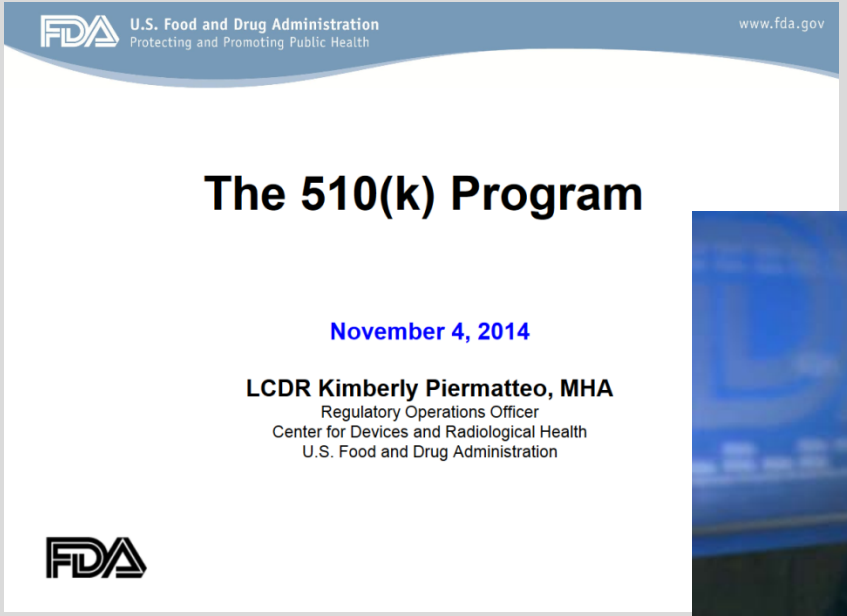
Overview of the 510(k) Process:
Guide for Third Party Reviewers

Vesa Vuniqi
Center for Devices and Radiological Health
U.S. Food and Drug Administration

Suggested Pre-requisite



CDRH Learn: The 510(k) Program (How to Study and Market Your Device)
fda.yorkcast.com/webcast/Play/d91af554691c4260b5eca0b2a28e636b1d

Overview of 510(k) Process

Learning Objectives

- Discuss history of 510(k)s and Third Party Review Program
- Review basic principles of 510(k) Program
- Explain 510(k) Flowchart

History of 510(k) and Third Party Reviews

History of 510(k)s

- **Medical Device Amendments of 1976**
  - Granted FDA authority to review medical devices
  - Established device classifications: Class I, II, III
- **Safe Medical Devices Act of 1990**
  - Defined substantial equivalence (SE) and special controls

History of Third Party Review Program

- **FDA Modernization Act (FDAMA) of 1997**
  - established Third Party 510(k) Pathway
- **FDA Reauthorization Act of 2017 (FDARA)**
  - identified program goals to strengthen the use of the Third Party Review Program

Basic Principles of 510(k) Program

What is a 510(k)?

- Premarket notification submission to FDA
- Demonstrates a device is substantially equivalent (SE)
  - "as safe and effective"
- To a legally marketed device
  - "predicate"
- Biggest CDRH premarket program
  - over 3000 submissions per year

FDA Guidance: Evaluation of Substantial Equivalence in a 510(k)
www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-program-evaluating-substantial-equivalence-premarket-notifications-510k

Predicate Device

- Preamendments
- Cleared through 510(k) process
- Reclassified from Class III to Class I or II
- Granted De Novo

Substantial Equivalence (SE)

- Legally marketed predicate
- Same intended use

  -AND-

- Same technological characteristics -OR-
- Different technological characteristics
  - Does not raise different questions of safety and effectiveness
- Testing methods and data support SE

Different Technological Characteristics

- Significant change from predicate in:
  - materials
  - design
  - energy source
  - other features

