmax DSIR (Delivery System), Model 10007. Nitric oxide delivery system for use with ventilators. Recall NumberZ-1223-2015<p>
REASON
Potential delivery failure alarm condition. INOmax DSIR with software version 2.0.4 and a certain variant of the monitor display may trigger a delivery failure alarm when the display brightness is set to its lowest level. If this condition occurs, therapy will be interrupted..<p>
RECALLING FIRM/MANUFACTURER
INO Therapeutics (dba Ikaria), Madison, WI on 1/14/2015 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
45 units.<p>
DISTRIBUTION
Nationwide<p>

3/11/2015 Philips Allura Xper X-Ray Angiographic Cl II
Company: Philips Medical Systems, Inc.
Date of Enforcement Report 3/11/2015
Class II:<p>
PRODUCT
Philips Medical System Allura Xper X-Ray Angiographic
Recall NumberZ-1120-2015<p>
REASON
In certain circumstances, a software error can lead to a situation where the five minute fluoroscopy audible signal does not sound.<p>
RECALLING FIRM/MANUFACTURER
Philips Medical Systems, Inc., Andover, MA 6/6/2014. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
7439<p>
DISTRIBUTION
Worldwide <p>

3/5/2015 Hospira Plum A+,Plum A+3 Infusion Systems
Class I
Company:Hospira Inc..
Date of Enforcement Report: 5/28/2014
Class I:<p>
PRODUCT
Plum A+ infusion pumps and Plum A+3 infusion pumps<p>
REASON
he Plum A+ and A+3 infusion pumps have an alarm that should sound when a therapy is interrupted. Some of the alarms may fail to sound in situations that should trigger it. It is possible for a long delay

before a health care professional becomes aware of the need to restore therapy..<p>
RECALLING FIRM/MANUFACTURER
Hospira Inc., Lake Forest, Illinois on 5/28/2014 <p>

3/4/2015 COMPASS SW, Cl II
Company:Iba Dosimetry Gmbh.
Date of Enforcement Report: 3/4/2015
Class II:<p>
PRODUCT
COMPASS SW Version 3.1, Catalog Number CS10-100, medical linear accelerator, radiological. Recall NumberZ-1212-2015<p>
REASON
Error in the software. During internal tests of the current development version of the Compass SW it was found that dose reconstruction for DMLC plans when the jaws move or mlc leaves reverse during beam on will not be scaled correctly for all control points.<p>
RECALLING FIRM/MANUFACTURER
Iba Dosimetry Gmbh, Schwarzenbruck, DE on 2/2/2015 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
Error in the software. During internal tests of the current development version of the Compass SW it was found that dose reconstruction for DMLC plans when the jaws move or mlc leaves reverse during beam on will not be scaled correctly for all control points.<p>
DISTRIBUTION
Worldwide<p>

3/4/2015 Spacelabs Healthcare qube Compact Monitor, Cl II
Company:Spacelabs Healthcare Inc.
Date of Enforcement Report: 3/4/2015
Class II:<p>
PRODUCT
Spacelabs Healthcare qube Compact Monitor, Model 91390. The Spacelabs Healthcare qube Compact Monitor (91390), functioning as either bedside or central monitors; passively displays data generated by Spacelabs Healthcare parameter modules, Flexports interfaces, and other SDLC based products in the form of waveform and numeric displays, trends and alarms. Key monitored parameters available on the Model 91390 when employing the Spacelabs Command Module, consist of ECG, respiration, invasive and noninvasive blood pressure, Sp02, temperature and cardiac output.
Recall NumberZ-1145-2015<p>
REASON
Spacelabs Healthcare qube Bedside Monitors, Model 91390, are recalled because the firm has received multiple reports of qube monitors failing to boot up or returning to factory default configuration settings following power on or reset..<p>
RECALLING FIRM/MANUFACTURER
Spacelabs Healthcare Inc., Snoqualmie, WA on 1/28/2015 Voluntary: Firm Initiated recall is ongoing.<p>
VOLUME OF PRODUCT IN COMMERCE
ttotal 2955 units (2117 units in US and 838 units outside US)<p>
DISTRIBUTION
Worldwide<p>

