510(k) Program Overview

FDA Small Business
Regulatory Education for Industry (REdI)
Atlanta, GA
May 9, 2017

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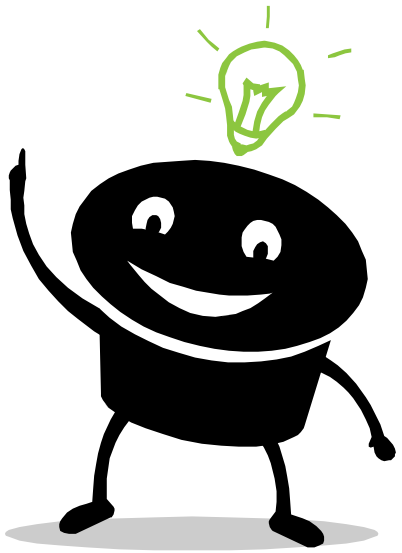
A Premarket Notification [510(k)] is the most prolific way to bring a new device to market.



Poll Question

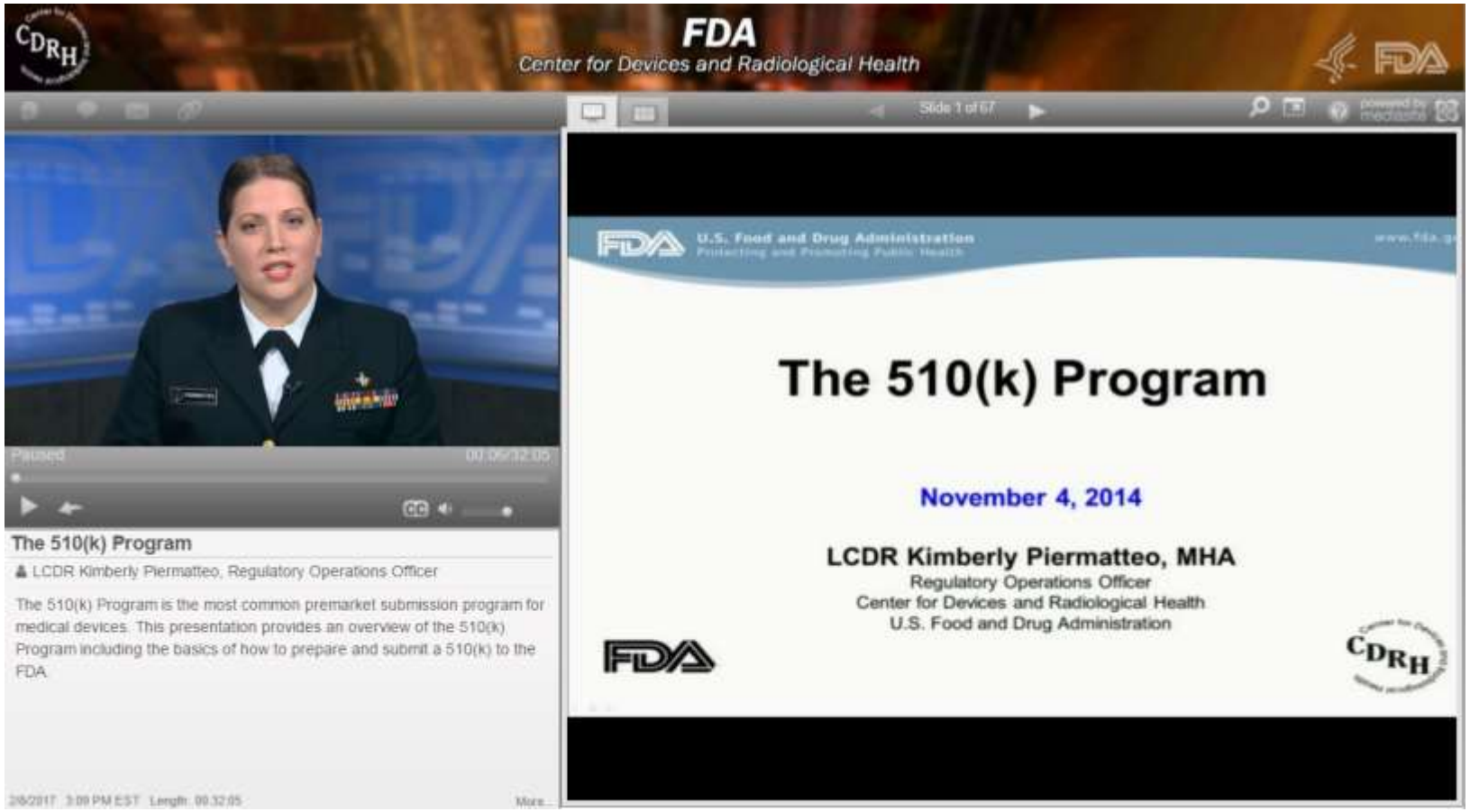
What is your 510(k) experience?

