Premarket Notification Submissions

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Topics

- What is a 510(k)
- When is a 510(k) Required
- Types of 510(k)s
- Content Required by Regulation
- Format of 510(k)s
- Documentation Required by FDA Software Guidance Document
- References and Resources

What is a 510(k)

- Section 510(k) of the Act [21 U.S.C. § 360(k)]:Each person who is required to register under this section and who proposes to begin the introduction of delivery for introduction into interstate commerce for commercial distribution of a device intended for human use shall, at least 90 days before making such introduction or delivery, report to the Secretary (in such form and manner as the Secretary shall by regulation prescribe)

When to Submit a 510(k)

- 21 CFR 807.81
  - ≥ 90 days before intend to distribute interstate
  - Change that could significantly affect the safety or effectiveness of the device
  - Change in the intended use
- FDA Guidance for Deciding When to Submit a 510(k) for a Change to an Existing Device

Types of 510(k)s

- Traditional 510(k)
- New 510(k) Paradigm
  - Abbreviated 510(k)
  - Special 510(k)

Information Required in 510(k)s 21 CFR 807.87

- Device name
- Establishment registration number
- Device class
- Performance standards
- Proposed labels, labeling & advertisements
- Statement of substantial equivalence
- 510(k) summary or statement
- Truth and accuracy statement

Information Required in 510(k)s , 21 CFR 807.87 cont.

- Financial certification or disclosure statement
- Any additional information regarding the device requested by the Commissioner that is necessary to make a finding as to whether or not the device is substantially equivalent to a device in commercial distribution

Format for Traditional and Abbreviated 510(k)s

- Medical Device User Fee Cover Sheet
- Certification of Compliance Form
- CDRH Premarket Review Submission Cover Sheet
- Standards Data Report for 510(k)s
- 510(k) Cover Letter
- Indications for Use Statement
- 510(k) Summary or 510(k) Statement

Format for Traditional and Abbreviated 510(k)s cont.

- Truthful and Accuracy Statement
- Class III Summary and Certification
- Financial Certification or Disclosure Statement
- Declarations of Conformity and Summary Reports
- Executive Summary
- Device Description

Format for Traditional and Abbreviated 510(k)s cont.

- Substantial Equivalence Discussion
- Proposed Labeling
- Sterilization and Shelf Life
- Biocompatibility
- Software
- Electromagnetic Compatibility and Electrical Safety

Format for Traditional and Abbreviated 510(k)s cont.

- Performance Testing – Bench
- Performance Testing – Animal
- Performance Testing – Clinical
- Other

Documentation Required By FDA Software Guidance

- Assess the Level of Concern (LOC) before mitigating any hazard and indicate the LOC in the 510(k)
- Level of documentation required to be submitted is determined by the LOC for the Device
- LOC is determined by answers to set of questions

Major Level of Concern

- Does the Software Device qualify as Blood Establishment Computer Software (BECS)?
- Is the Software Device intended to be used in combination with a drug or biologic?
- Is the Software Device an accessory to a medical device that has a Major Level of Concern?
- Prior to mitigation of hazards, could a failure of the Software Device result in death or serious injury, either to a patient or to a user of the device?

Moderate Level of Concern

- Is the Software Device an accessory to a medical device that has a Moderate Level of Concern?
- Prior to mitigation of hazards, could a failure of the Software Device result in Minor Injury, either to a patient or to a user of the device?
- Could a malfunction of, or a latent design flaw in, the Software Device lead to an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to Minor Injury?

Minor Level of Concern

- If the answer to all of the questions for Major and Moderate LOC are NO then the LOC is Minor.

Documentation by LOC

SOFTWARE DOCUMENTATION	MINOR CONCERN	MODERATE CONCERN	MAJOR CONCERN
Level of Concern	A statement indicating the Level of Concern and a description of the rationale for that level.		
Software Description	A summary overview of the features and software operating environment.		
Device Hazard Analysis	Tabular description of identified hardware and software hazards, including severity assessment and mitigations.		
Software Requirements Specification (SRS)	Summary of functional requirements from SRS.	The complete SRS document.	
Architecture Design Chart	No documentation is necessary in the submission.	Detailed depiction of functional units and software modules. May include state diagrams as well as flow charts.	

Documentation by LOC

SOFTWARE DOCUMENTATION	MINOR CONCERN	MODERATE CONCERN	MAJOR CONCERN
Software Design Specification (SDS)	No documentation is necessary in the submission.	Software design specification document.	
Traceability Analysis	Traceability among requirements, specifications, identified hazards and mitigations, and Verification and Validation testing.		
Software Development Environment Description	No documentation is necessary in the submission.	Summary of software life cycle development plan, including a summary of the configuration management and	Summary of software life cycle development plan. Annotated list of control documents generated during development process. Include the
		maintenance activities.	configuration management and maintenance plan documents.

