Welcome To Today's Webinar

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We'll get started in a few minutes

Today's Topic:

Content of Premarket Submissions for Device Software Functions, Final Guidance

July 20, 2023

Content of Premarket Submissions for Device Software Functions, Final Guidance

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Final Guidance

- **Content of Premarket Submissions for Device Software Functions, Guidance for Industry and Food and Drug Administrative Staff, issued on June 14, 2023**
  - www.fda.gov/regulatory-information/search-fda-guidance-documents/content-premarket-submissions-device-software-functions
  - www.federalregister.gov/documents/2021/11/04/2021-24061/content-of-premarket-submissions-for-device-software-functions-draft-guidance-for-industry-and-food

Learning Objectives

- ✓ Explain what is covered in guidance and why updates were made
- ✓ Describe purpose and scope of final guidance
- ✓ Describe Software Documentation Levels
- ✓ Describe Software Documentation Elements
- ✓ Discuss other regulatory considerations and updates

Background

Questions addressed by the guidance:

- What software documentation is recommended for a marketing submission?

- What should the documentation demonstrate?

What is not covered by the guidance?

- Doesn’t provide recommendations on how device software should be developed, verified, and validated

- Doesn’t recommend use of any specific software life cycle model or development methodology (such as waterfall model or other variations thereof, spiral model, agile model, etc.)

Why is there an update to the guidance?

Updates intended to:

- ✓ Foster timely access to safe and effective software devices
- ✓ Promote Least Burdensome Principles
- ✓ Provide clarity and simplicity
- ✓ Align with changes resulting from Section 3060 of the 21st Century Cures Act
- ✓ Harmonize with FDA-recognized voluntary consensus standards

- Replaces FDA's Guidance for Content of Premarket Submissions for Software Contained in Medical Devices issued on May 11, 2005
- Updates FDA's thinking related to documentation FDA recommends sponsors include for review of device software functions in premarket submissions
- Completes a MDUFA V Commitment

Comments from Draft Guidance

- Sought clarification on application of Documentation Levels for certain premarket submissions and requested more examples
- Suggested more flexibility in Documentation Level factors to reduce documentation burden
- Highlighted opportunity to apply recommendations to device constituent parts of combination products

Comments from Draft Guidance

- Emphasized ways to further align with IEC 62304
- Raised questions about appropriate software development methodology
- Observed few recommendations for artificial intelligence and machine learning (AI/ML)
- Noted general clarifications, editorial changes, and corrections

Notable Updates Since Draft Publication

- Simplified Documentation Level considerations and application
- Added more examples on how to apply Documentation Level
  - Increased from 5 to 27 examples
- Revised recommendations to address device constituent parts of a combination product and added CDER and OCP to the guidance

CDER = Center for Drug Evaluation and Research
OCP = Office of Combination Products

Notable Updates Since Draft Publication

- Harmonized risk terminology with ISO 14971
- Clarified leveraging of IEC 62304 to reduce burden while maintaining differences where appropriate
- Provided fully revised system and software architecture diagram examples
- Included general updates, corrections, and clarifications

Updated Software References to Help Prepare a Premarket Submission

The guidance complements other existing guidance documents, and aligns with current software practices and FDA-recognized voluntary consensus standards

Guidance Documents

- Multiple Function Device Products: Policy and Considerations
- Off-The-Shelf Software Use in Medical Devices
- Design Considerations and Premarket Submission Recommendations for Interoperable Medical Devices
- General Principles of Software Validation
- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices
- Cybersecurity for Networked Medical Devices Containing Off-The-Shelf (OTS) Software
- Applying Human Factors and Usability Engineering to Medical Devices

FDA-Recognized Voluntary Consensus Standards

- ANSI/AAMI/ISO 14971: Medical devices - Applications of risk management to medical devices
- ANSI/AAMI/IEC 62304: Medical Device Software - Software Life Cycle Processes
- ANSI/AAMI SW91: Classification of defects in health software

Purpose and Scope

Purpose

The guidance identifies software information considered to be generally necessary to evaluate safety and effectiveness of device software functions in a premarket submission.

- Least burdensome approach was applied to identify minimum amount of information generally needed to support a premarket submission for a device that uses software.
- Guidance describes information typically generated and documented during software development, verification, and design validation.
- FDA may request additional information needed to evaluate the submission during a premarket review.

