510(k) Submission Types and Reasons for Conversion

FDA Small Business Regulatory Education for Industry (REdI)

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help

Learning Objectives

- Provide an overview of the 510(k) process
- Describe the 510(k) Submission Types
- Discuss some common reasons for conversion
- Apply concepts to real-life example

Overview of 510(k) Process

What is a 510(k)?

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 PMA*.

Fun Fact:

It is the biggest premarket program in CDRH

- FDA receives ~3000 510(k) submissions per year
- ~90% are found SE and go to market

*21 CFR 807.92(a)(3)

When is a 510(k) Required?

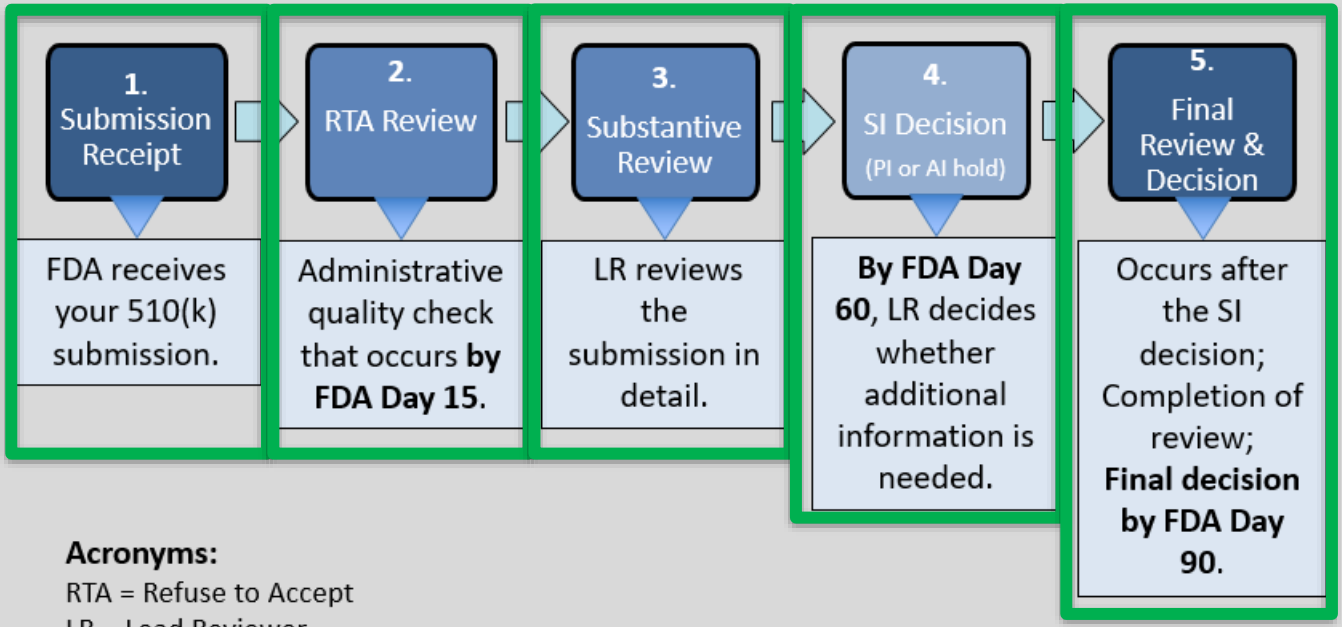
- Introducing device to market for the first time
- Modification(s) to device that could affect safety or effectiveness:
  - Intended use
  - labeling
- Reprocessing of a single use device (SUD)*

2017 Guidance: **“Deciding When to Submit a 510(k) for Change to an Existing Device”**

***FDA Guidance: Frequently-Asked-Questions about the Reprocessing and Reuse of Single-use devices by Third-party and Hospital Reprocessors**

