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Each manufacturer has flexibility in how to comply with the regulations. The US FDA provides guidance documents to provide explanation and current FDA thinking on many of the required regulations. The following table lists pertinent guidance documents from FDA that a manufacturer should reference in establishing processes and collecting records to demonstrate compliance with US regulations. This list is not meant to be comprehensive but represents the primary software related guidance documents.

Guidance	Comment
General Principles of Software Validation-2002	This guidance provides the most comprehensive overview of FDA expectations for software lifecycle activities and documentation.
Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices-2016	This guidance provides manufacturers with design considerations when developing interoperable medical devices, and recommendations regarding information to include in pre- market submissions and device labeling.
Display Devices for Diagnostic Radiology-2017	Recommendations for what to include in a 510(k) submission for display devices in diagnostic radiology.
Clinical Decision Support Software-draft issued on September 27, 2019	This guidance gives latest FDA thinking distinguishing decision support, medical device, and non-medical device software.
Content of Premarket Submissions for Management of Cybersecurity in Medical Devices-2014 - - - - - - Draft-2018	This guidance provides recommendations to consider and information to include in FDA medical device premarket submissions for effective cybersecurity management. Note: There is a new draft from 2018 that reflects current FDA expectations for cybersecurity activities and documentation.
Final Guidance: Postmarket Management of Cybersecurity in Medical Devices-2016	This guidance provides recommendations to industry for structured and comprehensive management of postmarket cybersecurity vulnerabilities for marketed and distributed medical devices throughout the product lifecycle.
Cybersecurity for Networked Medical Devices Containing Off-the-Shelf (OTS) Software-2005	The FDA issued guidance to clarify how existing regulations, including the Quality System (QS) Regulation, apply to such cybersecurity maintenance activities.
Applying Human Factors and Usability Engineering to Medical Devices-2016	The recommendations in this guidance document are intended to support manufacturers in improving the design of devices to minimize potential use errors and resulting harm. The FDA believes that these recommendations will enable manufacturers to assess and reduce risks associated with medical device use.
Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices-2005	This guidance identifies the sub-set of design history file software documentation that is to be included with the regulatory submission to FDA.

Guidance	Comment
Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act-2019	This guidance provides FDA's current thinking regarding the amended device definition and the resulting effect the amended definition has on FDA's guidance documents related to **medical device software**. The concepts detailed in this guidance are also reflected in the following three guidance documents.
General Wellness: Policy for Low Risk Devices-2019	This guidance provides clarity to FDA-CDRH compliance policy for low risk products that promote a healthy lifestyle (general wellness products). This guidance does not apply to products (e.g., drugs, biologics, dietary supplements, foods, or cosmetics) regulated by other FDA Centers or to combination products.
Policy for Device Software Functions and Mobile Medical Applications-2019	This guidance reflects FDA's approach for software applications intended for use on mobile platforms (mobile applications or "mobile apps") or on general-purpose computing platforms to clarify the **subset of software functions** to which the FDA intends to apply its authority.
Off-The-Shelf Software Use in Medical Devices-2019	Use this guidance along with the *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices* to address the many questions asked by medical device manufacturers regarding what they need to provide in a premarket submission to the FDA when they use OTS Software.
Medical Device Accessories – Describing Accessories and Classification Pathways-2017	FDA's updated policy concerning the classification of accessories and possibility of "down-classing" SaMD type accessories.