Scope

The guidance applies to all types of premarket submissions that include one or more device software function(s).

- Generally, apply to device constituent part of a combination product when device constituent part includes a device software function.
- This guidance does not apply to:
  - automated manufacturing and Quality System software or software that is not a device
  - software-related documentation that may be needed to evaluate postmarket software device issues
- Other guidance documents may recommend additional software-related documentation for premarket submissions; e.g., cybersecurity

Definitions

Function: a distinct purpose of the product, which could be the intended use, or subset of the intended use, of the product

Device Software Function: software function that meets definition of a device under section 201(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)

- Recommendations pertain to device software functions
- Recommendations reflect function-based approach described in guidance documents Policy for Device Software Functions and Mobile Medical Applications and Multiple Function Device Products: Policy and Considerations

Definitions, continued

Software verification: confirmation by objective evidence that the output of a particular phase of development meets all the input requirements for that phase.

- Software verification involves evaluating the consistency, completeness, and correctness of the software and its supporting documentation, as it is being developed, and provides support for a subsequent conclusion that software is validated.

Software validation: refers to establishing, by objective evidence, that the software specifications conform to user needs and intended uses, and that the particular requirements implemented through software can be consistently fulfilled.

- Software validation is a part of design validation of the finished device. It involves checking for proper operation of the software in its actual or simulated use environment, including integration into the final device where appropriate.

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Documentation Level

Documentation Level

Simplified Documentation Level in this guidance replaces Level of Concern (LoC) from 2005 Guidance

- Two Documentation Levels Defined for Devices:
  - **Basic**
  - **Enhanced**

Purpose of Documentation Level

Documentation Level helps to identify minimum amount of software information that would support a premarket submission

- Depends on device's risk to a patient, a user of a device, or others in the environment of use.
- Based on the risks of the device software function(s) in the context of the device's intended use
- Reflects the device as a whole

Enhanced Documentation

- Should be provided for any premarket submission that includes device software function(s)
  - where failure or flaw of any device software function(s) could present a hazardous situation with a probable risk of death or serious injury, either to a patient, user of the device, or others in the environment of use
- Risks should be assessed prior to implementing risk control measures
- Sponsor should consider risks in context of device intended use, for example, impacts to safety, treatment, or diagnosis, and other relevant considerations

Basic Documentation

- Should be provided for any premarket submission that includes device software functions where Enhanced Documentation does not apply

Considerations for Documentation Level

- Sponsor should consider all known or foreseeable software hazards and hazardous situations associated with device
  - including those resulting from reasonably foreseeable misuse, whether intentional or unintentional, prior to the implementation of risk control measures
- Includes likelihood that device functionality is intentionally or unintentionally compromised by inadequate device cybersecurity
- Sponsor is responsible for proactively and comprehensively considering risks as part of device's risk assessment

Considerations for Documentation Level

Individually assess devices within scope of guidance to determine appropriate Documentation levels.

- Guidance recommends Enhanced Documentation be provided in a premarket submission for devices intended to:
  - test blood donations for transfusion-transmitted infections;
  - determine blood donor and recipient compatibility;
  - automate blood cell separator devices intended for collection of blood components for transfusion or further manufacturing use;
  - blood establishment computer software (BECS).

- Guidance generally recommends Enhanced Documentation be provided in a premarket submission for Class III devices and device constituent parts of a combination product; **however, a sponsor may determine that an Enhanced Documentation level does not apply in certain cases, for which the sponsor should provide a detailed rationale as to why Basic Documentation is appropriate for the premarket submission.**

Example: Documentation Level (Appendix A)

A non-contact infrared thermometer intended for intermittent measurement of body temperature from the forehead.

Description	• Device is intended to measure body temperature from forehead using an infrared sensor. • Device is a hand-held, battery powered, reusable device for home and professional healthcare facility use.
Rationale	In general, a failure or latent flaw of the device software function(s) **would not** present a hazardous situation with a probable risk of death or serious injury to either a patient, user of the device, or others in the environment of use, prior to the implementation of risk control measures.
Outcome	**Basic Documentation Level**

Example: Documentation Level (Appendix A)

A facility-use continuous ventilator.