A. I have never submitted a 510(k)

B. I have submitted a 510(k)

C. Wait. What is a 510(k)?

Prerequisite: CDRH Learn Module



Learning Objectives

1. Review what a 510(k) is and when it's required

2. Discuss the decision-making process for demonstrating substantial equivalence

3. Learn what a 510(k) decision means

4. Discuss common questions about 510(k)s

Presentation Outline

- Overview of 510(k) Program
- Demonstrating Substantial Equivalence
- 510(k) Decisions
- Common 510(k) Questions
- Summary

Presentation Outline

- **Overview of 510(k) Program**
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A 510(k) is:

- Section 510(k) of Federal FD&C Act
- A Premarket Notification
- 21 CFR 807 Subpart E
- A marketing clearance application
- Allows FDA to determine Substantial Equivalence (SE)
- Types: Traditional, Abbreviated and Special
- Reviewed in 90 Calendar Days (MDUFA review goal)

Reference:

- Premarket Notification (510k)

A 510(k) is not:

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

References:

- FDA Forms
- Device Registration and Listing
- Premarket Approval (PMA)

When is a 510(k) Typically Required?

- **New Device**
  - Introducing a device to the market for the first time

- **Modification to a Legally Marketed Device**
  - Change in indications for use
  - Significant change(s) in design

References:

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

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What is Substantial Equivalence?

- Demonstration that a new device, as compared to a legally marketed device (also known as 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

Reference:

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

What is a Predicate Device?

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

References:

- How To Find and Effectively Use Predicate Devices
- Guidance – The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)], Section IV.C. Predicate Device(s)

Substantial Equivalence and Predicate Devices

- 510(k) review standard is comparative
  - **Primary predicate**
  - **Multiple predicates**
  - **Reference device**
    - Supports scientific methodology or standard reference values
    - Is not a predicate device
  - **Split predicates**
    - Inconsistent with 510(k) regulatory standard

Reference:

- Guidance – The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)], Section IV, C.1 Multiple Predicates and C.2 Reference Devices

