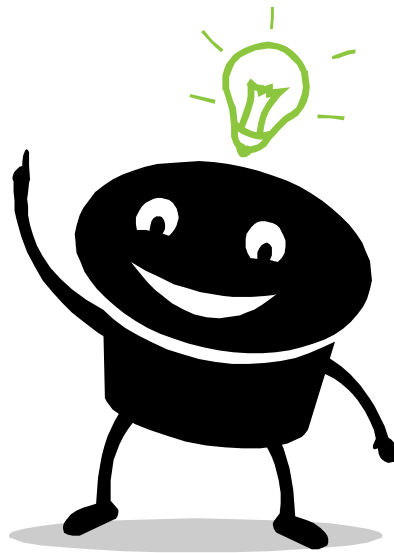


510(k) Program Overview

**FDA Small Business
Regulatory Education for Industry (REdI)
Rockville, MD
September 27, 2017**

CDR Kimberly Piermatteo, MHA
Consumer Safety Officer
Premarket Programs Branch
Division of Industry and Consumer Education
Office of Communication and Education
Center for Devices and Radiological Health
U.S. Food and Drug Administration

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

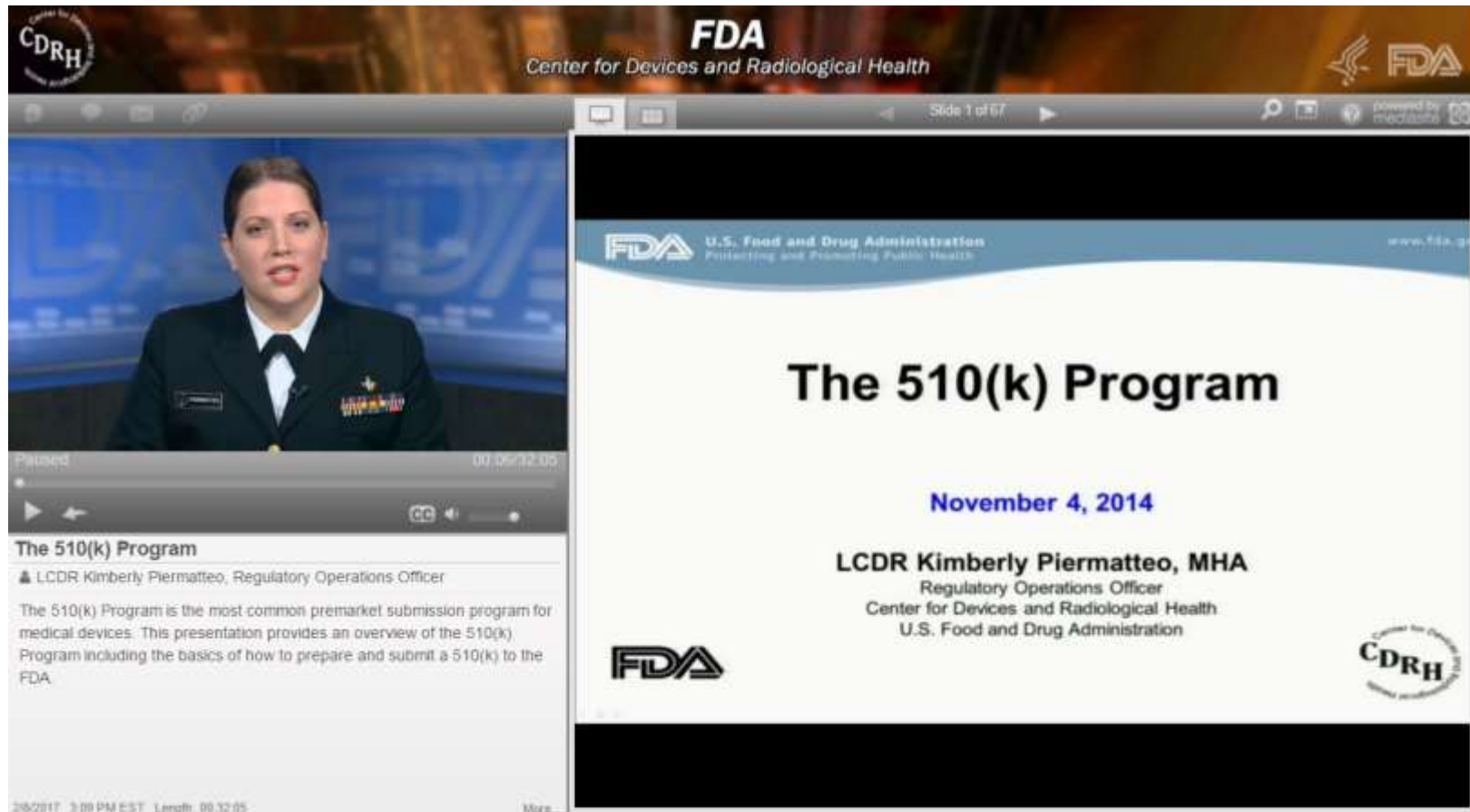


Poll Question

What is your 510(k) experience?

- A. Never submitted a 510(k)**
- B. Have submitted a 510(k)**

Prerequisite: CDRH Learn Module



The screenshot displays a video player interface. On the left, a video frame shows LCDR Kimberly Piermatteo, MHA, in a dark uniform with a name tag and medals. Below the video, the title 'The 510(k) Program' is listed, followed by the presenter's name and title. A brief description of the 510(k) program is provided. The main part of the screenshot is a presentation slide with the FDA logo at the top, the title 'The 510(k) Program', the date 'November 4, 2014', and the presenter's name and title. The slide also features the FDA and CDRH logos at the bottom.

CDRH
Center for Devices and Radiological Health

FDA
Center for Devices and Radiological Health

Slide 1 of 67

FDA U.S. Food and Drug Administration
Protecting and Promoting Public Health

The 510(k) Program

November 4, 2014

LCDR Kimberly Piermatteo, MHA
Regulatory Operations Officer
Center for Devices and Radiological Health
U.S. Food and Drug Administration

FDA

CDRH
Center for Devices and Radiological Health

Paused 00:05:32.00

The 510(k) Program
LCDR Kimberly Piermatteo, Regulatory Operations Officer
The 510(k) Program is the most common premarket submission program for medical devices. This presentation provides an overview of the 510(k) Program including the basics of how to prepare and submit a 510(k) to the FDA.

2/6/2017 3:09 PM EST Length: 00:32:05

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
- Questions

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 \(510k\)](https://www.fda.gov/oc/ohrt/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 \(K97-1\)](#)

Presentation Outline

- Overview of 510(k) Program
- **Demonstrating Substantial Equivalence**
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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:

- [FDA 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](#)
- [FDA 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:

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

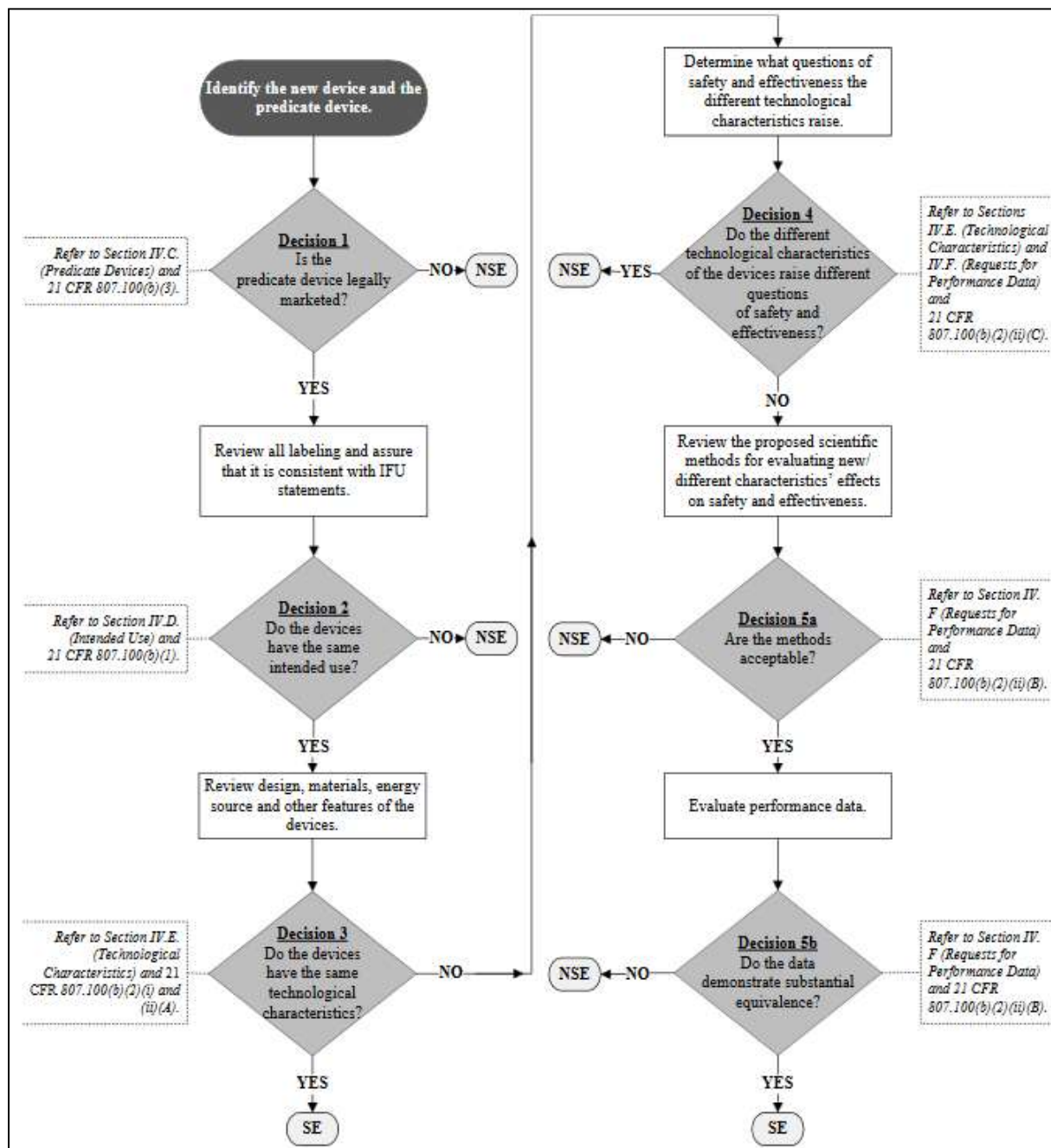
Product Codes

- 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:

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

510(k) Decision-Making Flowchart



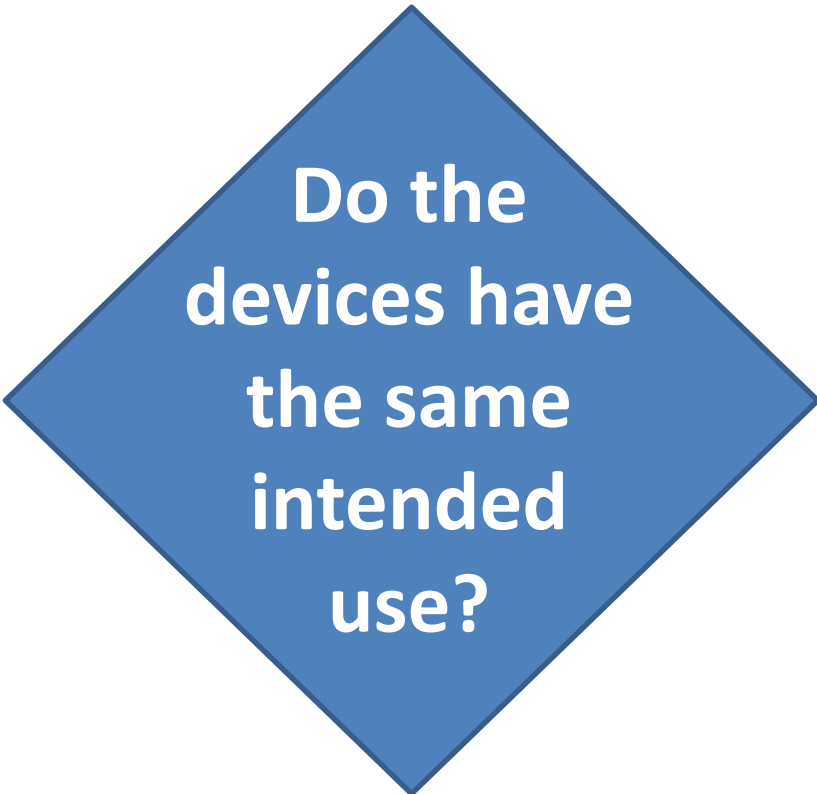
Flowchart: Decision Point 1



**Is the
predicate
device legally
marketed?**

- 510(k) Clearance
- Granted De Novo
- No market removal by FDA
- No judicial order by FDA