3/4/2015 Spacelabs Healthcare XPREZZON Bedside Monito Cl II
Company:Spacelabs Healthcare Inc.
Date of Enforcement Report: 3/4/2015
Class II:<p>
PRODUCT
Spacelabs Healthcare XPREZZON Bedside Monitor, Model 91393. The Spacelabs Healthcare XPREZZON Bedside Monitor passively displays data generated by Spacelabs parameter modules, Flexport interfaces, and other Spacelabs SDLG based products as waveform and numeric displays, trends and alarms. Key monitored parameters available on the model 91393, when employing the Spacelabs Command Module consist of EGG, respiration, invasive and noninvasive blood pressure, Sp02, temperature and cardiac output.
Recall Number Z-1144-2015<p>
REASON
Spacelabs Healthcare XPREZZON Bedside Monitors, Model 91393, are recalled because the firm has received multiple reports of XPREZZON monitors failing to boot up or returning to factory default configuration settings following power on or reset..<p>
RECALLING FIRM/MANUFACTURER
Spacelabs Healthcare Inc., Snoqualmie, WA on 1/28/2015 Voluntary: Firm Initiated recall is ongoing.<p>
VOLUME OF PRODUCT IN COMMERCE
total 1578 units (702 units in the US and 876 outside US)<p>
DISTRIBUTION
Worldwide<p>

3/4/2015 The Centricity PACS Workstation Cl II
Company: GE Healthcare It.
Date of Enforcement Report 3/4/2015
Class II:<p>
PRODUCT
The Centricity PACS Workstation is intended for use as a primary diagnostic and analysis tool for diagnostic images by trained healthcare professionals, including radiologists, physicians, technologists, clinicians and nurses. It is also intended for use as a clinical review workstation throughout the healthcare facility. The workstation interface provides the user with a means to display, manipulate, archive, print and export images when connected with the Centricity PACS infrastructure. Recall NumberZ-1214-2015<p>
REASON
Using Merge Exam in single Study Mode may result in Missing Study Record (Cannot Display Exam, Send Exam, etc). Exam merge in Single Study Mode may fail on "Subquery returned more than one value". Exam merge in Single Study Mode may fail and leave one exam linked to two or more studies.<p>
RECALLING FIRM/MANUFACTURER
GE Healthcare It, Barrington, IL 2/18/2013 Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
128 systems<p>
DISTRIBUTION
Nationwide and Bermuda<p>

2/25/2015 Alive ECG App 2.1.2, Cl II
Company:Alivecor SFO.
Date of Enforcement Report: 3/4/2015
Class II:<p>
PRODUCT

Alive ECG App 2.1.2 (a medical device application for the Apple iOS operating system, intended to be used with the AliveCor Heart Monitor. The AliveCor Heart Monitor is intended to record, store and transfer single-channel electrocardiogram (ECG) rhythms. The AliveCor Heart Monitor also displays ECG rhythms and detects the presence of atrial fibrillation and normal sinus rhythm (when prescribed or used under the care of a physician).
Recall NumberZ-1125-2015<p>
REASON
Alive ECG App version 2.1.2 (intended to be used with the AliveCor Heart Monitor) crashed upon use of the application.<p>
RECALLING FIRM/MANUFACTURER
Alivecor SFO, San Francisco, CA on 1/9/2015 Voluntary: Firm Initiated recall has been terminated <p>
VOLUME OF PRODUCT IN COMMERCE
5600 active users with Alive ECG app for iOS .<p>
DISTRIBUTION
Downloaded by Apple users - locations not shared by Apple.<p>

2/25/2015 Artis One, Cl II
Company: Siemens Medical Solutions USA, Inc
Date of Enforcement Report 2/25/2015
Class II:<p>
PRODUCT
Artis One; The Artis One is an angiography system developed for diagnostic interventional procedures including, but not limited to pediatric and obese patients. Procedures that can be performed with the Artis One include cardiac angiography, neuro-angiography, general angiography, rotational angiography, multipurpose angiography and whole body radiographic/fluoroscopic procedures as well as procedures next to the table for patient extremities. Additionally, angiographic procedures can be performed in the operating room, image guided surgery by x-ray, by image fusion, and by navigation systems.
Recall NumberZ-1119-2015<p>
REASON
The possibility exists that the monitor may fail and requires a power circle (shutdown and then power on) to resume operation. The problem is not systematic; but sporadic on single units.<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Mlavern, PA on 1/16/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
1<p>
DISTRIBUTION
State of MI<p>