Description	• Device is intended to provide continuous ventilation for adult, pediatric, and neonatal patients who require invasive or noninvasive respiratory support. • Allows clinicians to set ventilator control parameters, set alarm limits, and view monitored values and waveforms for patient management. • Includes respiratory monitoring as well as both mandatory and spontaneous ventilation modes. • Intended for use in professional healthcare facilities.
Rationale	A failure or latent flaw of the device software function(s), such as failure to provide appropriately timed ventilation, **would** present a hazardous situation with a probable risk of death or serious injury to a patient, prior to the implementation of risk control measures.
Outcome	**Enhanced Documentation Level**

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Software Documentation Elements

Overview of Software Documentation Elements

- Documentation Level Evaluation
- Software Description
- Risk Management File
- Software Requirements Specification (SRS)
- System and Software Architecture Design
- Software Design Specification (SDS)
- Software Development, Configuration Management, and Maintenance Practices
- Software Testing as Part of Verification and Validation
- Software Version History
- Unresolved Software Anomalies (e.g., Bugs, Defects, or Errors)

Documentation Level Evaluation

For Basic and Enhanced Documentation Levels:

Provide statement indicating the Documentation Level and a description of the rationale for that level.

- Guidance encourages sponsors to account for their device's intended use and to leverage their device's risk assessment when preparing the rationale for choosing a Documentation Level.
- Examples in Appendix A are provided to demonstrate how to implement the Documentation Level.
- During premarket review, FDA may request additional information that is needed to evaluate the submission.

Software Description

For Basic and Enhanced Documentation Levels:

Provide comprehensive software description, including overview of significant software features, analyses, inputs, outputs, and hardware platforms.

- Guidance provides a curated set of questions to help readers prepare focused device description information.
- Encourages inclusion of additional information, if needed, to further FDA's understanding of the device's functionality, such as images, flow charts, and state diagrams.
- For a modified device, guidance encourages description of software changes from previous premarket submission, which may include providing document number for previous submission and highlighting pertinent software changes (e.g., changes that affect safety and effectiveness) since last authorization.

Risk Management File

For Basic and Enhanced Documentation Levels:

Should include documentation demonstrating following three components:

1. **Risk Management Plan:** demonstrates how a manufacturer plans to approach a risk assessment for their device and evaluate the overall residual risk against the benefits of the intended use of the device.

2. **Risk Assessment:** documents (e.g., in a tabular format) known or foreseeable hazards and resulting hazardous situations, initial risk evaluation of the hazardous situation, risk control measures, residual risk evaluation after implemented risk control measures and traceability of risk control measures.

3. **Risk Management Report:** shows how the risk management plan has been appropriately implemented.

- FDA recommends sponsors refer to FDA-recognized version of ISO 14971 and account for the recommendations provided in the guidance "Multiple Function Device Products: Policy and Considerations"

Software Requirements Specification (SRS)

For Basic and Enhanced Documentation Levels:

Includes complete documentation, describing the needs or expectations for a system or software, presented in an organized format and with sufficient information to understand the traceability of the information with respect to the other software documentation elements.

- Recommendations acknowledge modern development practices and allow for additional forms of software requirements to be included in submission, such as well-elaborated stories, use cases, textual descriptions, screen mockups, and control flows.
- Section includes considerations for use when preparing SRS documentation to help facilitate a timely premarket review, such as:
  - Tips for formatting and labeling
  - Inclusion of traceability information
  - A manufacturer may highlight requirements they believe are most critical to the device's safety and effectiveness, and/or those that were modified since a previous clearance or approval.
- For additional details on what should be included in the software requirements specification, refer to the guidance, General Principles of Software Validation.

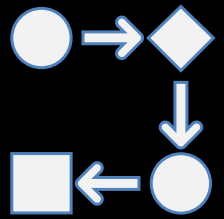
System and Software Architecture Diagram

For Basic and Enhanced Documentation Levels:

Provide detailed diagrams of the modules, layers, and interfaces that comprise the device, the data inputs, outputs, and flow, and how users or external products (including IT infrastructure and peripherals) interact with the system and software.

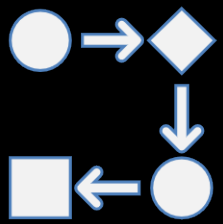
- Recommends that sponsors provide the appropriate level of detail to convey information in a manner that facilitates an efficient premarket review.
- Includes visual, language, and reference considerations that can be leveraged when developing the diagrams for a premarket submission.
- Appendix B of the guidance includes example system and software architecture diagrams.