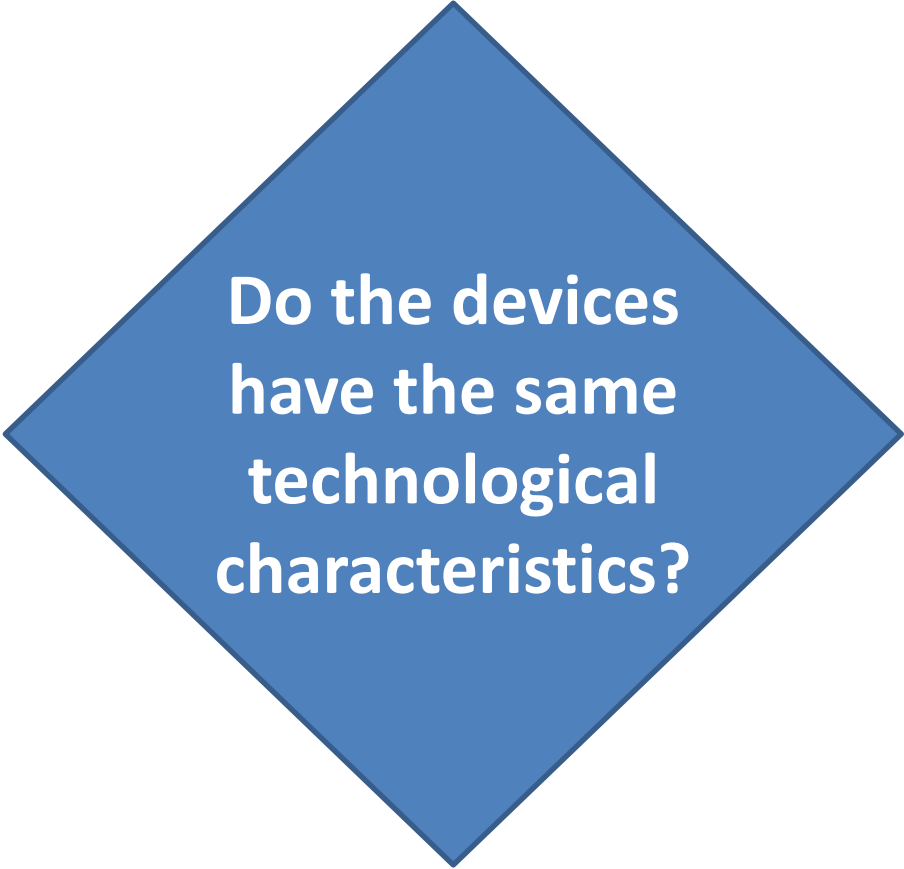
Flowchart: Decision Point 2



**Do the
devices have
the same
intended
use?**

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

Flowchart: Decision Point 3



**Do the devices
have the same
technological
characteristics?**

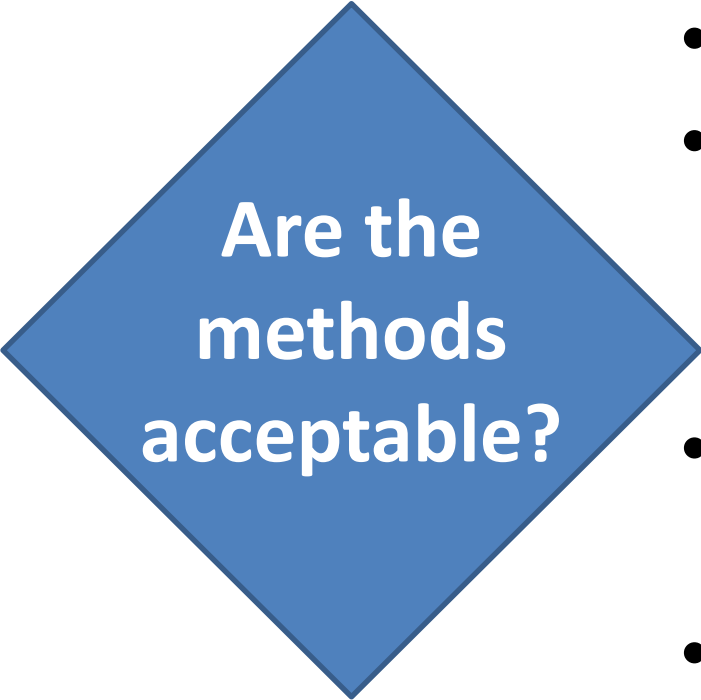
- Device Design
- Materials
- Energy Source(s)
- Software
- Hardware
- Other Features

Flowchart: Decision Point 4

Do the
different
technological
characteristics of
the devices raise
different
questions of
safety and
effectiveness?

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


Flowchart: Decision Point 5a



Are the
methods
acceptable?

- [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*)

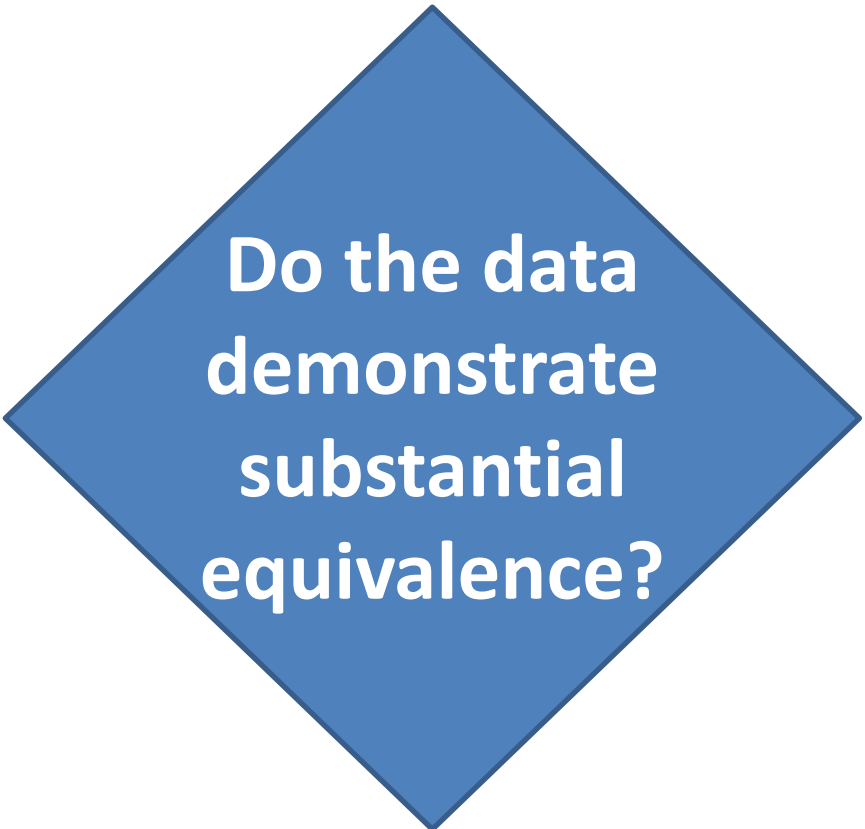


**Are the
methods
acceptable?**

Examples of Potential Performance Testing:

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

Flowchart: Decision Point 5b



**Do the data
demonstrate
substantial
equivalence?**

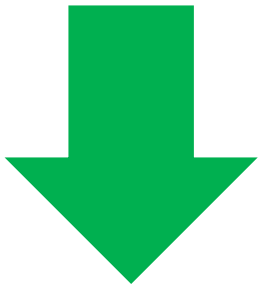
- Did your results meet targeted pass/fail criteria?
 - If not, provide a justification

Presentation Outline

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- **510(k) Decisions**
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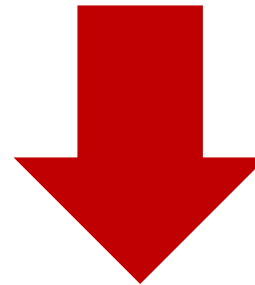
510(k) Decisions

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:

- [FDA 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 \(21 CFR 820\)](#)

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

Recent Class II Exemptions

- [21st Century Cures Act](#)
- July 11, 2017 Federal Register (FR) Notice: Medical Devices; Exemptions From Premarket Notification: Class II Devices ([FDA-2017-N-1129](#))
- A device type may have partial exemption limitations.
Example:
 - Catheter, biliary, surgical (Product Code [GCA](#), requires 510(k))
 - Catheter, biliary, surgical, exempt (Product Code [PTT](#), 510(k) exempt)
 - *Exemption is limited to surgical biliary catheters that do not include a balloon component.

Presentation Outline

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- Common 510(k) Questions
- **Questions**

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.)