High-Level Process Overview

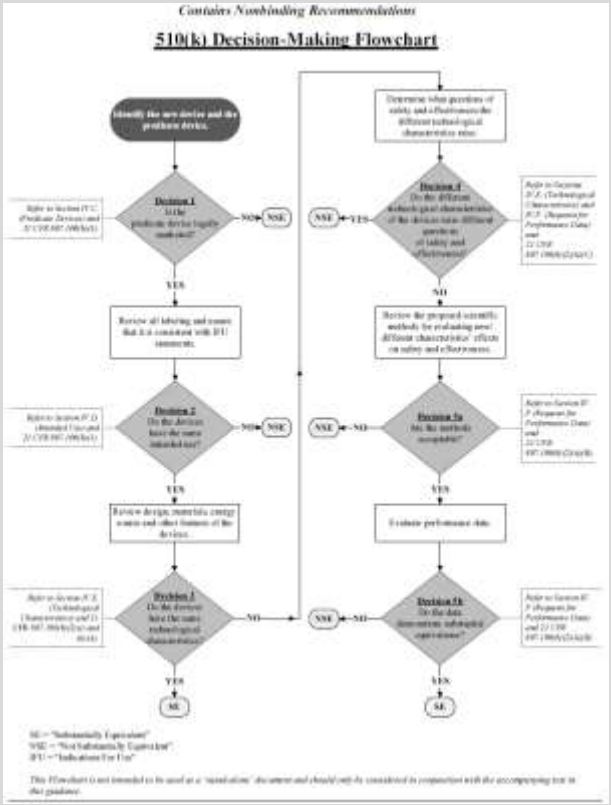
510(k) Submission Core Process



Acronyms:
RTA = Refuse to Accept
LR = Lead Reviewer
SI = Substantive Interaction
PI = Proceed Interactively
AI = Additional Information

FDA Guidance: Refuse to Accept Policy for 510(k)s

The 510(k) Flowchart



- 2014 Guidance: Evaluating Substantial Equivalence in Premarket Notifications
- Flowchart not intended to be used as a stand-alone document
- Decision questions are answered in order
- SE = answer all decision questions with a predicate.

Describe 510(k) Submission Types

510(k) Submission Types

- Traditional
- Abbreviated
  - Safety & Performance (S&P) Based Pathway
- Special
- Third Party

510(k) Submission Types

Commonalities

- All 510(k) submissions must identify a predicate
- All 510(k) submissions include content to demonstrate SE to the cited predicate(s)

Differences

- FDA review timeframe goals
- Different RTA criterion and checklists for different submission types
- The nature of the content can vary depending on 510(k) submission type
  - Summary reports vs. full reports

Traditional 510(k)

- Most common
- Used for any original 510(k) or for a change to a previously cleared device under 510(k)
- **All** data provided:
  - full test reports, etc.
- 90-day FDA review clock

FDA Guidance: Format for Traditional and Abbreviated 510(k)s

Abbreviated 510(k)

- Device relies on:
  - FDA guidance document(s)
  - Demonstration of compliance with special controls for the device type
  - Voluntary consensus standard(s)
    - Guidance- "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices"
- Summary reports
- 90-day FDA review clock

FDA Guidance: The Abbreviated 510(k) Program

Safety and Performance Based Pathway: Overview

- Expands on existing Abbreviated 510(k) Program
- Removes requirement for direct predicate comparison testing for some performance characteristics
  - Meet FDA-identified performance criteria to demonstrate device is as safe and effective as predicate device
- 90-day FDA review clock

FDA Guidance: Safety and Performance Based Pathway

Safety and Performance Based Pathway: Eligible Device Types

- Currently there are 7 device types appropriate for this pathway:
  - Spinal Plating System
  - Orthopedic Non-spinal Metallic Bone Screws and Washers
  - Cutaneous Electrodes for Recording Purposes
  - Conventional Foley Catheters
  - Fracture Fixation Plates
  - Surgical Sutures
  - Denture Base Resin-NEW!
  - Facet Screw Systems-NEW!
- Draft guidance:
  - Soft (Hydrophilic) Daily Wear Contact Lenses

Docket Number FDA-2018-D-1387 at www.regulations.gov

Safety and Performance Based Pathway: Eligibility Criteria

- The new device has
  - Same **indications for use**
  - Same **technological characteristics**
    - Does not raise different questions of safety and effectiveness
- Meets all the **FDA-identified performance criteria**

Special 510(k) Program

- Change to your device (IFU/labeling or technology)
- Performance data:
  - Not needed

  or
  - Well-established methods exist to evaluate the change
  - Can be reviewed in summary or risk analysis format
- 30-day FDA review clock

FDA Guidance: The Special 510(k) Program

Well-Established Methods

- Previously-cleared 510(k)
- Recognized consensus standard
- Widely available/accepted methods/premarket submission

Summary/Risk Analysis

Device Change	Risks	V & V Method	Acceptance Criteria	Summary of Results

- Summary of design control procedures (21 CFR 820.30)
  - Results from verification and validation (V&V) activities
- SE determination can be made with summary information
- Examples outlined in Appendix C of guidance

Quality System (QS) Regulation/Medical Device Good Manufacturing Practices

Third Party Review Program

- Traditional, Abbreviated, or Special
- Review completed by accredited 3rd party*
- Certain low/moderate risk devices are eligible*
- 30 FDA days for supervisory review
- 3P510k@fda.hhs.gov

