Preparing a Robust 510(k) Submission

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Agenda

Finding a Predicate Device
Guidance Documents
Content of the 510(k)
Summary Document
RTA Checklist
Ecoryp Review
Finding the Predicate
Product Code Classification Database

• Use this tool to help locate a predicate device includes
• Helpful information:
  o Trade name of a similar device
  o Manufacturer(s) of similar device(s)
  o How long on the market (i.e. pre-amendments or not
  o 510(k) numbers for post-amendments devices
  o Classification information for your device.
Then What?

• Once you know your classification, search the 510(k) database

• Try using only one online search box

• The search consists of exact matches – so use one descriptive word only

• Searching by product code is usually most effective

• Name of original applicant only – not updated to reflect current owner or changes in trade name
A 510(K) is a premarket submission made to FDA to demonstrate that the device to be marketed is at least as safe and effective, that is, substantially equivalent, to a legally marketed device (21 CFR §807.92(a)(3)) that is not subject to premarket approval.

Learn more...

Search Database

510K Number

Type

Product Code

Contor

Combination Products

Applicant Name

Cleared/Approved In Vitro Products

Device Name

Third Party Reviewed

Panel

Clinical Trials

Decision

Decision Date

Sort by

Decision Date (descending)
Effectively Using Predicate Device

- Identify predicate most similar to your device

- Pay attention closely to indications for use and technological characteristics

- You may use more than one predicate device to help demonstrate substantial equivalence in certain circumstances

- The use of split predicates is no longer accepted

- You may identify “reference devices” to support scientific methodology or standard reference values
The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]

Guidance for Industry and Food and Drug Administration Staff

Document issued on: July 28, 2014

The draft of this document issued on December 27, 2011.

Guidance Documents
Always Check for Specific Guidance Documents

- However, don’t overlook the general guidance for biocompatibility, software contained in medical device, electromagnetic compatibility, etc.

- Device specific guidance documents describe in detail the information which should be included in the 510(k) to enable FDA to determine SE for that particular type of device

- Guidance documents should be consulted at the device planning stage

- In addition, the design control requirements of QSR should be reviewed since much of the information and data developed to meet design controls is the same information included in the 510(k)
Guidance Documents (Medical Devices and Radiation-Emitting Products)

Cross-Center Final Guidance

Office of Compliance Final Guidance

Office of the Center Director Final Guidance

Office of Communication and Education Final Guidance

Office of Device Evaluation Final Guidance 2010 - 2016


Office of In Vitro Diagnostics and Radiological Health Final Guidance

What is guidance?

Guidance documents are documents prepared for FDA staff, regulated industry, and the public that describe the agency's interpretation of or policy on a regulatory issue. Guidance documents include, but are not limited to, documents that relate to:

- the design, production, labeling, promotion, manufacturing, and testing of regulated products
- the processing, content, and evaluation or approval of submissions
- inspection and enforcement policies
Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices
Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

This draft guidance document is distributed for comment purposes only.

Document issued on: July 14, 2015.

You should submit comments and suggestions regarding this draft document within 90 days of publication in the Federal Register of the notice announcing the availability of the draft guidance. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify all comments with the docket number listed in the notice of availability that publishes in the Federal Register.
| **Device** | Orthosis, Spine, Plate, Laminoplasty, Metal |
| **Regulation Description** | Spinal interlaminal fixation orthosis. |
| **Definition** | This device is a plate that is attached to the lamina after a laminoplasty or laminectomy procedure. |
| **Regulation Medical Specialty** | Orthopedic |
| **Review Panel** | Orthopedic |
| **Product Code** | NQW |
| **Premarket Review** | Office of Device Evaluation (ODE) Division of Orthopedic Devices (DOD) Posterior Spine Devices Branch (PSDB) |
| **Submission Type** | 510(k) |
| **Regulation Number** | 888.3050 |
| **Device Class** | 2 |
| **Total Product Life Cycle (TPLC)** | TPLC Product Code Report |
| **GMP Exempt?** | No |
- 11-199 ASTM F565-04 (Reapproved 2013) Standard Practice for Care and Handling of Orthopedic Implants and Instruments |
| **Implanted Device?** | Yes |
| **Life-Sustain/Support Device?** | No |
| **Third Party Review** | Not Third Party Eligible |
Content of the 510(k) (Traditional)
How to Prepare a Traditional 510(k)

- Introduction
- Find a Predicate Device
- Locate Guidance Documents
- Content and Format of a Traditional 510(k)
- Alternate 510(k) Format – STED Pilot Program
- Where to Submit a 510(k)

Introduction

There are three types of Premarket Notification 510(k)s that may be submitted to FDA: Traditional, Special, and Abbreviated. The Special and Abbreviated 510(k) methods were developed under "The New 510(k) Paradigm" to help streamline the 510(k) review process. The Traditional 510(k) and Abbreviated 510(k) methods can only be used if certain criteria are met. The Traditional 510(k) method can be used under any circumstances.

