



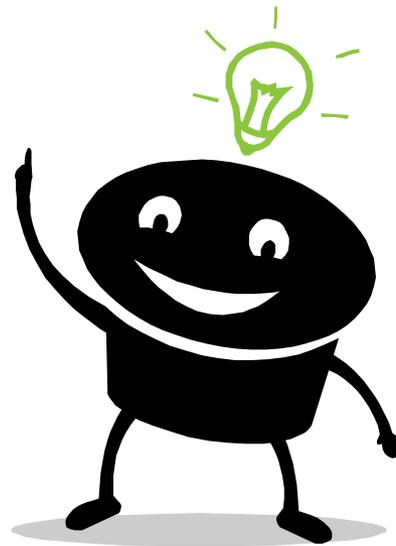
# The 510(k) Program

**FDA Small Business  
Regulatory Education for Industry (REdI)**  
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**A Premarket Notification [510(k)]  
is one of the major pathways for  
bringing a device to market.**



# What's your 510(k) experience?



# Learning Objectives

1. To understand medical device classifications and how classifications apply to 510(k)s
2. To describe what a 510(k) is, when it is required and the different types of 510(k) submissions
3. To describe the content of a 510(k) and what should be submitted to the FDA
4. To discuss the 510(k) submission process including how and when the FDA will communicate with submitters regarding their 510(k)
5. To describe 510(k) decisions and what they mean
6. To identify common 510(k) inquiries received from industry and how to address them

# Presentation Outline

- Device Classification As It Relates to 510(k)s
- Overview of 510(k) Program
- Content of a 510(k)
- 510(k) Submission Process
- 510(k) Decisions
- Common 510(k) Inquiries from Industry
- Summary and Discussion

# Presentation Outline

- **Device Classification As It Relates to 510(k)s**
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# Medical Device Classifications

- **Class I = Low Risk Devices**
  - Subject to general controls
  - Most, but not all, class I devices are exempt from premarket notification [510(k)]
  
- **Class II = Moderate Risk Devices**
  - **Subject to general and special controls**
  - **Most, but not all, Class II devices require a premarket notification [510(k)]**
  
- **Class III = High Risk Devices**
  - Subject to general controls and premarket approval

# Product Codes

- Three letter codes
- Used by FDA to identify and track similar medical devices
- Used by 510(k) submitters to search for a predicate device(s)
- Found on most 510(k) clearance letters

## References:

- [Guidance: Medical Device Classification Product Codes](#)
- [Product Classification Database](#)



# Example: Product Classification Database

Device	Pump, Infusion
Regulation Description	Infusion pump.
Regulation Medical Specialty	General Hospital
Review Panel	General Hospital
Product Code	FRN
Premarket Review	<u>Office of Device Evaluation (ODE)</u> Division of Anesthesiology, General Hospital, Infection Control, and Dental Devices (DAGRID) General Hospital Devices Branch (GHDB)
<b>Submission Type</b>	510(k)
Regulation Number	<u>880.5725</u>
Device Class	2
Total Product Life Cycle (TPLC)	<u>TPLC Product Code Report</u>
GMP Exempt?	No

**What do you do if you cannot  
determine the appropriate device  
classification?**

**513(g) Program**

# 513(g) Program

- There is a 513(g) User Fee. For FY2016, it is \$3,529 (\$1,765 for a small business)
- FDA responses to requests for information about the regulatory requirements applicable to a particular device DO NOT constitute FDA clearance or approval for distribution of that particular device in the U.S.

## References:

- [Guidance - FDA and Industry Procedures for Section 513\(g\) Requests for Information under the Federal Food, Drug, and Cosmetic Act](#)
- [Guidance - User Fees for 513\(g\) Requests for Information](#)

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## A 510(k) is:

- A Premarket Notification
- Section 510(k) of Federal FD&C Act
- 21 CFR 807 Subpart E
- It is a marketing clearance application
- 510(k)s are “cleared”
- Allows FDA to determine Substantial Equivalence

## A 510(k) is not:

- A Form
- Establishment Registration
- Device Listing
- Premarket Approval (PMA)

## Reference:

- [Premarket Notification \(510k\)](#)

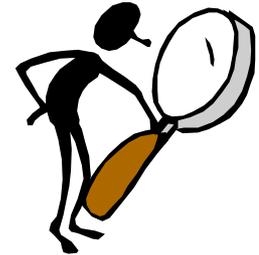
# What is Substantial Equivalence (SE)?