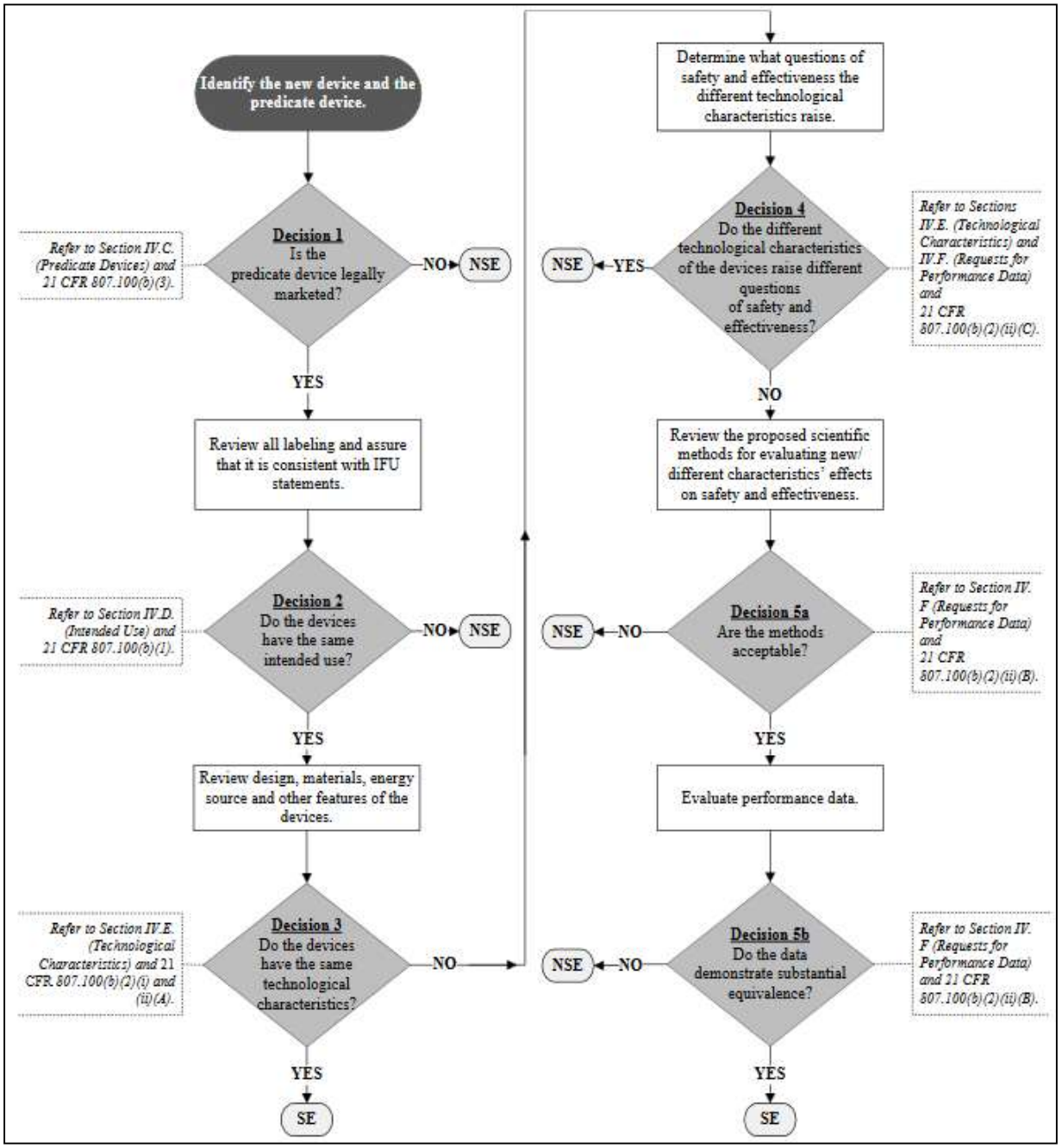
Product Codes

- 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
- **Note**: A single regulation often has multiple product codes.
  - Example: 7 Product Codes under 21 CFR 868.5895 for a Continuous Ventilator (MOD, NOU, ONZ, CBK, NQY, MNT, MNS)

References:

- Guidance - Medical Device Classification Product Codes
- Product Classification Database