There is no Premarket Notification 510(k) "form" to complete. A 510(k) is a document containing information required under 21 CFR 807 Subpart E. All 510(k)s are based on the concept of substantial equivalence (SE) to a legally marketed (predicate) device. All 510(k)s provide a comparison between the device to be marketed and the predicate device or devices.

For more information on the regulatory framework, policies, and practices underlying FDA's 510(k) review, please refer to the guidance The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notification [510(k)].
Content of a 510(k)

- Introduction
- General Information
- Table of Contents (recommended)
- 510(k) Acceptance Checklist (recommended)
- Statement of Indications for Use
- 510(k) Statement or Summary
- Truthful and Accuracy Statement
- Proposed Labeling
- Specifications
- Substantial Equivalence Comparison
- Performance
- Additional requirements, as appropriate

Introduction

The 510(k) regulation is found in 21 CFR 807 Subpart E and includes information required in a 510(k). The 510(k) is not a form. The information should be provided in an organized, tabulated document. The 510(k) should provide sufficient detail for FDA to be able to determine that the device is substantially equivalent (SE) to another similar legally marketed device(s). Some sections will contain only one page; others may contain 50 or more pages. The average 510(k) is about 35 pages; others may run to 100 or more depending on the complexity of the device. For any device, the 510(k) is formatted essentially the same way and contains the same basic information (required elements).
Content of a Traditional 510(k)

1. Medical Device User Fee Cover Sheet (Form FDA 3601)
2. CDRH Pre-market Review Submission Cover Sheet
3. 510(k) Cover Letter
4. Indications for Use Statement
5. 510(k) Summary or 510(k) Statement
6. Truthful and Accuracy Statement
7. Class III Summary and Certification
8. Financial Certification or Disclosure Statement
9. Declarations of Conformity and Summary Reports
10. Executive Summary
11. Device Description
Content of a Traditional 510(k)

12. Substantial Equivalence Discussion
13. Proposed Labeling
14. Sterilization and Shelf Life
15. Biocompatibility
16. Software
17. Electromagnetic Compatibility and Electrical Safety
18. Performance Testing – Bench
19. Performance Testing – Animal
20. Performance Testing – Clinical
21. Other
The Most Important (?)

- If any section is more important than another, it is the Substantial Equivalence (SE) Discussion

- Include a comparison table that identifies all the device characteristics and how they compare

- Do they introduce any new technologies?

- Do they raise new questions of safety and effectiveness?

- Give supporting rationale for differences
Areas to Consider in SE section

- Intended use
- Indications for use
- Target population
- Anatomical site
- Where used (hospital, home, ambulance)
- Energy used and/or delivered
- Human factors
- Design
- Thermal safety
- Radiation safety
- Performance
- Standards met
- Materials
- Biocompatibility
- Compatibility with the environment and other devices
- Sterility
- Electrical safety
- Mechanical safety
- Chemical safety
Summary Document
Device Summary

• Appendix B of the 510(k) Program: Evaluating Substantial Equivalence:
  o Helps compliance with the requirements of 21 CFR 807.92
  o If additional testing or information are requested submit a revised 510(k) Summary

• The following must be included in the 510(k) Summary, or FDA recommends:
  o The submitter's name, address, telephone number, a contact person, and the date the summary was prepared
  o The name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known
  o List all applicable names and model numbers
  o If the submission is bundled list all applicable classification regulations and product codes
  o An identification of the legally marketed device to which equivalence is claimed
Device Summary cont’d

- FDA recommends inclusion of the 510(k) number of the predicate device
- If using an exempt device as a predicate, list the classification regulation and the product code
- If using a device that has been reclassified from Class III to II as a predicate, where a 510(k) has not been submitted give the PMA number
- A description of the device
  - Information found in the labeling or promotional material
  - An explanation of how the device functions
  - The scientific concepts that form the basis for the device
  - The significant physical and performance characteristics of the device, such as device design, material used, and physical properties
Contents of the Device Description

• List all key device components included in the submission (e.g., catheter, cable wire, leads)
• Briefly explain the differences among models
• Device Characteristics, such as:
  • Software
  • Biologics/ drugs
  • Patient-contacting materials, coatings, additives
  • Single-use, sterile and sterilization method
  • Environment of Use
  • Brief explanation of how the device works, energy source
  • If material conforms to an FDA recognized consensus standard for medical use
  • Key performance specifications/characteristics of the device
Intended Use, Indications of Use