- Demonstration that a new device, as compared to a predicate device, has...
  - the same intended use **and**
  - the same technological characteristics,
    - **Or** differences in technological characteristics do not raise different questions regarding safety and effectiveness

## References:

- [Guidance – The 510\(k\) Program: Evaluating Substantial Equivalence in Premarket Notifications \[510\(k\)\]](#)
- [Medical Device Webinar “The 510\(k\) Program Guidance: Evaluating Substantial Equivalence in Premarket Notifications” \[8/15/2014\]](#)

# What is a Predicate Device?



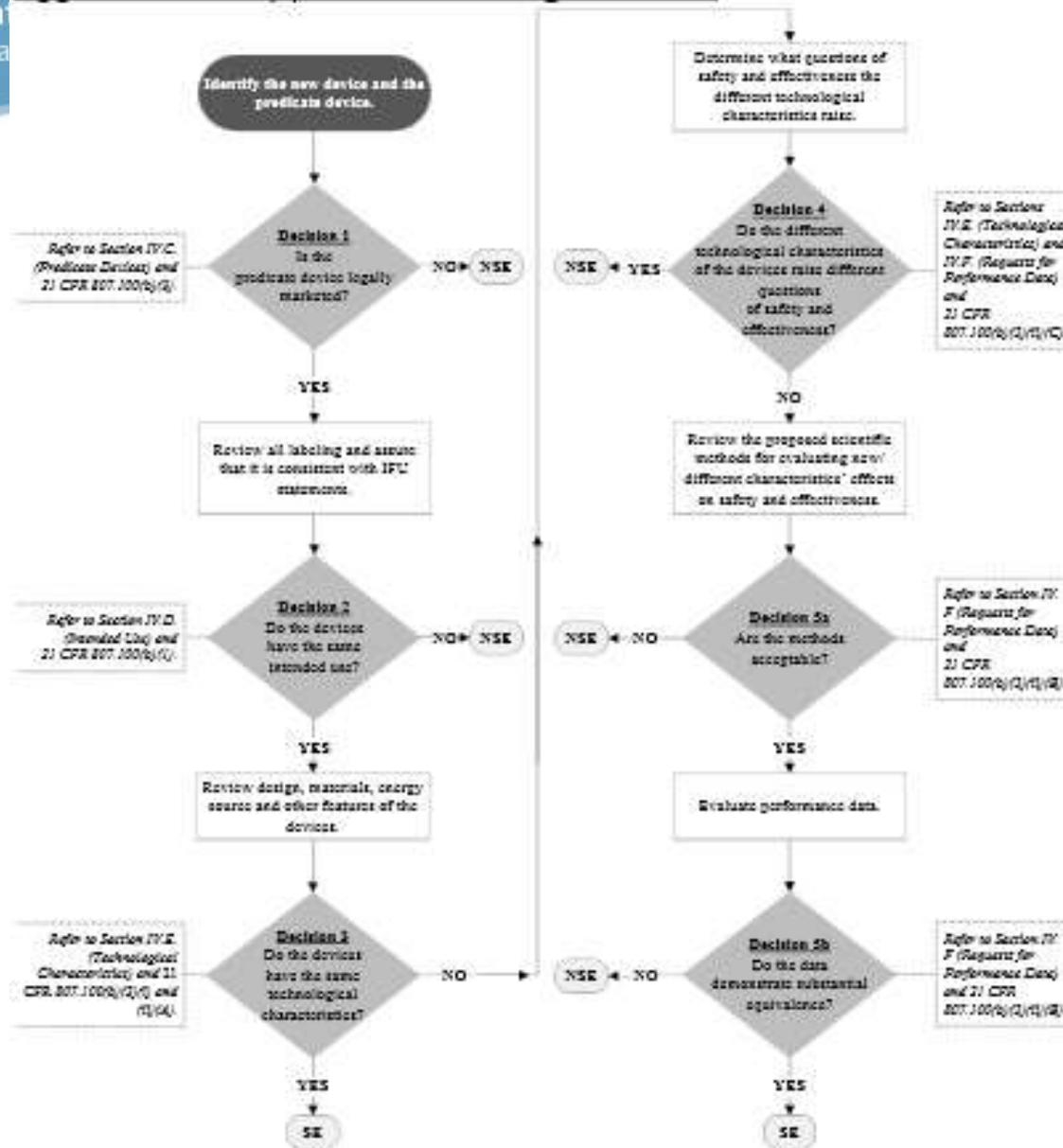
- A legally marketed device, previously cleared through the 510(k) process mainly, that is used for comparison to a new device for the purpose of determining substantial equivalence (21 CFR 807.92(a)(3))

