



REAL-TIME PMA SUPPLEMENT: CHECKLIST

Copyright

© Copyright 2020 Crisis Prevention and Recovery, LLC. (CPRLLC), all rights reserved. SoftwareCPR® is a division of Crisis Prevention and Recovery, LLC and the SoftwareCPR® logo is a registered trademark.

SoftwareCPR® authorizes its clients and SoftwareCPR.com subscribers use of this document for internal review and training. **Any other use or dissemination of this document is expressly prohibited** unless the document is provided to you directly from SoftwareCPR® or you receive the written authorization of SoftwareCPR®.

Legal Disclaimer

The training document example that follows **should only be applied in the appropriate context with oversight by regulatory and software professionals with direct knowledge and experience with the topics presented.** The document should not be used as a cookbook or taken literally without knowledgeable evaluation of current interpretations and enforcement.

While SoftwareCPR® attempts to ensure the accuracy of information presented, no guarantees are made since regulatory interpretations and enforcement practices are constantly changing, and are not entirely uniform in their application.

Disclaimer of Warranties:

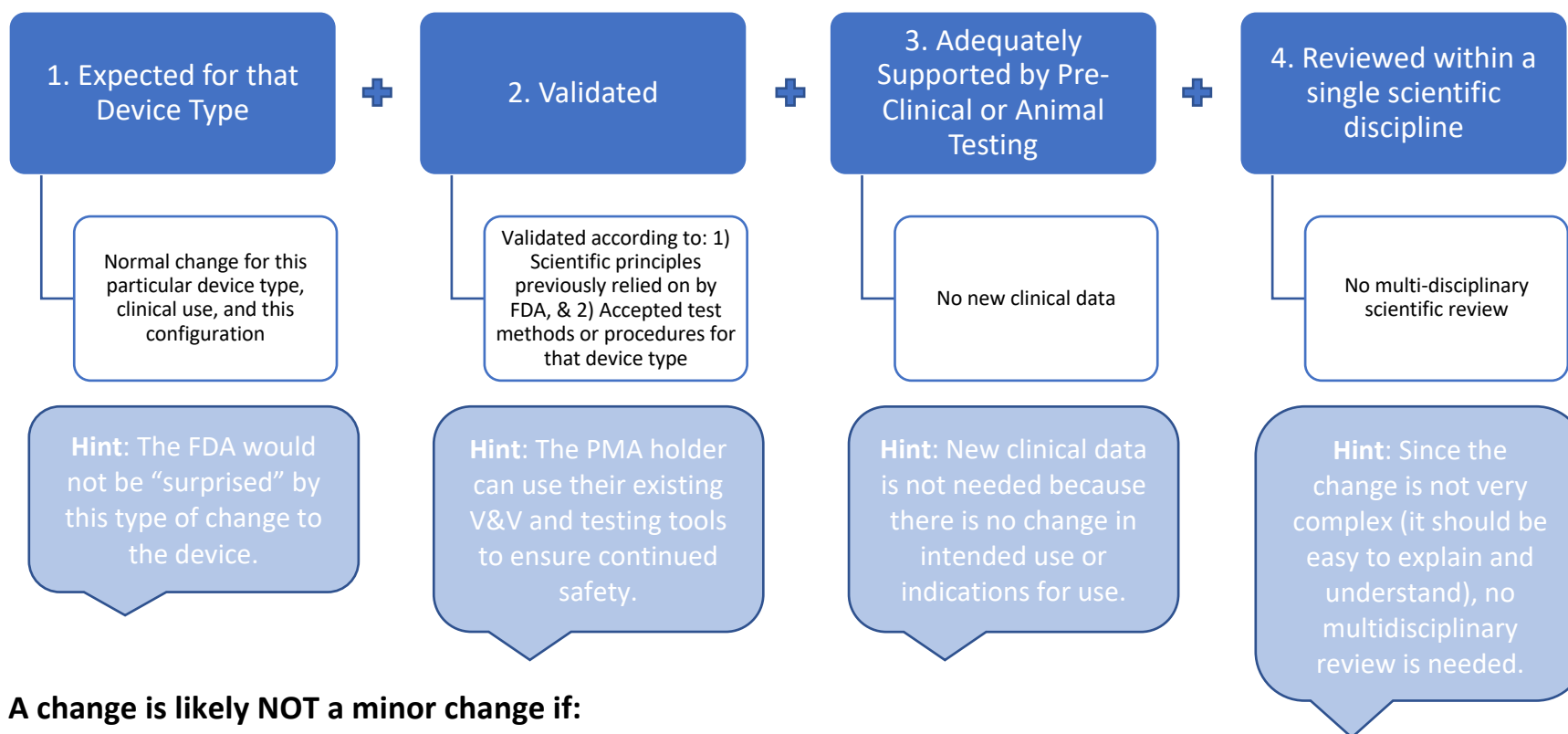
The information is provided AS IS, without warranties of any kind. CPRLLC does not represent or warrant that any information or data provided herein is suitable for a particular purpose. CPRLLC hereby disclaims and negates any and all warranties, whether express or implied, relating to such information and data, including the warranties of merchantability and fitness for a particular purpose.

“Real-Time PMA Supplement: Checklist” Job Aid

prepared by Amy Sellers with input from SoftwareCPR® Partner, John Murray

A device modification is appropriate for real-time PMA Supplement review if it is a minor, expected change.¹

A change is likely a minor change if it is (all four must be true):



A change is likely NOT a minor change if:

- The change will modify the intended use of the device
- The change will modify the patient population for the device
- The change will modify a risk item in the device

¹Checklist based on the December 2019 FDA Guidance document *Real-Time Premarket Approval Application (PMA) Supplements*.