2/25/2015 BodyGuard 323 pump, Cl II
Company:CME America, LLC.
Date of Enforcement Report: 2/25/2015
Class II:<p>
PRODUCT
BodyGuard 323 pump, models 100-510PXSI, 100-516PXS, 100-517PXS, 100-518PXS, 100-603XSA and 100-603XSAP
Recall NumberZ-1126-2015<p>
REASON
CME America is recalling the BodyGuard and BodyGuard 323 Infusion pumps due to the potential for an over delivery.<p>
RECALLING FIRM/MANUFACTURER
CME America, LLC, Golden, CO on 1/16/2015 Voluntary: Firm Initiated recall is ongoing <p>

VOLUME OF PRODUCT IN COMMERCE
3,186<p>
DISTRIBUTION
Nationwide Distribution and VA/military/govt consignees and the country of Canada<p>

2/18/2015 Aquarius iNtuition Client Viewer, Cl II
Company:TeraRecon, Inc.
Date of Enforcement Report: 2/18/2015
Class II:<p>
PRODUCT
Aquarius iNtuition Client Viewer. Findings Workflow module, RECIST 1.1: Picture Archiving and Communications System; Findings Workflow Modules 4.4.11.82.6784, 4.4.11.116.7134, 4.4.11.144.7589. A fully-configured iNtuition system is capable of various image processing and visualization functions, including basic features and advanced post processing modules. The system can be configured as a server with some, all, or none of its optional features disabled. The intended use of the device is to provide solutions to various medical image-analysis and viewing problems, which come about as modalities generate more and more images. It also supports image distribution over networks, and is DICOM compliant.
Recall NumberZ-1070-2015<p>
REASON
Software anomaly related to RECIST1.1 target lesion evaluation criteria in Findings Workflow Module within the Aquarius iNtuition Client Viewer..<p>
RECALLING FIRM/MANUFACTURER
TeraRecon, Inc., Foster City, CA on 1/21/2015 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
91<p>
DISTRIBUTION
Nationwide and Internationally<p>

2/18/2015 EPWorks software used in Xltek Protektor, Cl II
Company: Natus Medical Incorporated
Date of Enforcement Report 2/18/2015
Class II:<p>
PRODUCT
EPWorks software used in the Xltek Protektor Stimulator Product Usage: Intraoperative diagnosis of acute dysfunction in corticospinal axonal conduction brought about by mechanical trauma (traction, shearing, laceration, or compression) or vascular insufficiency.
Recall NumberZ-1068-2015<p>
REASON
Software error occurs when using remote monitoring; if the remote user tries to stop the free run waveform group, the system will display a message informing the user that they do not have sufficient privilege.<p>
RECALLING FIRM/MANUFACTURER
Natus Medical Incorporated, Oakville, ON, Canada on 1/2/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
928 units<p>
DISTRIBUTION
Nationwide.<p>

2/18/2015 EPWorks software used in the Protektor 32, Cl II

Company: Natus Medical Incorporated
Date of Enforcement Report 2/18/2015
Class II:<p>
PRODUCT
Puritan Bennett 980 Ventilator System, Model No. PB980 Ventilator (980xxxxxxxx), The EPWorks software used in the Protektor 32 Product Usage: Uses electroencephalography (EEG), evoked potentials (EP), electromyography (EMG) and transcranial motor evoked potentials (TcMEP) stimulation techniques to provide healthcare professionals with information to help assess patient s neurological status during surgery.
Recall NumberZ-1067-2015<p>
REASON
Software error occurs when using remote monitoring; if the remote user tries to stop the free run waveform group, the system will display a message informing the user that they do not have sufficient privilege.<p>
RECALLING FIRM/MANUFACTURER
Natus Medical Incorporated, Oakville, ON, Canada on 1/2/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
248 units<p>
DISTRIBUTION
Nationwid.<p>