## Reference:

- [How To Find and Effectively Use Predicate Devices](#)



# 510(k) Decision- Making Flow Chart



SE = "Substantially Equivalent"  
NSE = "Not Substantially Equivalent"  
IFU = "Instructions For Use"

# Establishing Substantial Equivalence

## *Decision Points From Flowchart*

1. Is the predicate device legally marketed?
2. Do the devices have the same intended use?
3. Do the devices have the same technological characteristics?
4. Do the different technological characteristics of the devices raise different questions of safety and effectiveness?
5. Two Parts:
  - a) Are the methods acceptable?
  - b) Do the data demonstrate substantial equivalence?

# When is a 510(k) Typically Required?

- Introducing a device to the market for the first time
- Changing the indications for use of a previously cleared device
- Making significant modification(s) to a previously cleared device

## References:

- [Is a new 510\(k\) required for a modification to the device?](#)
- [Deciding When to Submit a 510\(k\) for a Change to an Existing Device \(K97-1\)](#)

# Types of 510(k) Submissions

Traditional 510(k)  
Abbreviated 510(k)  
Special 510(k)

# Traditional 510(k)

- Required elements (21 CFR 807.87)
- Relies on the demonstration of substantial equivalence
- **The Traditional 510(k) method may be used under any circumstance**

## References:

- [How to Prepare A Traditional 510\(k\)](#)
- [510\(k\) Forms](#)

# Abbreviated 510(k)

- Relies on the use of guidance documents, special controls, and recognized standards
- Required elements (21 CFR 807.87)
- Under certain conditions, submitters may not need to submit test data in an abbreviated 510(k)

## Reference:

- [How to Prepare An Abbreviated 510\(k\)](#)

# Special 510(k)

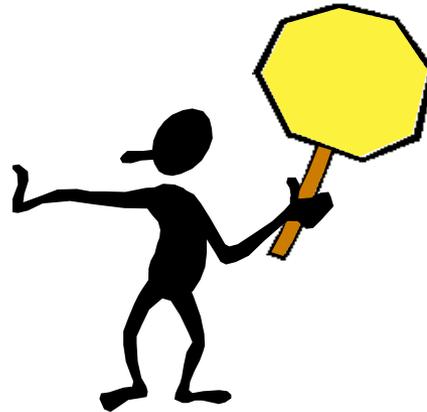
- Required elements (21 CFR 807.87)
- Device modification to a submitter's own legally marketed device
- Modification does NOT affect the intended use or fundamental scientific technology
- Specific data are not evaluated by FDA

Reference:

- [How to Prepare A Special 510\(k\)](#)

# What do you do if...

You have a low or moderate risk device with no identifiable predicate device?