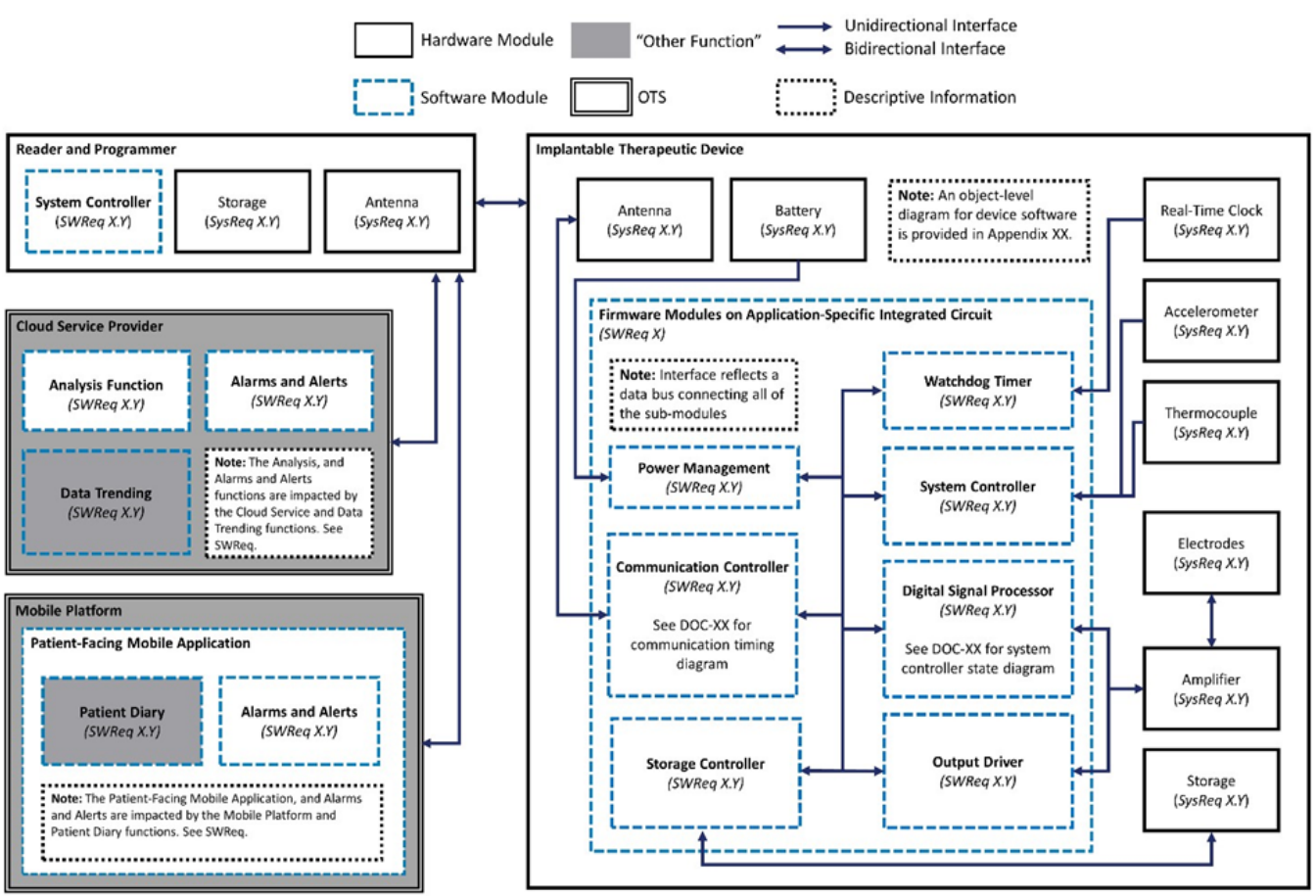
Appendix B: System and Software Architecture Diagram Examples



- Examples demonstrate how considerations described in System and Software Architecture Diagram section can be implemented into a system and software architecture diagram.
- Examples are intended for illustration purposes only and are not intended to document a comprehensive system and software architecture diagram for a specific device or system.
- Approaches illustrated can be applied to any system and software architecture diagram.
- Examples do not preclude the use of off-the-shelf architectural modeling languages or platforms.

Appendix B: System and Software Architecture Diagram Example - Figure 2





SysReq refers to the system requirement(s). Refer to the *System Requirements Document* (SysRS-XX Rev. X) for detailed information.
SWReq refers to the software requirement(s). Refer to the *Software Requirements Document* (SRS-XX Rev. X) for detailed information.

Software Design Specification (SDS)

Basic Documentation Level

FDA is not recommending the SDS as part of the premarket submission.

Sponsor should document this information on the design via the design history file for the device. During premarket review, FDA may request additional information, if needed, to evaluate the safety and effectiveness of the device.

Enhanced Documentation Level

Includes:

- singular SDS document or set of SDS documents that provide the technical design details of how the software functions,
- how the software design completely and correctly implements all the requirements of the SRS, and
- how the software design traces to the SRS in terms of intended use, functionality, safety, and effectiveness.

Software Development, Configuration Management, and Maintenance Practices

May provide a Declaration of Conformity to the currently FDA-recognized version of ANSI/AAMI IEC 62304 Medical Device Software - Software Life Cycle Processes

OR

For Basic Documentation Level

Alternatively, recommends providing a summary of the processes and procedures that are in place to manage the software life cycle development, software configuration and change management and software maintenance activities.

For Enhanced Documentation Level

Alternatively, recommends providing a complete configuration management and maintenance plan document in addition to the summary documentation requested for the Basic Documentation Level.

Software Testing as part of Verification and Validation

Basic Documentation Level

Recommends providing a summary description of the testing activities at the unit, integration and system levels. System level test protocol including expected results, observed results, pass/fail determination, and system level test report.

Enhanced Documentation Level

Recommends providing the Basic Documentation Level PLUS unit and integration level test protocols including expected results, observed results, pass/fail determination, and unit and integration level test reports.

- Definition section of guidance includes important information pertaining to FDA's thinking on verification and validation, as it relates to this guidance.
- Sponsor is encouraged to appropriately reference performance testing material in the submission to facilitate navigation between submission sections, reduce instances of duplication, and improve readability

Software Version History

For Basic and Enhanced Documentation Levels:

Recommends a history of tested software versions including the date, version number, and a brief description of all changes relative to the previously tested software version.

- FDA recommends beginning with version that became subject to design controls, as described in 21 CFR 820.30.
- Version history typically takes form of a line-item tabulation including the date, version number that was tested (including, if applicable, bench, animal and clinical testing) and a brief description of all changes in the version relative to the previously tested version.
- Last entry in a line-item tabulation should be the final version to be incorporated in the released device. This entry should also include any differences between the tested version of software and the released version, along with an assessment of the potential effect of the differences on the safety and effectiveness of the device.

Unresolved Software Anomalies

For Basic and Enhanced Documentation Levels:

Recommends to provide a list of remaining unresolved software anomalies with an evaluation of the impact of each unresolved software anomaly on the device's safety and effectiveness.

- This section recommends the following information (e.g., in tabular format) is provided for each unresolved anomaly:
  - A description of problem;
  - Identification of how anomaly was discovered and, where possible, identification of its root cause(s);
  - Evaluation of impact of anomaly on device's safety and effectiveness, including operator usage and human factors considerations;
  - Outcome of evaluation; and
  - Risk-based rationale for not correcting or fixing anomaly in alignment with sponsor's risk management plan or procedure(s).

- Encourages communication of unresolved anomalies to end user(s) as appropriate to assist in proper device operation

- Reference to ANSI/AAMI SW91 *Classification of defects in health software* is provided

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Other Regulatory Considerations and Updates

Regulatory Considerations for Software Functions

- You may consider following reference materials to learn more about FDA's regulatory considerations for software functions:
  - Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act
  - General Wellness: Policy for Low Risk Devices
  - Policy for Device Software Functions and Mobile Medical Applications
  - Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices
  - How to Determine if Your Product is a Medical Device
  - Clinical Decision Support Software

- We encourage you to also explore the Digital Health Policy Navigator, which can help orient you to potential policy considerations for a given software function.