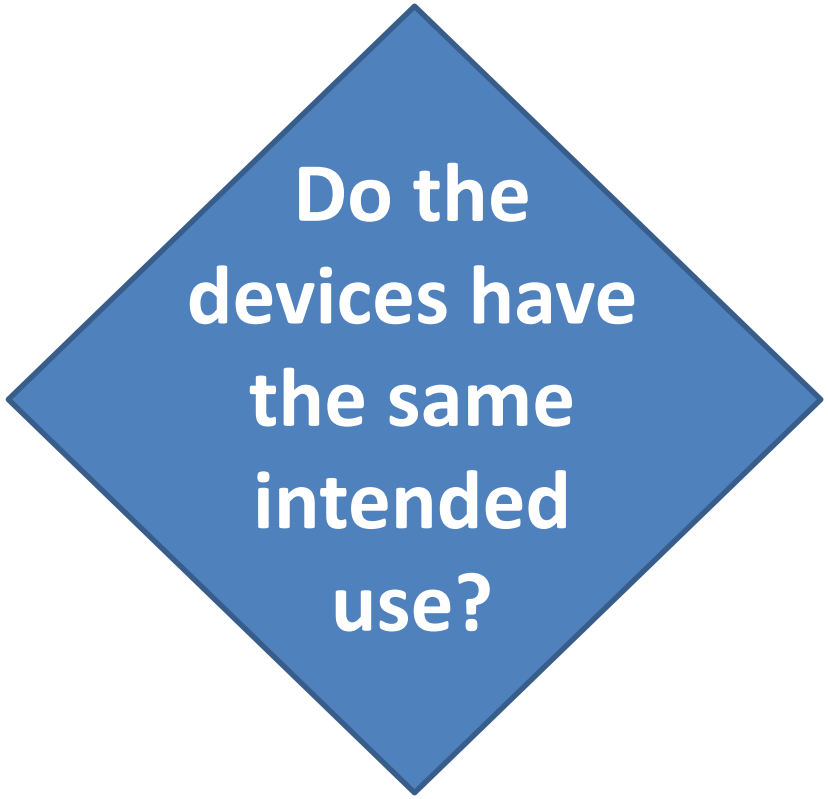
510(k) Decision-Making Flowchart



Flowchart: Decision Point 1

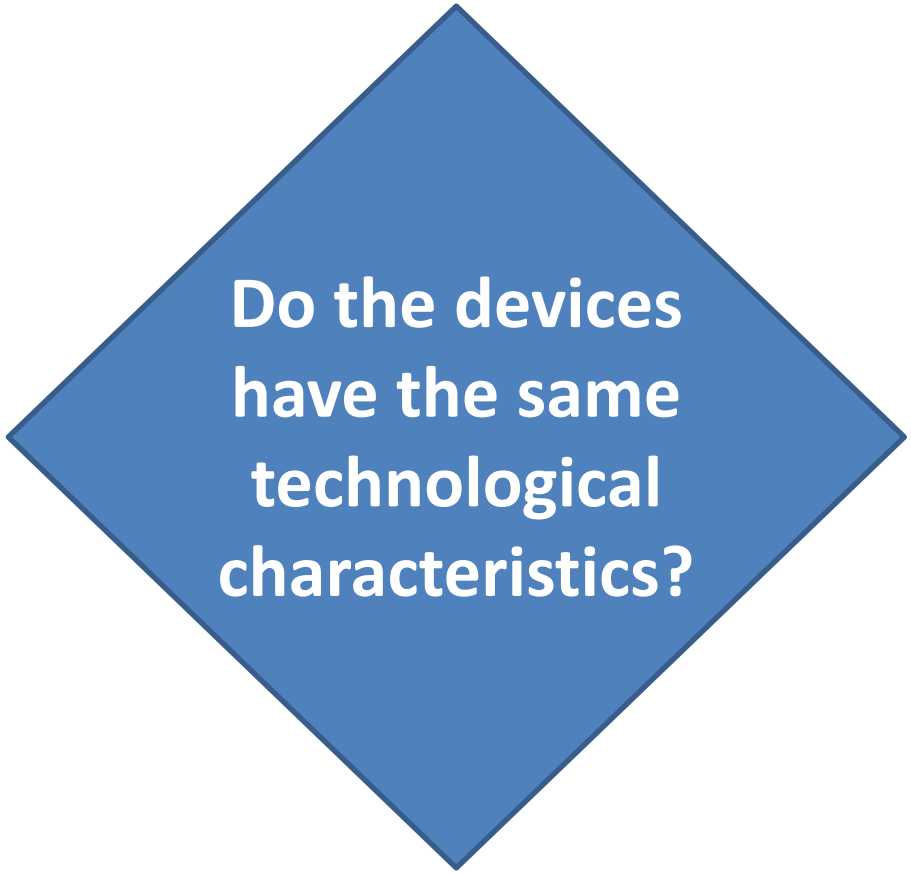
- 510(k) Clearance
- Granted *de novo*
- No market removal by FDA
- No judicial order by FDA