**Consider *de novo***

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# Content of a 510(k)

- Medical Device User Fee Cover Sheet (Form FDA 3601)
- CDRH Premarket Review Submission Cover Sheet
- 510(k) Cover Letter
- **Indications for Use Statement**
- **510(k) Summary** or 510(k) Statement
- Truthful and Accuracy Statement
- Class III Summary and Certification
- Financial Certification or Disclosure Statement
- **Declarations of Conformity and Guidance Documents**
- Executive Summary
- **Device Description**
- **Substantial Equivalence Discussion**
- **Proposed Labeling**
- **Sterilization and Shelf Life**
- **Biocompatibility**
- **Software**
- **Electromagnetic Compatibility and Electrical Safety**
- **Performance Testing – Bench**
- **Performance Testing – Animal**
- **Performance Testing – Clinical**
- Other

# Intended Use and Indications for Use

- **Intended Use:** General purpose of the device or its function, and encompasses the indications for use
  - **Indications for Use:** As defined in 21 CFR 814.20(b)(3)(i), describes the disease or condition the device will diagnose, treat, prevent, cure, or mitigate, including a description of the patient population for which the device is intended
- Must be consistent throughout your 510(k), including the indications for use statement, proposed labeling, etc.
- Recommended Format for Indications for Use Statement ([Form FDA 3881](#))

# 510(k) Summary

- High level discussion of the content within the 510(k)
- Must include elements in [21 CFR 807.92](#)
- Must include sufficient detail to provide an understanding of the basis for a determination of substantial equivalence
- FDA will verify the accuracy and completeness of the 510(k) Summary information during the 510(k) review

## Reference:

- [Guidance – The 510\(k\) Program: Evaluating Substantial Equivalence in Premarket Notifications \[510\(k\)\], Appendix B. The 510\(k\) Summary Document Requirements](#)

# FDA Recognized Consensus Standards (Declarations of Conformity)

- Voluntary program
- Used to simplify and streamline the 510(k) review process
- Submitters can only declare conformance to FDA recognized consensus standards
- Must document extent of conformance in 510(k) application ([Form FDA 3654](#) - Standards Data Report for 510(k)s)

## References:

- [Guidance - Recognition and Use of Consensus Standards](#)
- [Guidance - Frequently Asked Questions on Recognition of Consensus Standards](#)
- [Recognized Consensus Standards Database](#)

# CDRH Learn: Standards

## Standards

Standards Overview *(New module 9/15/15)*

[Presentation](#) [Printable Slides](#) [Transcript](#)

Standards Resources *(New module 9/15/15)*

[Presentation](#) [Printable Slides](#) [Transcript](#)

CDRH Standards Recognition Process *(New module 9/15/15)*

[Presentation](#) [Printable Slides](#) [Transcript](#)

# FDA Guidance Documents

- Represents FDA's current thinking on a topic
- May be device specific or general
- Does not create or confer any rights for or on any person and does not operate to bind FDA or the public
- Alternative approaches may be used if the approach satisfies the requirements of the applicable statutes and regulations

## Reference:

- [Guidance Documents \(Medical Devices and Radiation-Emitting Products\)](#)

# Example: Product Classification Database

## Recognized Consensus Standards

- [ISO 7886-2 First edition 1996-05-15 Sterile hypodermic syringes for single use - Part 2: Syringes for use with power-driven syringe pumps](#)
- [ISO 26825 First edition 2008-08-15 Anaesthetic and respiratory equipment - User-applied labels for syringes containing drugs used during anaesthesia - Colours, design and performance](#)
- [ISO 23908 First edition 2011-06-11 Sharps injury protection - Requirements and test methods - Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling](#)
- [ISO 9626 First edition 1991-09-01 Stainless steel needle tubing for the manufacture of medical devices \[Including: Amendment 1 \(2001\)\]](#)

## Guidance Documents

- [Guidance for Industry and FDA Staff - Total Product Life Cycle: Infusion Pump - Premarket Notification \[510\(k\)\] Submissions \*\*Text\*\*](#)
- [Guidance on the Content of Premarket Notification \[510\(k\)\] Submissions for External Infusion Pumps](#)

# Device Description

- Within a 510(k) the device description should include:
  - Overall description of the device design (e.g. physical specifications, dimensions, design tolerances, engineering drawings, figures, etc.)
  - Materials (e.g. list all patient contacting components)
  - Energy sources
  - Other key technological features

# Substantial Equivalence Discussion

- Substantial Equivalence is defined in section [513\(i\) of the FD&C Act](#)
- Utilize 510(k) Decision-Making Flowchart
- 510(k) review standard is comparative (i.e. new device compared to predicate device)
  - Multiple predicate devices are ok under certain circumstances
  - Split predicates are inconsistent with 510(k) regulatory standard
  - Reference devices may be used to support scientific methodology or standard reference values. Reference devices are not predicate devices.