Level 2 Guidance Updates

- The "Off-The-Shelf Software Use in Medical Devices: Guidance for Industry and Food and Drug Administration Staff" will be revised with a Level 2-update to reflect finalization of this guidance

Additional Guidance Updates

The following device-specific guidances will be updated with a cover sheet:

- Blood Glucose Monitoring Test Systems for Prescription Point-of-Care Use
- Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices
- The Content of Investigational Device Exemption (IDE) and Premarket Approval (PMA) Applications for Artificial Pancreas Device Systems
- Implanted Brain-Computer Interface (BCI) Devices for Patients with Paralysis or Amputation - Non-clinical Testing and Clinical Considerations
- Peripheral Vascular Atherectomy Devices - Premarket Notification [510(k)] Submissions
- Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use
- Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery
- Display Devices for Diagnostic Radiology
- Infusion Pumps Total Product Life Cycle
- Investigational Device Exemptions (IDEs) for Devices Indicated for Nocturnal Home Hemodialysis
- Policy Clarification and Premarket Notification [510(k)] Submissions for Ultrasonic Diathermy Devices
- Computer-Assisted Detection Devices Applied to Radiology Images and Radiology Device Data - Premarket Notification [510(k)] Submissions

60-Day Transition Period

- FDA anticipates that Agency and industry will need up to 60 days after publication of this guidance to operationalize the recommendations discussed
  - CDRH intends to review any such information if submitted at any time
  - FDA's eSTAR may accommodate either recommendations during this period

Guidance Summary

- Simplifies organization and content of software documentation elements as well as the documentation categorization levels
- Makes recommendations to aid in the preparation of the software documentation, consistent with Least Burdensome Principles
- Complements other existing guidance documents that provide recommendations related to software (e.g., “Multiple Function Device Products: Policy and Considerations”)

Guidance Summary

- Harmonizes with software-related consensus standards
- Reflects changes to FD&C Act made by 21st Century Cures Act
- Supersedes “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices”, May 2005


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Let's Take Your Questions

- **To Ask a Question:**
  1. Raise your hand in Zoom 

  2. Moderator will announce your name and invite you to ask your question
  3. Unmute yourself when prompted in Zoom to ask your question

- **When Asking a Question:**
  - Ask one question only
  - Keep question short
  - No questions about specific submissions

- **After Question is Answered:**
  - Mute yourself and lower your hand
  - If you have more questions - raise your hand again

Thanks for Joining Today!

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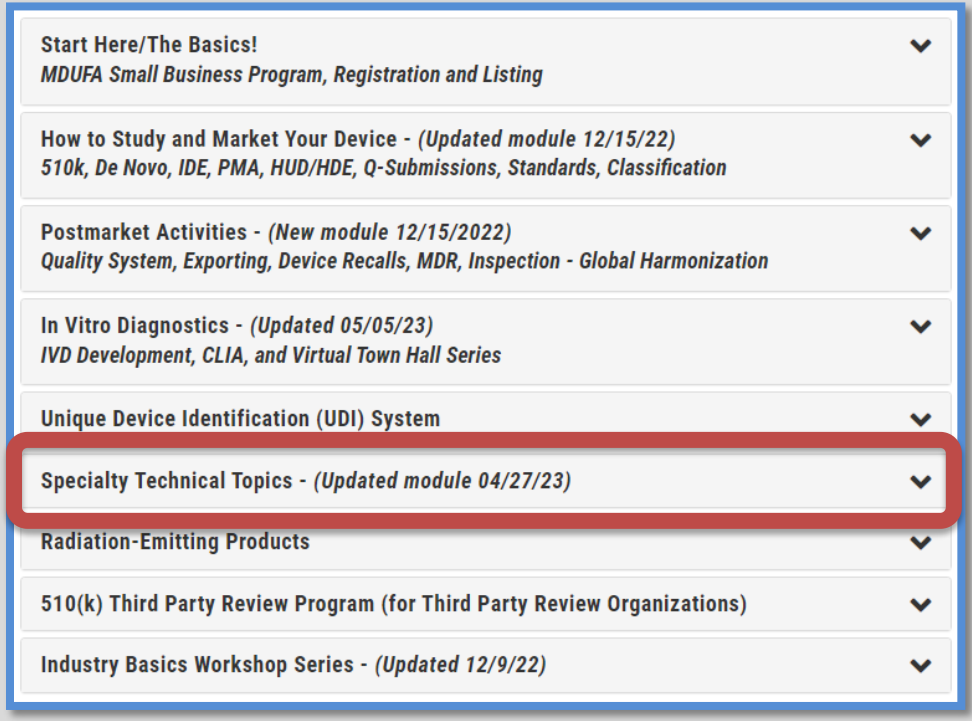