Flowchart: Decision Point 2



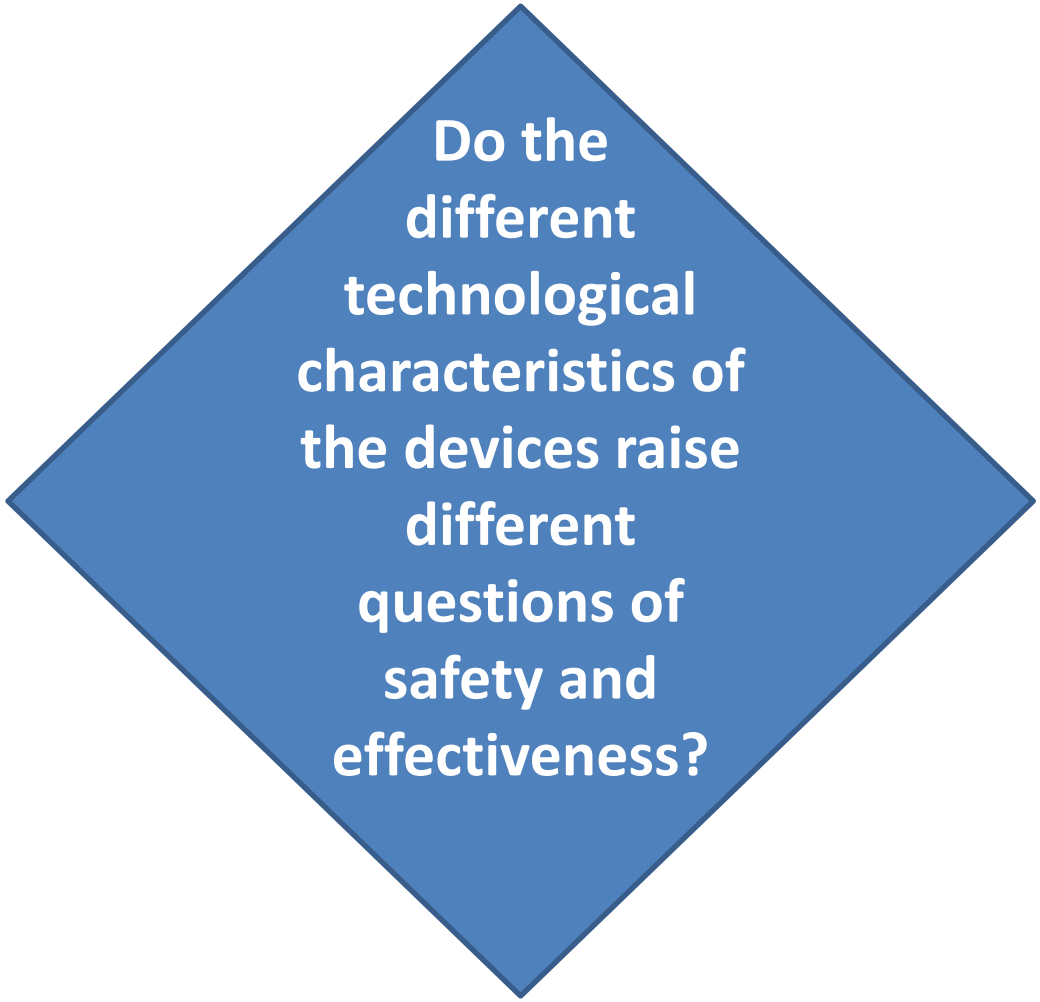
- Device Purpose/Function
- Prescription Use (Rx) vs. Over the Counter (OTC)
- Patient Population
- Environment of Use

Flowchart: Decision Point 3



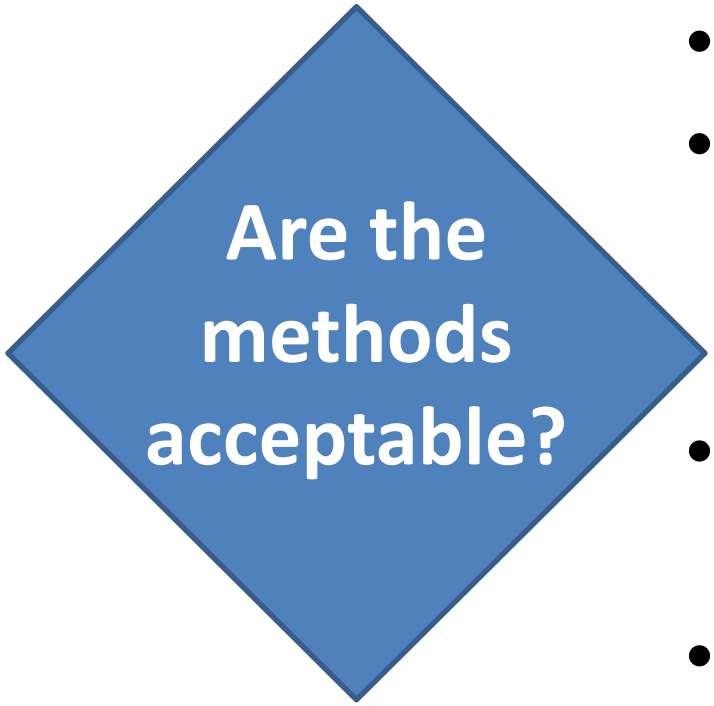
- Device Design
- Materials
- Energy Source(s)
- Software
- Hardware
- Other Features