# Labeling

- Comply with Device Labeling Requirements ([21 CFR 801](#))
- Copies of all proposed labels, labeling, package inserts, service manuals, instructions for use, advertising and/or promotional materials
- The directions for use should include a specific intended use statement and any warnings, contraindications, or limitations
- Labeling submitted should be **final draft**
- Copies of labeling for the predicate device is recommended

## Reference:

- [Introduction to Medical Device Labeling](#)

# Sterilization/Shelf Life

- Sterilization is defined as a validated process used to render a product free of all forms of viable microorganisms
- Labeling must provide adequate instructions for reusable devices
- Shelf Life is device specific and should be supported by appropriate bench tests and/or sterilization (packaging) validation
  - Real-time or accelerated aging testing

## References:

- [Updated 510\(k\) Sterility Review Guidance K90-1](#)
- [\[Draft Guidance\] Submission and Review of Sterility Information in Premarket Notification \(510\(k\)\) Submissions for Devices Labeled as Sterile \(Intended to supersede K90-1\)](#)
- [Liquid Chemical Sterilization](#)
- [Guidance - Content and Format of Premarket Notification \[510\(k\)\] Submissions for Liquid Chemical Sterilants/High Level Disinfectants](#)

# Biocompatibility

- To determine the potential toxicity resulting from contact of the component materials of the device with the body
- Appropriate tests are determined based on the nature, degree, frequency and duration of its exposure to the body
- The final product should be tested (this includes after sterilization, if applicable)
- Include: test methods, acceptance criteria and test results for review

## References:

- [Special Considerations – Biocompatibility](#)
- [Guidance - Use of ISO 10993 "Biological Evaluation of Medical Devices Part-1: Evaluation and Testing"](#)
- [510\(k\) Memorandum - #G95-1 Table 1 Initial Evaluation Tests for Consideration](#)
- [\[Draft Guidance\] Use of International Standard ISO- 10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing](#)

# Software

- Software development and validation should be based on the level of risk of the software
- The extent of documentation that we recommend you submit is proportional to the Level of Concern associated with the device
- Level of Concern (Major, Moderate or Minor)

## References:

- [Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices](#)
- [Guidance - Off-The-Shelf Software Use in Medical Devices](#)
- [Mobile Medical Applications](#)

# Electromagnetic Compatibility (EMC)/ Electrical Safety

- Electrical Safety (e.g. electric shock, burns, or electrical interference, leakage current, etc.) and Electromagnetic Compatibility (EMC)
- Recognized Consensus Standards [IEC 60601-1-2](#) Medical Electrical Equipment or an equivalent method

## References:

- [Electromagnetic Compatibility \(EMC\)](#)
- [Guidance - Radio Frequency Wireless Technology in Medical Devices](#)
- [Wireless Medical Devices](#)

# Performance Testing

- Bench, Animal, or Clinical
- Necessary performance tests depend on the complexity of the device and its intended use and indications
- Consider FDA Guidance Documents
- Consider comparative testing to demonstrate substantial equivalence
- Include: test methods, acceptance criteria and test results for review

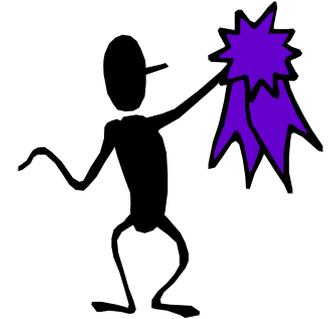
# Performance Testing - Clinical

- Most 510(k)s do not require clinical data
- Clinical data may be requested in the following situations:
  1. New or Modified Indications for Use – Same Intended Use
  2. Significant Technological Differences
  3. Non-clinical Testing Methods are Limited or Inappropriate Because of the Indications for Use or Device Technology

## Reference:

- [Guidance – The 510\(k\) Program: Evaluating Substantial Equivalence in Premarket Notifications \[510\(k\)\]](#)