2/18/2015 SoftPath Laboratory Information System, Cl II

Company:SCC Soft Computer
Date of Enforcement Report: 2/18/2015
Class II:<p>
PRODUCT
SoftPath Laboratory Information System. Versions 4.3.0.8, 4.3.0.9, 4.3.0.10, 4.3.0.11, 4.3.0.12, 4.3.0.14, 4.3.0.15, and 4.4.0.0
Recall NumberZ-1065-2015<p>
REASON
Modifications to diagnostic text may be: 1) Saved to the database but not appear on the report sent to the physician; or 2) Documented on the report, but not saved to the database.<p>
RECALLING FIRM/MANUFACTURER
SCC Soft Computer, Clearwater, FL on 11/262014 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
108<p>
DISTRIBUTION
Nationwide and Canada<p>

2/11/2015 Puritan Bennett 980 Ventilator System, Cl II

Company: Covidien LP (formerly Nellcor Puritan Bennett Inc.)
Date of Enforcement Report 2/11/2015
Class II:<p>
PRODUCT
Puritan Bennett 980 Ventilator System, Model No. PB980 Ventilator (980xxxxxxxx), The Puritan BennettTM 980 Ventilator System is designed for use on Neonatal (NICU) through Adult patient populations who require respiratory support or mechanical ventilation and weigh a minimum of 0.3 kg (0.66 lb). It is suitable for service in a hospital (institutions) and intra-hospital transport to provide continuous positive pressure ventilator support, delivered invasively or noninvasively, to patients who require the following types of ventilator support: "Positive Pressure Ventilation, delivered invasively (via

endotracheal tube or trach tube) or non-invasively (via mask or nasal prongs) "Assist/ Control, SIMV or Spontaneous modes of ventilation. Recall NumberZ-1058-2015<p>
REASON
Covidien is issuing a voluntary field action for all Puritan Bennett 980 ventilators due to occasional GUI transient resets that last approximately 30 seconds.<p>
RECALLING FIRM/MANUFACTURER
Covidien LP (formerly Nellcor Puritan Bennett Inc.) on 1/12/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
418 units<p>
DISTRIBUTION
Nationwide and Canada.<p>

2/11/2015 Fresenius Crit Line in a Clip, Cl II
Company: Fresenius Medical Care Holdings, Inc.
Date of Enforcement Report 2/11/2015
Class II:<p>
PRODUCT
Fresenius Crit Line in a Clip (CLiC) with SW version 2.51 Model Number: CL10041001. A continuous real-time monitor for non-invasive hematocrit, oxygen saturation and percent change in blood volume calculation during hemodialysis treatment.
Recall NumberZ-1047-2015<p>
REASON
Potential for misinterpretation of the graphic display of the Blood Volume (BV) slope.<p>
RECALLING FIRM/MANUFACTURER
Fresenius Medical Care Holdings, Inc.Waltham, MA on 12/19/2014. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
35 units<p>
DISTRIBUTION
CT, NY<p>

2/11/2015 Carl Zeiss FORUM Archive and Viewer, Cl II
Company: Carl Zeiss Meditec AG
Date of Enforcement Report 2/11/2015
Class II:<p>
PRODUCT
FORUM Archive and Viewer, version 3.1, v 3.1.1, (DVD Format) and v 3.2, v 3.2.1.(DVD and USB Flash Drive Format). Catalog numbers: 000000-20107-750 (DVD with either FORUM v 3.1 or v 3.1.1) 000000-2058-601 (DVD with either FORUM v 3.2 or 3.2.1); 000000-2084-928 (USB drive with FORUM 3.2.1). ophthalmic image management system.
Recall NumberZ-1049-2015<p>
REASON
Software defect in the FORUM Viewer versions 3.1 and 3.2 which may lead to misinterpretation of the optical coherence tomography (OCT) data.<p>
RECALLING FIRM/MANUFACTURER
Carl Zeiss Meditec AG, Jana, DE on 1/22/2015. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
985<p>
DISTRIBUTION
Nationwide.<p>