Resources

Slide Number	Cited Resource	URL
18, 47	Policy for Device Software Functions and Mobile Medical Applications	www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-device-software-functions-and-mobile-medical-applications
18	Multiple Function Device Products: Policy and Considerations	www.fda.gov/regulatory-information/search-fda-guidance-documents/multiple-function-device-products-policy-and-considerations
36	General Principles of Software Validation	www.fda.gov/regulatory-information/search-fda-guidance-documents/general-principles-software-validation
47	Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act	www.fda.gov/regulatory-information/search-fda-guidance-documents/changes-existing-medical-software-policies-resulting-section-3060-21st-century-cures-act

Resources

Slide Number	Cited Resource	URL
47	General Wellness: Policy for Low Risk Devices	www.fda.gov/regulatory-information/search-fda-guidance-documents/general-wellness-policy-low-risk-devices
47	Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices	www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-device-data-systems-medical-image-storage-devices-and-medical-image-communications-devices
47	How to Determine if Your Product is a Medical Device	www.fda.gov/medical-devices/classify-your-medical-device/how-determine-if-your-product-medical-device
47	Clinical Decision Support Software	www.fda.gov/regulatory-information/search-fda-guidance-documents/clinical-decision-support-software
47	Digital Health Policy Navigator	www.fda.gov/medical-devices/digital-health-center-excellence/digital-health-policy-navigator

Resources

Slide Number	Cited Resource	URL
48	Off-The-Shelf Software Use in Medical Devices	www.fda.gov/regulatory-information/search-fda-guidance-documents/shelf-software-use-medical-devices
49	Blood Glucose Monitoring Test Systems for Prescription Point-of-Care Use	www.fda.gov/regulatory-information/search-fda-guidance-documents/blood-glucose-monitoring-test-systems-prescription-point-care-use
49	Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices	www.fda.gov/regulatory-information/search-fda-guidance-documents/submission-premarket-notifications-magnetic-resonance-diagnostic-devices
49	The Content of Investigational Device Exemption (IDE) and Premarket Approval (PMA) Applications for Artificial Pancreas Device Systems	www.fda.gov/regulatory-information/search-fda-guidance-documents/content-investigational-device-exemption-ide-and-premarket-approval-pma-applications-artificial

Resources

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49	Implanted Brain-Computer Interface (BCI) Devices for Patients with Paralysis or Amputation - Non-clinical Testing and Clinical Considerations	www.fda.gov/regulatory-information/search-fda-guidance-documents/implanted-brain-computer-interface-bci-devices-patients-paralysis-or-amputation-non-clinical-testing
49	Peripheral Vascular Atherectomy Devices - Premarket Notification [510(k)] Submissions	www.fda.gov/regulatory-information/search-fda-guidance-documents/peripheral-vascular-atherectomy-devices-premarket-notification-510k-submissions
49	Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use	www.fda.gov/regulatory-information/search-fda-guidance-documents/self-monitoring-blood-glucose-test-systems-over-counter-use
49	Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery	www.fda.gov/regulatory-information/search-fda-guidance-documents/premarket-notification-510k-submissions-electrosurgical-devices-general-surgery

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49	Display Devices for Diagnostic Radiology	www.fda.gov/regulatory-information/search-fda-guidance-documents/display-devices-diagnostic-radiology
49	Infusion Pumps Total Product Life Cycle	www.fda.gov/regulatory-information/search-fda-guidance-documents/infusion-pumps-total-product-life-cycle
49	Investigational Device Exemptions (IDEs) for Devices Indicated for Nocturnal Home Hemodialysis	www.fda.gov/regulatory-information/search-fda-guidance-documents/investigational-device-exemptions-ides-devices-indicated-nocturnal-home-hemodialysis
49	Policy Clarification and Premarket Notification [510(k)] Submissions for Ultrasonic Diathermy Devices	www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-clarification-and-premarket-notification-510k-submissions-ultrasonic-diathermy-devices

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