# Key Considerations



- Information is complete and organized
  - Include a table of contents
  - Use tabs and paginate properly
  - Utilize tables and graphs appropriately and effectively
  - Use visual aids whenever possible
- Clearly identify basic 510(k) requirements (e.g. 510(k) Summary, Indications for Use Form, etc.)
- Be consistent throughout the submission
- Follow current applicable guidance documents and device specific checklists

# Pre-Sub for a 510(k)

- [Guidance: Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff](#) [**Pre-Sub for a 510(k) is under Appendix 1.C**]
- Method to obtain FDA feedback prior to submission of your 510(k); typically for unique situations (e.g. need for clinical data)
- Submit a formal written request to the FDA
- Request either a formal written response, meeting, or teleconference to address your concerns, questions, etc.
- Subject to eCopy requirements

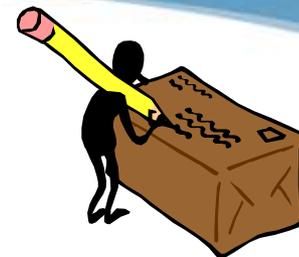
## References:

- [CDRH Learn Module - Requests for Feedback: The Pre-Submission Program and Meetings with CDRH Staff](#)
- [Medical Device Webinar - Pre-Submissions and Meetings with FDA Staff](#) [2/28/2014]

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# Submission to FDA



- You must submit **two copies** of your 510(k)
- One of your two copies must be submitted in an electronic format (i.e. eCopy)
- FDA does NOT return the 510(k) submission after review
- Address:  
Food and Drug Administration  
Center for Devices and Radiological Health  
Document Control Center (DCC) - WO66-G609  
10903 New Hampshire Avenue  
Silver Spring, Maryland 20993-0002

## Reference:

- [Addresses for Submissions](#)

# eCopy Program

- Valid eCopy is a requirement for Premarket Submissions
- An eCopy is defined as an exact duplicate of the paper submission, created and submitted on a compact disc (CD), digital video disc (DVD), or a flash drive
- An eCopy is accompanied by a paper copy of the signed cover letter and the complete paper submission
- Questions regarding eCopy requirements or responses to eCopy holds should be sent to [CDRH-eCopyinfo@fda.hhs.gov](mailto:CDRH-eCopyinfo@fda.hhs.gov)

## References:

- [eCopy Program for Medical Device Submissions](#)
- [Guidance - eCopy Program for Medical Device Submissions](#)

# 510(k) User Fees

- 510(k) Submissions are subject to User Fees
- User Fees must be received on or before the time the application is submitted
- FDA will not accept the 510(k) for filing if the fee is not paid
- There is a Standard User Fee and a Small Business reduced User Fee. For FY2016, the Standard Fee is \$5,228 and the Small Business Fee is \$2,614.

## References:

- [Premarket Notification \[510\(k\)\] Review Fees](#)
- [Guidance FY 2016 Medical Device User Fee Small Business Qualification and Certification](#)



# 510(k) Submission Process

## Important Notes:

- Days are Calendar Days
- The timeline is based on the MDUFA III Performance Goals
- This timeline has been simplified

## References:

- [510\(k\) Submission Process](#)
- [Guidance - Types of Communication During the Review of Medical Device Submissions](#)
- [Guidance – FDA and Industry Actions on Premarket Notification \(510\(k\)\) Submissions: Effect on FDA Review Clock and Goals](#)

Day 1: FDA receives 510(k) submission.



By Day 7

FDA sends **Acknowledgement Letter**.

**OR**

FDA sends **Hold Letter** if unresolved issues with User Fee and/or eCopy.



By Day 15

FDA conducts **Acceptance Review**.

FDA informs submitter if 510(k) is accepted for **Substantive Review** or placed on **RTA Hold**.



By Day 60

FDA conducts **Substantive Review**.

FDA communicates via a **Substantive Interaction** to inform the submitter that the FDA will either proceed with **Interactive Review** or that the 510(k) will be placed on hold and **Additional Information** is required.



By Day 90

FDA sends final **MDUFA Decision** on 510(k).