• The intended use of the is a general description of the diseases or conditions that the device will diagnose, treat, prevent, cure, or mitigate
• Include the patient population for which the device is intended
• If the indication statements are different from those of the predicate, the summary must explain why the differences are not critical and why they do not affect the safety and effectiveness
• The 510(k) Summary should include the Indications for Use, which should be identical to that proposed on the Indications for Use Sheet and the labeling
• If the Indications for Use are different from those of the predicate device, a brief explanation is required to address why the differences in the Indications do not affect the safety and effectiveness, and do not alter the intended use of the device
Technological Characteristics

• If the device has the same technological characteristics as the predicate a summary of the technological characteristics of the new device in comparison to those of the predicate device.

• If the device has different technological characteristics from the predicate device, a summary of how the technological characteristics of the device compare to the predicate.

• If the SE is based on performance data, include:
  o A brief discussion of the nonclinical tests
  o A high level summary of the tests that were used
  o Reference to any guidance document used for the testing
  o If an FDA recognized consensus standard was used/relied upon list the standard (e.g., ASTM FXXXX-last 2 numbers of the year).
Clinical Data

• A brief description of the subjects, a discussion of the safety or effectiveness data obtained from the testing, with specific reference to adverse effects and complications, and any other information relevant to SE.

• FDA recommends Level of Evidence identified and Location of Study:
  o Randomized, multi-arm, “blinded” study with concurrent sham (placebo) control
  o Randomized, multi-arm, “blinded” study with concurrent (“active”) control
  o Randomized, multi-arm, un“blinded” study with a control
  o Non-randomized study with concurrent (“active”) control
  o Single-arm study with patient serving as own control, or Historical Control, or Literature Control
  o Single-arm study with Objective Performance Criteria, Performance Goals, Registry, Observational study
  o Systematic review with Meta-analysis
Conclusions from Studies

- The conclusions drawn from the nonclinical and clinical tests that demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device
- Brief summary of why the device is substantially equivalent to the predicate
- If the FDA determines that other information needs to be included within the 510(k) Summary, such information must be included
RTA Checklist
Acceptance Checklist
for Traditional 510(k)s

(Should be completed within 15 days of DCC receipt)

The following information is not intended to serve as a comprehensive review. FDA recommends that the submitter include this completed checklist as part of the submission.

510(k)#:  K  Date Received by DCC:

Lead Reviewer:

Branch:  Division:  Center/Office:

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete; it means the reviewer did not assess the element during the RTA review and that the element will be assessed during substantive review.

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<tr>
<th>Preliminary Questions</th>
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<tbody>
<tr>
<td>Answers in the shaded blocks indicate consultation with a Center advisor is needed. (Boxes checked in this section represent FDAs preliminary assessment of these questions at the time of administrative review.)</td>
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<th>Yes</th>
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Reason for RTA Checklist

- Sets the stage
- Gives insight into FDA review process
- Helps organize thinking for the 510(k)
- Note: There is one for each type of 510(k): Traditional, Special, Abbreviated
Ecoby Review
eCopy Program for Medical Device Submissions: Frequently Asked Questions

The FAQs found here address the following eCopy Program topics:

- **Technical Standards for an eCopy** - Your eCopy must meet the technical standards outlined in Attachment 1 of the eCopy guidance. If your eCopy does not meet the technical standards, it will fail the loading process.

- **eCopy Hold Letters** - If your eCopy fails the loading process, you will receive an eCopy hold letter that states the specific reason(s) for the failure. You are required to submit a replacement eCopy that addresses the reason(s) identified in your eCopy hold letter.

- **General Questions**

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**Technical Standards for an eCopy**

*Where can I find the technical standards for an eCopy?*

Refer to the [eCopy guidance](#). The first part of the guidance describes the eCopy program and Attachment 1 of the guidance describes the technical standards.
Why Ecory?

- Know the Ecory Requirements
- Ecory is required for 510(k) submissions
- Take the time to open every file for review of requirements
- Ecory holds are frustrating and costly!
Tips to Live By

• Organize, Organize, Organize
• Know the possible predicates
• Compare the attributes of your device to the predicates – find the closest one
• Determine if your device has a submission guidance document – and follow it if so
• Review and re-review the 510(k) guidance
• Work on the RTA checklist early and often
• Do the Ecipy review
• Consider outside help (another set of eyes)
THANK YOU.

Questions?

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