2/11/2015 Radiometer ABL90 FLEX analyzer, Cl II
Company:Radiometer America Inc
Date of Enforcement Report: 2/11/2015
Class II:<p>
PRODUCT
ABL90 FLEX analyzer, Model number 393-090. A portable, automated analyzer that measures pH, blood gases, electrolytes, glucose, lactate, bilirubin and oximetry in whole blood. Recall Number Z-1046-2015<p>
REASON
The ABL90 analyzer does not always use the most recent calibration data to calculate patient results. This can in some cases lead to a biased patient result.<p>
RECALLING FIRM/MANUFACTURER
Radiometer America Inc., Westlake, OH on 12/82014 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
5002 units<p>
DISTRIBUTION
Nationwide and Internationally <p>

2/11/2015 SoftLab with SA HIS, Cl II
Company:SCC Soft Computer
Date of Enforcement Report: 2/11/2015
Class II:<p>
PRODUCT
SoftLab with SA HIS versions 4.0.7.0-4.0.7.1 SoftLab is a laboratory information system to be used in a medical research or clinical laboratory.
Recall NumberZ-1038-2015<p>
REASON
The interface fails to send abnormal flags for Reference Lab test results.<p>
RECALLING FIRM/MANUFACTURER
SCC Soft Computer, Clearwater, FL on 5/202014 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
28<p>
DISTRIBUTION
Nationwide and Canada<p>

2/11/2015 Animas Vibe Insulin Infusion Pump, Cl II
Company: Annimas Corp.
Date of Enforcement Report 2/11/2015
Class II:<p>
PRODUCT
Animas Vibe Insulin Infusion Pump. This product is indicated for continuous subcutaneous infusion of insulin for the treatment of diabetes and has a continuous glucose monitoring feature. Recall Number Z-1034-2015<p>
REASON
ICalibration factors in the pump overwritten during a programming step. The force sensor could send a lower signal value to the pump processor, with loss of prime warnings, occlusion alarms and the pump unable to detect a cartridge during the prime sequence. Field action initiated 8/29/2011.<p>
RECALLING FIRM/MANUFACTURER
Animas Corporation, West Chester, PA 9/6/2011. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
1235<p>
DISTRIBUTION
No US distribution, Distributors are located in France, Germany, Sweden and United Kingdom.<p>

2/4/2015 GE Revolution CT Cl II
Company:GE Healthcare
Date of Enforcement Report 2/4/2015
Class II:<p>
PRODUCT
The Revolution CT is a multi-slice (256 detector row) CT scanner consisting of a gantry, patient table, scanner desktop (operator console), system cabinet, power distribution unit (POU). and interconnecting cables.The system includes image acquisition hardware, image acquisition and reconstruction software, and associated accessories.
Recall NumberZ-0955-2015<p>
REASON
A required quality control test was not performed during installation associated with the software of the Revolution CT scanner.<p>
RECALLING FIRM/MANUFACTURER
GE Healthcare, Waukesha, WI 11/12/2014. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
13<p>
DISTRIBUTION
CA, FL, IL, NY, UT and WA.<p>

2/4/2015 Siemens Syngo RT Therapist, Cl II
Company:Siemens Medical Solutions USA, Inc.
Date of Enforcement Report: 2/4/2015
Class II:<p>
PRODUCT
Ysio Max, Luminos dRF Max and Agile Max systems with software version VE10 and Syngo RT Therapist: The intended use of the SIEMENS branded ARTISTE, ONCOR and PRIMUS family of linear accelerator systems is to deliver X-Ray photon and electron radiation for the therapeutic treatment of cancer
Recall NumberZ-1013-2015<p>
REASON
Combination of CTVision with syngo RT Therapist / syngo RT Oncologist 4.3.SP1 automatic registration in Adaptive Targeting might result in wrong offset calculations. Applying this offset can lead to patient mistreatment. Cone Beam imaging is not affected by this problem.<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Malvern, PA on 1/2/2015 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
3<p>
DISTRIBUTION
UT, WI, NY <p>

2/4/2015 INNOKAS MEDICAL VC150 Vital Signs Monitor, Cl II
Company: INNOKAS MEDICAL OY.
Date of Enforcement Report 2/4/2015
Class II:<p>
PRODUCT
VC150 Vital Signs Monitor (VC150 monitor equipped with Masimo SpO2 technique only); Innokas Medical CARESCAPE VC150 Rx Only Innokas Medical Oy. Catalog numbers 2067980-002, 2067980-006, 2067980-010, and 2067980-014.
Recall NumberZ-1022-2015<p>