By Day 100

If MDUFA Decision is not reached by Day 100, FDA provides **Missed MDUFA Decision Communication** that identifies outstanding review issues.

# 510(k) Submission Process

## Timeline of Communication during 510(k) Review

Day 1: FDA receives 510(k) submission.



By Day 7

FDA sends **Acknowledgement Letter**.

**OR**

FDA sends **Hold Letter** if unresolved issues with User Fee and/or eCopy.



# 510(k) Submission Process

By Day 15

FDA conducts **Acceptance Review**.

FDA informs submitter if 510(k) is accepted for **Substantive Review** or placed on **RTA Hold**.



# Refuse to Accept (RTA) Policy



- [Guidance – Refuse to Accept Policy for 510\(k\)s \(Aug. 4, 2015\)](#)
- Is the 510(k) submission administratively complete for substantive review?
- Early Review – 15 calendar days from receipt
- Necessary elements and content of a complete 510(k) submission
- FDA clock begins on the date of receipt when the 510(k) is “accepted for review.”

# 510(k) Submission Process

By Day 60

FDA conducts **Substantive Review**.

FDA communicates via a **Substantive Interaction** to inform the submitter that the FDA will either proceed with **Interactive Review** or that the 510(k) will be placed on hold and **Additional Information** is required.



# Substantive Interaction

FDA Notification that:

1. The 510(k) will not be placed on hold and outstanding deficiencies will be resolved via **Interactive Review, or**
2. The 510(k) is being placed on hold via an **Additional Information** request which identifies the outstanding deficiencies that need to be addressed before substantive review can continue.

# Interactive Review

- Informal interaction between FDA and submitters during the review of 510(k) submissions
- FDA review clock does not stop
  - 510(k) submission is not placed on hold
- Not subject to eCopy requirements unless submitted through the DCC
- Benefits: Ensures FDA's concerns are clearly communicated; minimizes the number of review cycles; and reduces overall time to a decision

## Reference:

- [Guidance - Types of Communication During the Review of Medical Device Submissions](#)

# Additional Information (AI) Requests

- Additional information is necessary to continue or complete the 510(k) review
- 510(k) submission is placed on hold and FDA review clock stops
- Submitter has up to 180 calendar days from the date of the AI Request to provide a complete response to DCC
- AI Responses are subject to eCopy requirements

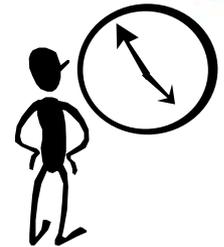
# 510(k) Submission Process

By Day 90

FDA sends final MDUFA Decision on 510(k).



# MDUFA III Performance Goals



510(k) Submission Type	FDA Review Days
Traditional and Abbreviated	90
Special	30

Reference:

- [MDUFA III Performance Goals](#)

# 510(k) Submission Process

## By Day 100

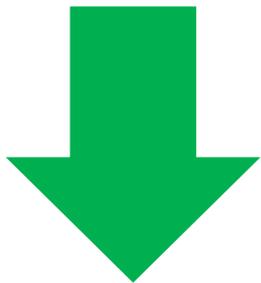
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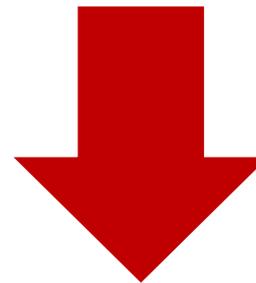
# 510(k) Decisions

## SE Decision



Device To Market

## NSE Decision



Resubmit another 510(k) with new data, PMA, *de novo* or reclassification petition

# Why Might You Receive a NSE Decision?

1. There is no predicate device
2. Your device has a NEW intended use compared to the predicate device
3. Your device has different technological characteristics compared to the predicate device and raises different questions regarding safety and effectiveness
4. You did not demonstrate that your device is at least as safe and effective as the predicate

# What Happens After a Device is Cleared?

- The following are posted on the [FDA's public 510\(k\) database](#):
  - SE Letter
  - Indications for Use Form
  - 510(k) Summary (if provided instead of 510(k) Statement)

\*NOTE: For [510\(k\) Statements](#), submitters must make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person (21 CFR 807.93).