FDA Guidance: 510(k) Third Party Review Program

	Traditional	Abbreviated	S&P Pathway	Special	Third Party
Overview of differences/ similarities	Most common	Similar to Traditional in terms of timeline	Expansion of Abbreviated	Used for modifications to own device	Review of certain low/moderate risk devices. FDA performs supervisory review
FDA review time	90-days	90-days	90-days	30-days	30-days
Data needs	All data provided	Relies on standards, guidance, special controls	Meets FDA identified performance criteria	Only **Summary**-level information focusing on the **modifications**	Relies on standards, guidance, special controls
Guidance	yes	yes	yes	yes	yes

Knowledge Check

What is the FDA MDUFA review time for an S&P Pathway submission?

a. 30-day

b. 60-day

c. 90-day

Common Reasons for Conversion

Conversion:
Special to Traditional

- No well-established methods
- Summary or Risk Analysis format is not appropriate for the proposed change(s).
- The subject device is not the submitters own device

Conversion: Abbreviated to Traditional

- Summary reports provided that do not reference:
  - Guidance
  - Special controls
  - Standards

Conversion Case Study

Scenario

	Cleared Device	Current Device
		
Indications for Use	Same	Same
Material	Same	Same
Sterilization Method	Non-sterile	Sterilized via gamma irradiation
Screw length	30-60mm	25-60mm

Special 510(k)

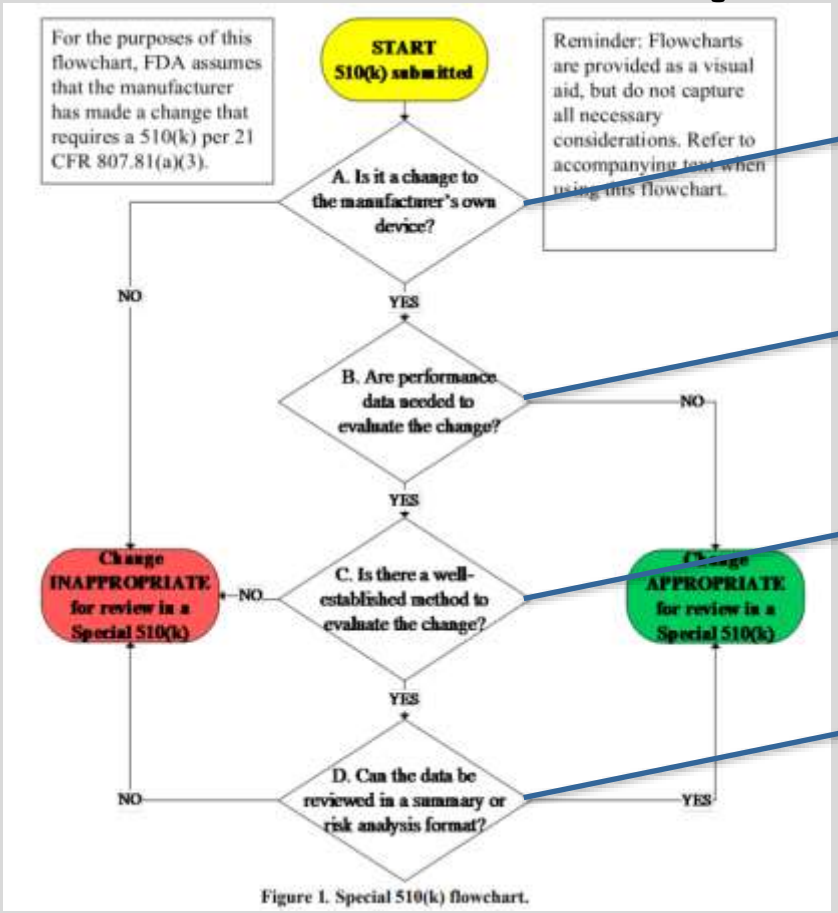


Figure 1. Special 510(k) flowchart.

A - Is it a change to the manufacturer's own device?

B – Are performance data needed to evaluate the change?

C – Is there a well-established method to evaluate the change?

D – Can the data be reviewed in a summary or risk analysis format?

Performance Data Needed?

Device Change	Risks	V & V Method	Acceptance Criteria	Summary of Results
Sterilized via gamma irradiation	Potential for infection or rejection	biocompatibility, sterility, pyrogenicity, package integrity, and shelf-life	FDA guidance	Scientifically-based rationale supporting no further biocomp testing needed
Smaller Screw length	Potential to create new worst-case	Finite Element Analysis/Mechanical testing	FDA guidance/ compare testing to FDA cleared device	Summary of results shows no new worst-case

Well-Established Methods?

Device Change	Well-established methods
Sterilized via gamma irradiation	FDA guidance Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile
Smaller Screw length	FDA guidance: Spinal Systems 510(k)s

Summary/Risk Analysis Format?

Device Change	Can the change be evaluated in a summary or risk analysis format?
Sterilized via gamma irradiation	Yes • The methods are standardized, and the results can be summarized • SE determination **NOT** dependent on underlying data, such as images, raw graphs, or line item data
Smaller Screw length	No • Methods outlined in FDA guidance • Results CANNOT be summarized • SE determination dependent on underlying data such as images, raw graphs, or line item data

Special 510(k)

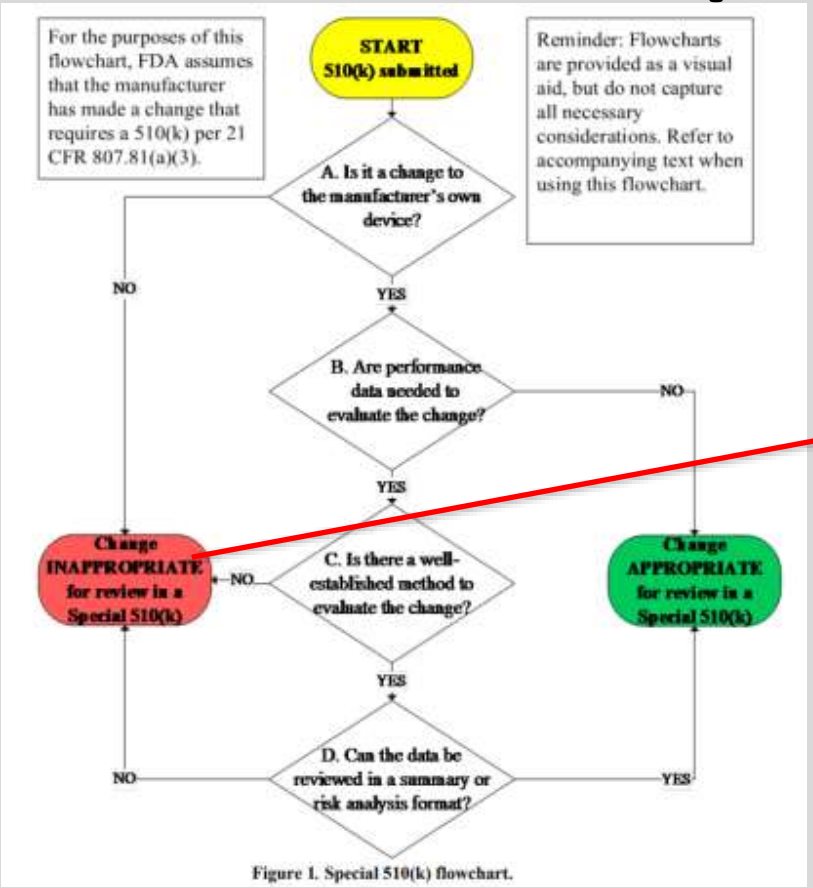


Figure 1. Special 510(k) flowchart.

No, there is a change that is inappropriate for review as a special 510(k).

Knowledge Check

If the device change was ONLY the sterilization method, could it have been reviewed as a Special?

a. Yes

b. No

c. It depends

Resources

Slide #	Cited Resource	URL
5	21 CFR 807.92(a)(3)	www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=807.92
6	Deciding When to Submit a 510(k) for Change to an Existing Device	www.fda.gov/regulatory-information/search-fda-guidance-documents/deciding-when-submit-510k-change-existing-device
6	Frequently-Asked-Questions about the Reprocessing and Reuse of Single-Use Devices by Third-Party and Hospital Reprocessors	www.fda.gov/regulatory-information/search-fda-guidance-documents/frequently-asked-questions-about-reprocessing-and-reuse-single-use-devices-third-party-and-hospital
7	Refuse to Accept Policy for 510(k)s	www.fda.gov/regulatory-information/search-fda-guidance-documents/refuse-accept-policy-510ks
12	Format for Traditional and Abbreviated 510(k)s	www.fda.gov/regulatory-information/search-fda-guidance-documents/format-traditional-and-abbreviated-510ks
13	The Abbreviated 510(k) Program guidance	www.fda.gov/regulatory-information/search-fda-guidance-documents/abbreviated-510k-program

Resources

Slide #	Cited Resource	URL
16	The Special 510(k) Program	www.fda.gov/regulatory-information/search-fda-guidance-documents/special-510k-program
18	Quality System (QS) Regulation/Medical Device Good Manufacturing Practices	www.fda.gov/medical-devices/postmarket-requirements-devices/quality-system-qs-regulationmedical-device-good-manufacturing-practices
19	List of Devices for Third Party Review	www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfThirdParty/current.cfm
19	Current List of FDA-Recognized 510(k) Third Party Review Organizations	www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfthirdparty/accredit.cfm
19	510(k) Third Party Review Program	www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-third-party-review-program

Summary

- Provided a high-level overview of 510(k) process
- Described 510(k) Submission Types and Third Party review program
- Discussed some common reasons for conversion
- Applied key concepts to a real-life conversion example

Questions