Flowchart: Decision Point 4



- If Yes = Not Substantially Equivalent (NSE) Decision
- If No = Scientific Review of Performance Data

Flowchart: Decision Point 5a



- Special Controls
- Device-Specific or Cross-Cutting FDA Guidance Documents
- Applicable FDA Recognized Consensus Standard(s)
- Pre-Submission Program

Flowchart: Decision Point 5a (*cont'd*)

Examples of Potential Performance Testing:

- Non-clinical:
  - Engineering
  - Electromagnetic Compatibility (EMC)
  - Sterility
  - Stability/Shelf-Life
  - Software Validation
- Animal:
  - Biocompatibility
- Clinical

Flowchart: Decision Point 5b

- Did your results meet targeted pass/fail criteria?
  - If not, provide a justification

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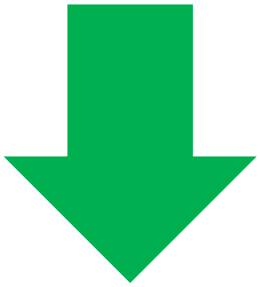
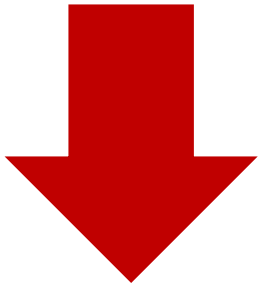
510(k) Decisions

SE Decision



Device To Market

NSE Decision



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

Reference:

- Guidance – The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)], Section IV.A.3. Categories of NSE Determinations

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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Changes to an Existing Device

- A new 510(k) is needed 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))

- Changes to the following may require a new 510(k):
  - Intended Use
  - Design
  - Materials
  - Sterilization Method

- If no new 510(k) is needed, document the decision-making process and the basis for the conclusion per compliance with the Quality System Regulation (21 CFR 820)

UPDATE: Changes to an Existing Device

- On August 8, 2016, FDA published two draft guidance documents:
  - Deciding When to Submit a 510(k) for a Change to an Existing Device
    - Applies to medical device changes broadly
  - Deciding When to Submit a 510(k) for a Software Change to an Existing Device
    - Focuses on software-specific changes
- Draft Guidance include:
  - Clarification of key terms
  - Explanation on how to use risk assessment
  - Updated flowcharts
  - Specific examples of changes that would or would not require a new 510(k)

References:

- FDA-2016-D-2021; FDA-2011-D-0453
- CDRH Learn Module "Two Draft Guidance Documents Clarifying When to Submit a 510(k) for a Change to an Existing Device" [August 25, 2016]

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
- No new 510(k) clearance letter will be issued

510(k) and Quality Systems (QS)

- Documentation of compliance not required in a 510(k) Submission
  - Note: For a Special 510(k), a declaration of conformity with design controls must be provided in the submission

- No pre-approval QS inspection prior to 510(k) clearance

References:

- Quality System (QS) Regulation/Medical Device Good Manufacturing Practices
- How to Prepare a Special 510(k)

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Summary

1. The 510(k) review standard is comparative.

2. When determining substantial equivalence, FDA follows the 510(k) Decision-Making Flowchart.

3. A 510(k) found substantially equivalent is considered "cleared" by the FDA and may then be legally marketed in the U.S.

Questions

Please complete the session survey:

surveymonkey.com/r/DEV-D1S05

Call to Action

- Utilize the 510(k) Decision-Making Flowchart
- Identify and become familiar with relevant resources and references (e.g., Public Databases, Guidance Documents, CDRH Learn Modules, contact DICE either by phone or e-mail, etc.)


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