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# Common 510(k) Inquiries from Industry

1. Changes to an Existing Device
2. Bundling
3. Transfer 510(k) Ownership



# Changes to an Existing Device

- Sponsors need to submit a new 510(k) only when a change, or the sum of the incremental changes "could significantly affect the safety or effectiveness of the device ([21 CFR 807.81\(a\)\(3\)](#))
- Examples of modifications that may require a 510(k) submission include, but are not limited to, the following:
  - Intended Use
  - Sterilization Method
  - Material Changes
  - Design Changes

## References:

- [Is a new 510\(k\) required for a modification to the device?](#)
- [Guidance - Deciding When to Submit a 510\(k\) for Change to an Existing Device \(K97-1\)](#)

# Bundling



- The inclusion of multiple devices or multiple indications for use for a device in a single premarket submission
- In determining whether a bundled submission can be reviewed during the course of **one review**, FDA may consider whether: (i) the supporting data are similar; (ii) primarily one review division/group will be involved; and (iii) the devices or indications for use are similar

Reference:

- [Guidance - Bundling Multiple Devices or Multiple Indications in a Single Submission](#)

# Transfer of 510(k) Ownership

- A cleared 510(k) may be bought, sold, or transferred from one owner to another
- FDA is not involved in the financial transaction

## Reminders:

- New owner should maintain documentation of transfer and all appropriate device records
- New owner must manufacture device according to 510(k) cleared specifications
- New and previous owners must update registration and listing
- A copy of the transfer should accompany all shipments to the U.S.
- No new 510(k) clearance letter will be issued
- You may inform FDA by submitting an “Amendment to Cleared 510(k),” citing 510(k) number, but this is not required

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# Summary

1. The appropriate classification for a device will indicate whether or not 510(k) clearance is required before the device can be legally marketed.
2. The 510(k) review standard is comparative i.e. substantial equivalence must be demonstrated for a new device compared to a legally marketed predicate device.
3. A 510(k) should contain all the content necessary to demonstrate the safety and effectiveness of the new device compared to a predicate device.

# Summary

4. FDA will communicate with submitters during the review of their 510(k)s based on specified performance goals.
5. A 510(k) which is found substantially equivalent can then be legally marketed in the U.S.
6. Common 510(k) inquiries include whether or not a new 510(k) is required when making changes to an existing device; if bundling is appropriate in a single 510(k); and what to do when the ownership of a 510(k) is transferred.

# Industry Education Resources

## Three Resources

### 1. CDRH Learn – Multi-Media Industry Education

- over 80 modules
- videos, audio recordings, power point presentations, software-based “how to” modules
- mobile-friendly: access CDRH Learn on your portable devices  
<http://www.fda.gov/Training/CDRHLearn>

### 2. Device Advice – Text-Based Education

- comprehensive regulatory information on premarket and postmarket topics  
[www.fda.gov/MedicalDevices/DeviceRegulationandGuidance](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance)

### 3. Division of Industry and Consumer Education (DICE)

- Contact DICE if you have a question
- Email: [DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)
- Phone: 1(800) 638-2014 or (301) 796-7100 (Hours: 9 am-12:30 pm; 1 pm-4:30pm EST)
- Web: <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ContactUs--DivisionofIndustryandConsumerEducation/default.htm>

# CDRH Learn: 510(k) Modules

## How to Study and Market Your Device - (New modules 9/15/15)

*510k, de novo, IDE, Pre-Submissions, Standards, Classification, Bioresearch Monitoring*

### Premarket Notification (510k)

The 510(k) Program

[Presentation](#)  [Printable Slides](#) [Transcript](#)

Premarket Notification 510(k) Overview

[Presentation](#)  [Printable Slides](#)

510(k) Format Guidance, Including Standards Form, and Extensions/Clinical Trial Form and 510(k)

[Presentation](#)  [Printable Slides](#)

510(k) Third Party Review

[Presentation](#)  [Printable Slides](#)

510(k) Electronic Submission Pilot Program

[Printable Slides](#) [Transcript](#)

# Discussion



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