REASON
If the SpO2 or RRa value is violating the respective alarm limit at the time of switching to monitoring mode, the monitor does not issue visual and audible alarms.<p>
RECALLING FIRM/MANUFACTURER
INNOKAS MEDICAL OY, KEMPELE, FL 12/3/2014. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
20<p>
DISTRIBUTION
Nationwide and Europe<p>

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2/4/2015 Mobius Airo® Mobile Intraoperative CT, Cl II
Company:Mobius Imaging, LLC
Date of Enforcement Report: 2/4/2015
Class II:<p>
PRODUCT
Airo® Mobile Intraoperative CT I Airo®; Model #: MobiCT-32
Recall NumberZ-1016-2015<p>
REASON
There is a risk that during the transfer of an image and navigation data to the Brainlab Curve Image Guided Surgery Navigation System after a CT scan, an error may occur, causing either no navigation data or incorrect navigation data being transferred to the curve.<p>
RECALLING FIRM/MANUFACTURER
Mobius Imaging, LLC, Ayer, MA on 12/82014 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
21 devices distributed. 15 of these devices affected by the software v. 1.1.1+ patch<p>
DISTRIBUTION
Nationwide and Internationally <p>

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2/4/2015 Philips BrightView Cl II
Company: Philips Medical Systems, Inc.
Date of Enforcement Report 2/4/2015
Class II:<p>
PRODUCT
BrightView model number: 882478 BrightView X model number: 882480 BrightView XCT model number: 882482 and 882454 Medical Device for imaging
Recall NumberZ-1011-2015<p>
REASON
Unintended detector and gantry movement due to software issues.<p>
RECALLING FIRM/MANUFACTURER
Philips Medical Systems, Inc.,Cleveland, OH 11/12/2014. Voluntary: Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
1064<p>
DISTRIBUTION
Nationwide and Internationally<p>

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1/28/2015 TEGRIS System, Cl II
Company:Maquet Medical Systems USA
Date of Enforcement Report: 1/28/2015
Class II:<p>
PRODUCT
TEGRIS System manufactured by MAQUET GMBH in Germany The Maquet Tegris OR Integration System is designed to be used as the cental operating unit in an operating room. The integration system has two main functions: Recording and distribution of images and videos and interaction with

medical and non-medical devices.
Recall NumberZ-0993-2015<p>
REASON
The wrong movement results on the MAGNUS OR table. The button commands on the TEGRIS touchscreen for Lower Leg Up and Upper Leg Down are switched in the software for the integration with the MAGNUS operating table system.<p>
RECALLING FIRM/MANUFACTURER
Maquet Medical Systems USA, Wayne, NJ on 8/21/2014 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
6<p>
DISTRIBUTION
Nationwide<p>

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1/28/2015 Siemens Ysio Max, Luminos dRF Max and Agile CI II
Company:Siemens Medical Solutions USA, Inc.
Date of Enforcement Report: 1/28/2015
Class II:<p>
PRODUCT
Ysio Max, Luminos dRF Max and Agile Max systems with software version VE10 and SmartOrtho license. The Ysio Max is a radiographic system used in hospitals, clinics, and medical practices. Ysio Max enables radiographic and tomographic exposures of the whole body including: skull, chest, abdomen, and extremities and may be used on pediatric, adult and bariatric patients. It can also be used for intravenous, small interventions (like biopsy, punctures, etc.) and emergency (trauma, critical ill) applications. Exposures may be taken with the patient sitting, standing, or in the prone position. The Ysio Max system is not meant for mammography. The Ysio Max uses integrated or portable digital detectors for generating diagnostic images by converting x-rays into electronic signals. Ysio Max is also designed to be used with conventional film/screen or Computed Radiography (CR) cassettes.
Recall NumberZ-0994-2015<p>
REASON
Potential for composed images to be flipped before being sent to PACS on systems with software version VE10 and SmartOrtho license. Flipped images may be reversed so the associated annotations, e.g. labels (R/L), may be displayed incorrectly, potentially leading to misdiagnosis.<p>
RECALLING FIRM/MANUFACTURER
Siemens Medical Solutions USA, Inc, Malvern, PA on 12/15/2014 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
11<p>
DISTRIBUTION
US Distribution to states of: ID, IL, MI, MN, MO, ND and PA.. <p>