Documentation by LOC

SOFTWARE DOCUMENTATION	MINOR CONCERN	MODERATE CONCERN	MAJOR CONCERN
Verification and Validation Documentation	Software functional test plan, pass / fail criteria, and results.	Description of V&V activities at the unit, integration, and system level. System level test protocol, including pass/fail criteria, and tests results.	Description of V&V activities at the unit, integration, and system level. Unit, integration and system level test protocols, including pass/fail criteria, test report, summary, and tests results.
Revision Level History	Revision history log, including release version number and date.		
Unresolved Anomalies (Bugs or Defects)	No documentation is necessary in the submission.	List of remaining software anomalies, annotated with an explanation of the impact on safety or effectiveness, including operator usage and human factors.	

Software Description

- A summary overview of the features and software operating environment
  - comprehensive overview of the device features that are controlled by software
  - describe the intended operational environment
- Should include
  - programming language
  - hardware platform
  - operating system (if applicable)
  - use of Off-the-Shelf software (if applicable)

Device Hazard Analysis

- Should take into account all device hazards associated with the device's intended use, including both hardware and software hazards
  - identification of the hazardous event
  - severity of the hazard
  - cause(s) of the hazard
  - method of control (e.g., alarm, hardware design)
  - trace control to device design/requirements, that eliminate, reduce, or warn of a hazardous event; and to verification that the method of control was implemented correctly

Software Requirements Specification (SRS)

- SRS documents the requirements for the software
- Typically includes functional, performance, interface, design, developmental, and other requirements for the software
- Describes what the Software Device is supposed to do

Architecture Design Chart

- Typically a flowchart or similar depiction of the relationships among the major functional units in the Software device including relationships to hardware and to data flows such as networking.
- Detailed information such as state diagrams may be useful to clearly depict the relationships among the software functional units.

Software Design Specification

- SRS describes what the Software Device will do and the Software Design Specification (SDS) describes how the requirements in the SRS are implemented
- Describes the implementation of the requirements for the Software Device

Traceability Analysis

- Links together your product design requirements, design specifications, and testing requirements
- Provides a means of tying together identified hazards with the implementation and testing of the mitigations

Software Development Description

- A summary of the software development life cycle plan
- Include an annotated list of the control/baseline documents generated during the software development process
- A list or description of software coding standards
- Information on configuration management and maintenance plan

Verification and Validation (V&V)

- Moderate Level of Concern devices
  - Submit a summary list of validation and verification activities and the results of these activities. Submit your pass/fail criteria. Ensure that the Traceability Analysis effectively links these activities and results to your design requirements and specifications.

V & V cont.

- Submit the information recommended above for Moderate Level of Concern devices and
  - A description of any tests that were not passed
  - Include any modifications made in response to failed tests and documentation of results demonstrating that the modifications were effective.
  - Include examples of unit integration testing and a summary of the results.

Revision Level History

History of software revisions generated during the course of product development. Should include clinical version and identify at what point the history begins and what the criteria was used for listing a revision (e.g., each version submitted to formal test after a certain project phase).

Unresolved Anomalies

- A list of all unresolved software anomalies and identify:
  - Problem
  - Impact on device performance
  - Any plans or timeframes for correcting the problem (where appropriate)
  - Annotate each item with an explanation of the impact of the anomaly on device safety or effectiveness, including operator usage and human factors issues.

Unresolved Anomalies cont.

- Communicate this list to the end user as appropriate to assist in the proper operation of the device
  - Where it is practical to do so, you should include any mitigations or possible work-arounds for unresolved anomalies

Abbreviated 510(k)

- Special control
  - Device specific guidance document
  - 90 day review
- Minimally reduces the amount of information to be included in the 510(k)
- Creates potential risk for inspectional issues regarding compliance with the applicable standard

Special 510(k)

- If no change to:
  - Intended use
  - Fundamental scientific technology
- Summary of design control activities
  - Hazard analysis method
  - Summary of verification and validation
  - Submit documentation for modification that prompted the submission
- Declaration of conformity to design controls defined in 21 CFR 820.30

Notes

- The pre-market submission guidance provides guidance on “what to submit” with a pre-market submission.
- It is not intended to define all software development process requirements or all documentation required for compliance with the Quality System (QS) regulation.

References

- Format for Traditional and Abbreviated 510(k)s http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm
- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089543.htm
- General Principles of Software Validation http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm085281.htm

References cont.

- Guidance for Off-the-Shelf Software Use in Medical Devices http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM073779.pdf
- Deciding When to Submit a 510(k) for a Change to an Existing Device http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080235.htm
- The New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080187.htm

References cont.

- CDRH Learn: Overview of the Premarket Notification Process – 510(k) http://www.fda.gov/Training/CDRHLearn/ucm162015.htm#510k
- 510(k) Database http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm
- FDA Recognized Consensus Standards http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm