

# **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?

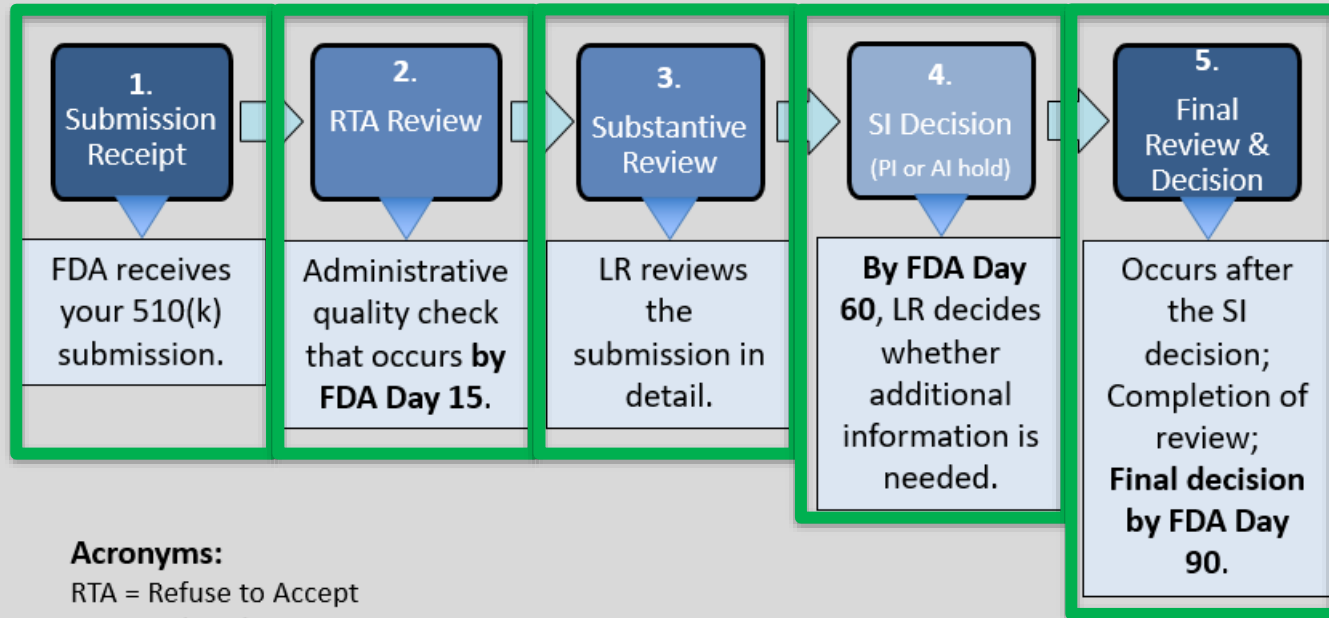
- Introducing device to market for the first time
- Modification(s) to device that could affect safety or effectiveness:
  - Intended use
  - labeling
- Reprocessing of a single use device (SUD)\*

## **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

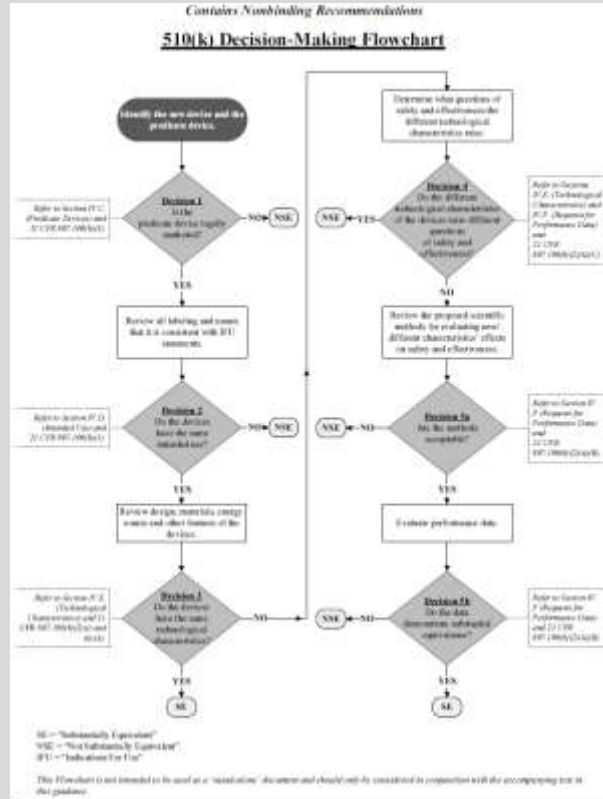
SI = Substantive Interaction

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

# 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](https://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 neededor
  - Well-established methods exist to evaluate the change
  - Can be reviewed in summary or risk analysis format
- 30-day FDA review clock

# 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

# Third Party Review Program

- Traditional, Abbreviated, or Special
- Review completed by accredited 3<sup>rd</sup> party\*
- Certain low/moderate risk devices are eligible\*
- 30 FDA days for supervisory review
- [3P510k@fda.hhs.gov](mailto:3P510k@fda.hhs.gov)

	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 <b>Summary</b> -level information focusing on the <b>modifications</b>	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

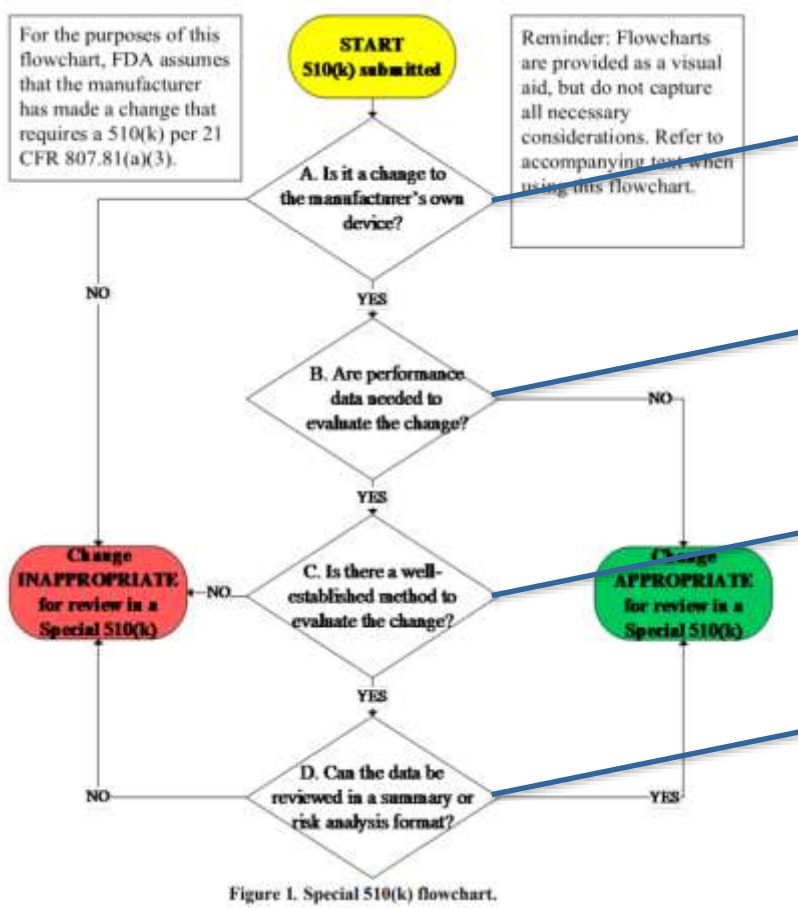
- Summary reports provided that do not reference:
  - Guidance
  - Special controls
  - Standards

# 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)



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	<p>Yes</p> <ul style="list-style-type: none"> <li>• The methods are standardized, and the results can be summarized</li> <li>• SE determination <b><u>NOT</u></b> dependent on underlying data, such as images, raw graphs, or line item data</li> </ul>
Smaller Screw length	<p>No</p> <ul style="list-style-type: none"> <li>• Methods outlined in FDA guidance</li> <li>• Results CANNOT be summarized</li> <li>• SE determination dependent on underlying data such as images, raw graphs, or line item data</li> </ul>

# Special 510(k)

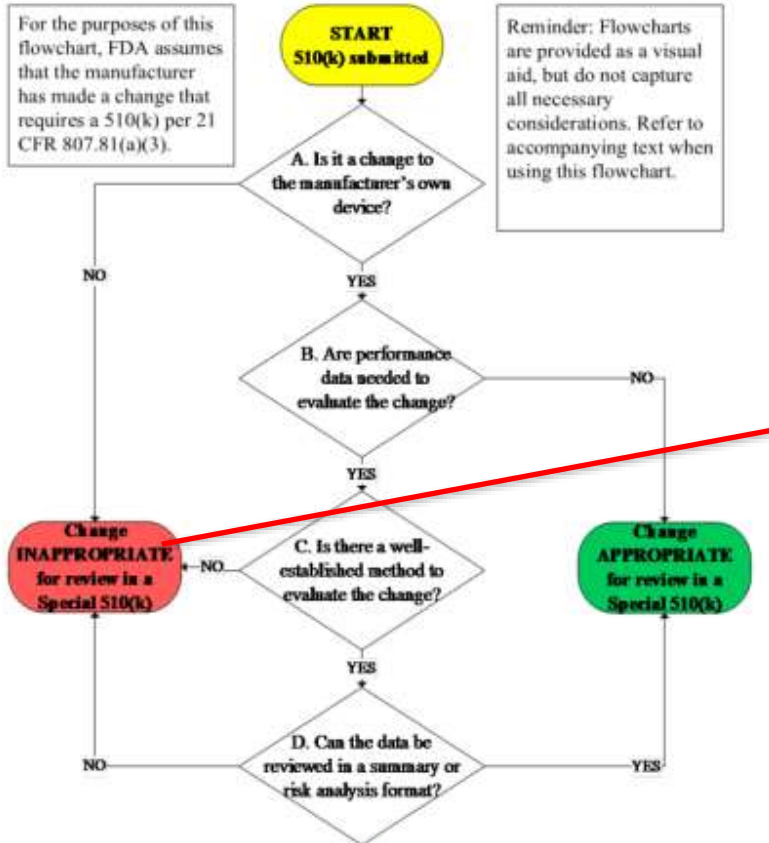


Figure 1. Special 510(k) flowchart.

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

# Resources



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

# 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