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1/28/2015 VITROS Software Version 3.1, CI II
Company:Ortho-Clinical Diagnostics
Date of Enforcement Report: 1/28/2015
Class II:<p>
PRODUCT
VITROS Software Version 3.1 utilized on the following systems: 1) 4600 Chemistry Systems (VITROS 5,1 FS System family member, 2) 5600 Integrated System 1) VITROS 4600 - in vitro quantitative measurement of a variety of analytes, 2) VITROS 5600 - in vitro quantitative, semi-quantitative, and qualitative measurement of analytes
Recall NumberZ-1004-2015<p>
REASON
Calibration may not occur when using calibrator barcode labels supplied with VITROS Chemisty

Products Calibrator Kit 2.<p>
RECALLING FIRM/MANUFACTURER
Ortho-Clinical Diagnostics, Rochester, NY on 9/29/2014 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
12 units<p>
DISTRIBUTION
Nationwide and Internationally <p>

1/21/2015 Siemens ADVIA® Chemistry XPT, Cl II
Company:Siemens Healthcare Diagnostics, Inc.
Date of Enforcement Report: 1/21/2015
Class II:<p>
PRODUCT
ADVIA® Chemistry XPT interfaced to the CentraLink" Data Management System V14x in specific configurations: The CentraLink system software is a network solution provider and multi-system data manager for the instruments and lab automation systems (LAS) within the lab. The CentraLink software consolidates data from all connected instruments so that an operator can review and edit patient and quality control results from a single location.
Recall NumberZ-0987-2015<p>
REASON
Enabling sending of preliminary/initial results on the ADVIA Chemistry XPT creates a risk that a critical result could be overwritten by the same result rather than showing the repeated result on CentraLink. A result could be erroneous and critical and appear to be verified upon repeat.on..<p>
RECALLING FIRM/MANUFACTURER
Siemens Healthcare Diagnostics, Inc., Newark, DE on 12/16/2014 Voluntary: Firm Initiated recall is ongoing <p><p>
VOLUME OF PRODUCT IN COMMERCE
7<p>
DISTRIBUTION
Distributed in the state of WA. <p>

1/21/2015 Phadia 1000 Instrument, Cl II
Company:Phadia US Inc
Date of Enforcement Report: 1/21/2015
Class II:<p>
PRODUCT
Phadia 1000 Instrument (introduced as UniCAP 1000), Article number: 12-3800-01 (All instrument software versions since launch in 2003); Multiple ImmunoCAP assays for Allergen Testing, FDA Cleared for use on Phadia 1000 instrument with IU statement-see attachments. Software utilized in multiple ImmunoCAP assays for Allergen Testing, FDA Cleared for use on Phadia 1000 instrument with IU statement-see attachments.
Recall NumberZ-0947-2015<p>
REASON
During an investigation of instrument logs it was determined that In specific circumstances involving multiple steps, a rack sequencing error may occur. This will result in a mismatch between the sample ID and the test result reported for all subsequent sample racks in that run..<p>
RECALLING FIRM/MANUFACTURER
Phadia US Inc, Portage, MI on 11/20/2014 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
146<p>
DISTRIBUTION
Nationwide <p>

1/21/2015 BrainLab iPlan RT Dose, Cl II
Company:Brainlab AG
Date of Enforcement Report: 1/21/2015
Class II:<p>
PRODUCT
Plan RT Dose is a stereotactic radiation treatment planning system that is intended for use in stereotactic, conformal, computer planned, Linac based radiation treatment of cranial, head and neck, and extracranial lesions.
Recall NumberZ-0956-2015<p>
REASON
iPlan RT Radiation Treatment Planning Software: Potentially incorrect patient positioning when using multiple localized CT image data sets..<p>
RECALLING FIRM/MANUFACTURER
Brainlab AG, Feldkirchen, DE on 11/19/2014 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
1,412 systems total<p>
DISTRIBUTION
Nationwide and Internationally <p>

1/21/2015 Ortho Clinical VITROS 5600, Cl II
Company:Ortho-Clinical Diagnostics
Date of Enforcement Report: 1/21/2015
Class II:<p>
PRODUCT
VITROS 5600 Integrated System, Catalog Number 6802413, IVD --- Ortho Clinical Diagnostics. For use in the in vitro quantitative, semi-quantitative, and qualitative measurement of a variety of analytes of clinical interest, using VITROS Chemistry Products Slides, VITROS Chemistry Products MicroTip Reagents and VITROS Immunodiagnostic Products Reagents. Recall NumberZ-0969-2015<p>
REASON
Software Anomaly: the firm has identified an anomaly with VITROS System Software Version 3.1 and below, and determined that the software may not properly identify an expired calibration..<p>
RECALLING FIRM/MANUFACTURER
Ortho-Clinical Diagnostics, Rochester, NY on 11/19/2014 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
1830 Total: USA - 877, Foreign - 953<p>
DISTRIBUTION
Nationwide and Internationally <p>

1/21/2015 Ortho Clinical VITROS 4600 Chemistry System, Cl II
Company:Ortho-Clinical Diagnostics
Date of Enforcement Report: 1/21/2015
Class II:<p>
PRODUCT
VITROS 4600 Chemistry System (VITROS 5,1 FS System family member), Catalog Number 6802445, IVD --- Ortho Clinical Diagnostics. The VITROS 4600 Chemistry System is intended for use in the in vitro quantitative measurement of a variety of analytes of clinical interest, using both VITROS Chemistry Products Slides (colorimetric endpoint, rate, ion-selective electrode, and immunorate methods) and VITROS Chemistry Products MicroTip liquid reagents (spectrophotometric and spectrophotometric immunoassay methods).
Recall NumberZ-0968-2015<p>
REASON
Software Anomaly: the firm has identified an anomaly with VITROS System Software Version 3.1 and

below, and determined that the software may not properly identify an expired calibration.<p>
RECALLING FIRM/MANUFACTURER
Ortho-Clinical Diagnostics, Rochester, NY on 11/19/2014 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
339 Total: USA - 102, Foreign - 237<p>
DISTRIBUTION
Nationwide and Internationally <p>

1/21/2015 VITROS 3600, Cl II
Company:Ortho-Clinical Diagnostics
Date of Enforcement Report: 1/21/2015
Class II:<p>
PRODUCT
VITROS 3600 Immunodiagnostic System, Catalog Number 6802783, IVD --- Ortho Clinical Diagnostics. For use in the in vitro quantitative, semi-quantitative and qualitative measurement of a variety of analytes of clinical interest, using VITROS Immunodiagnostic Products Reagents. Recall Number Z-0967-2015<p>
REASON
Software Anomaly: the firm has identified an anomaly with VITROS System Software Version 3.1 and below, and determined that the software may not properly identify an expired calibration..<p>
RECALLING FIRM/MANUFACTURER
Ortho-Clinical Diagnostics, Rochester, NY on 11/19/2014 Voluntary: Firm Initiated recall is ongoing <p>
VOLUME OF PRODUCT IN COMMERCE
658 total: USA - 144, Foreign - 514<p>
DISTRIBUTION
Nationwide and Internationally <p>

1/8/2015 McKesson Cardiology ECG Management, Cl II
Company:McKesson Israel Ltd..
Date of Enforcement Report 1/8/2015
Class II:<p>
PRODUCT
McKesson Cardiology ECG Management It is a software application designed to import, display, store, analyze, distribute and manage information related to ECG procedures of adult and pediatric patients from external ECG devices.
Recall NumberZ-0910-2015<p>
REASON
Software error discovered in the McKesson Cardiology ECG Management with software versions 13.1 and 13.1.1.<p>
RECALLING FIRM/MANUFACTURER
McKesson Israel Ltd., Tel Aviv, Israel, on 12/19/2014. Firm Initiated recall is ongoing. <p>
VOLUME OF PRODUCT IN COMMERCE
9<p>
DISTRIBUTION
USA including MA, MS, NH, NC, TX, WA and Internationally to the United Kingdom. <p>