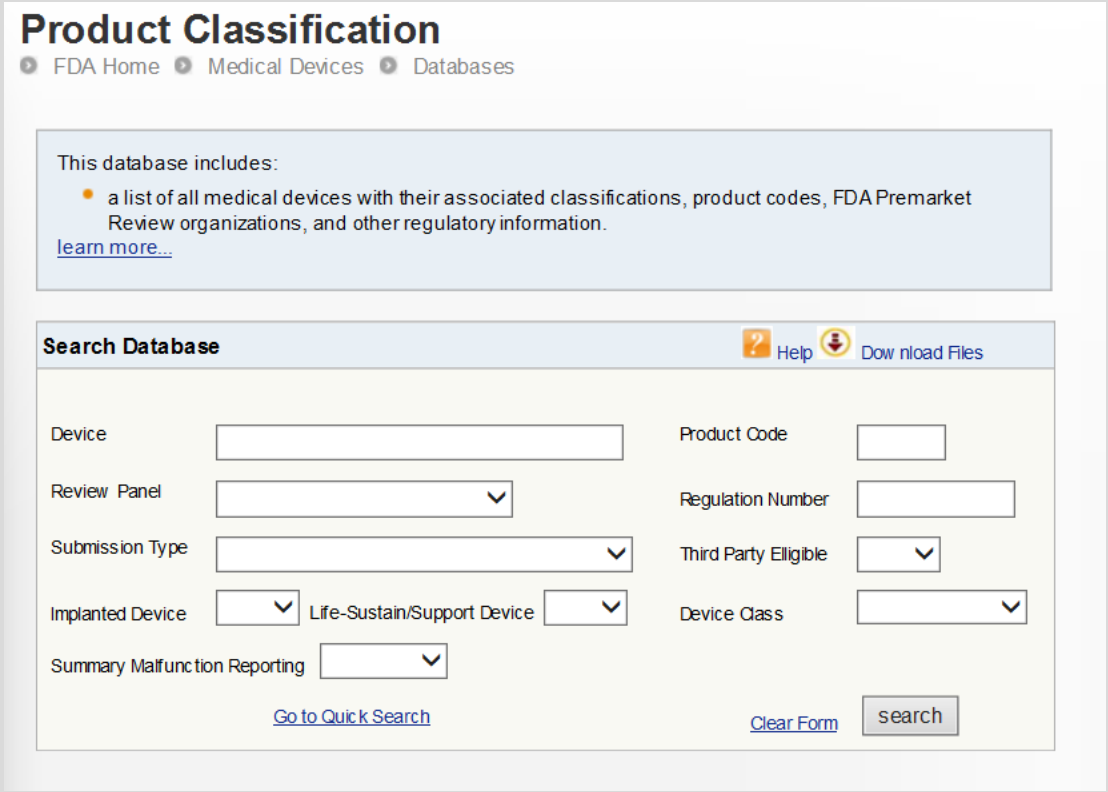
Product Codes

- FDA creates a three letter code
- Used to classify and track medical devices
- One classification regulation may have multiple product codes
  - distinguish differences in technology or indications for use

Product Codes

- Listed on 510(k) SE Letters
- Identify Third Party eligible device types
- Useful to identify predicate devices
- Required for various premarket and postmarket activities:
  - device listing, importing and exporting

Product Classification Database



www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm

Example:
Non-Invasive Blood Pressure Device

Product Classification

FDA Home › Medical Devices › Databases

This database includes:

- a list of all medical devices with their associated classifications, product codes, FDA Premarket Review organizations, and other regulatory information.

learn more...

Search Database

Help Download Files

Device: non-invasive blood pressure

Review Panel:

Submission Type:

Implanted Device:

Life-Sustain/Support Device:

Summary Malfunction Reporting:

Product Code:

Regulation Number:

Third Party Elligible:

Device Class:

Go to Quick Search

Clear Form

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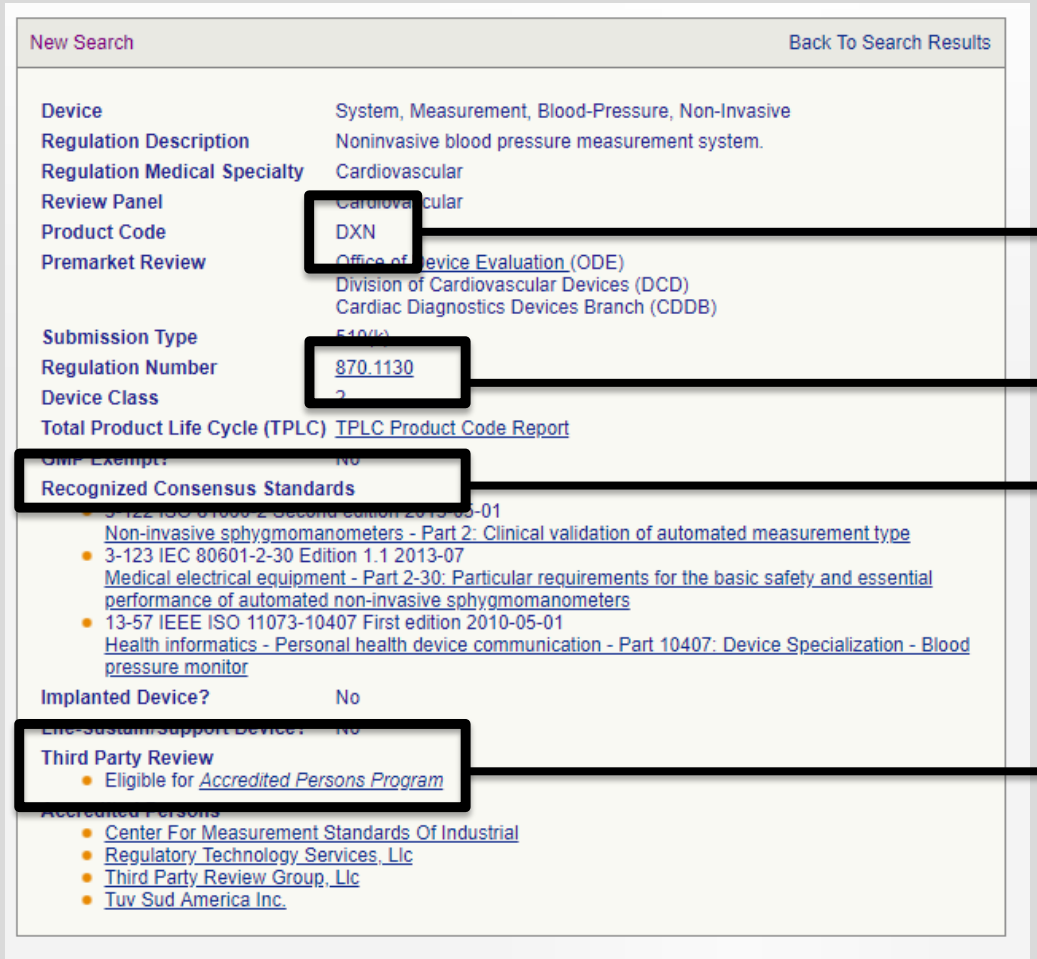


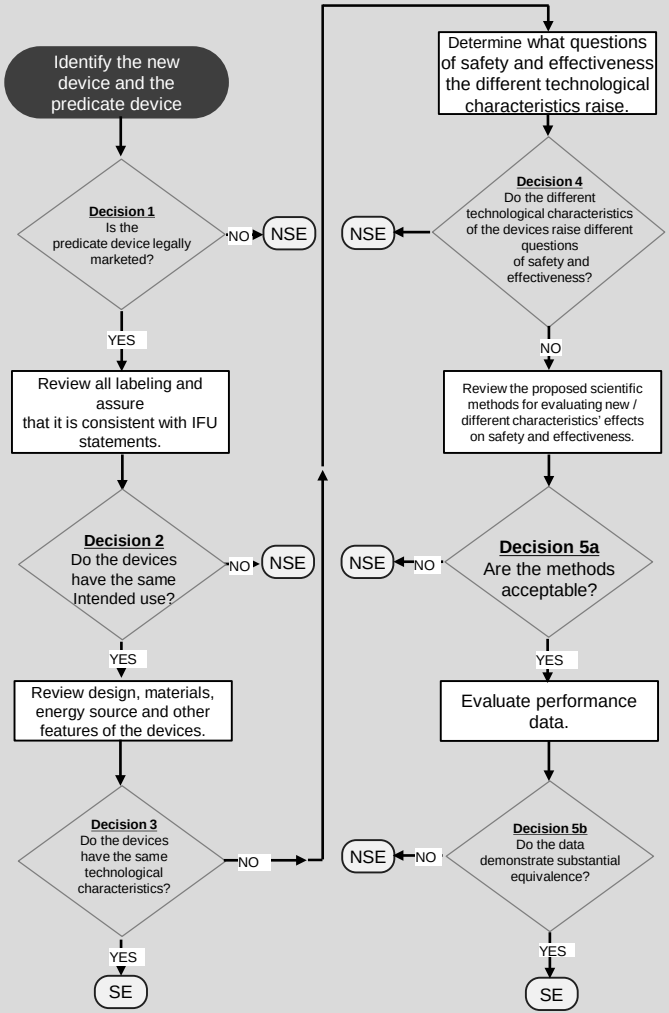
Product Code

Regulation Number

Consensus Standards

Third Party Eligibility

510(k) Review Flowchart

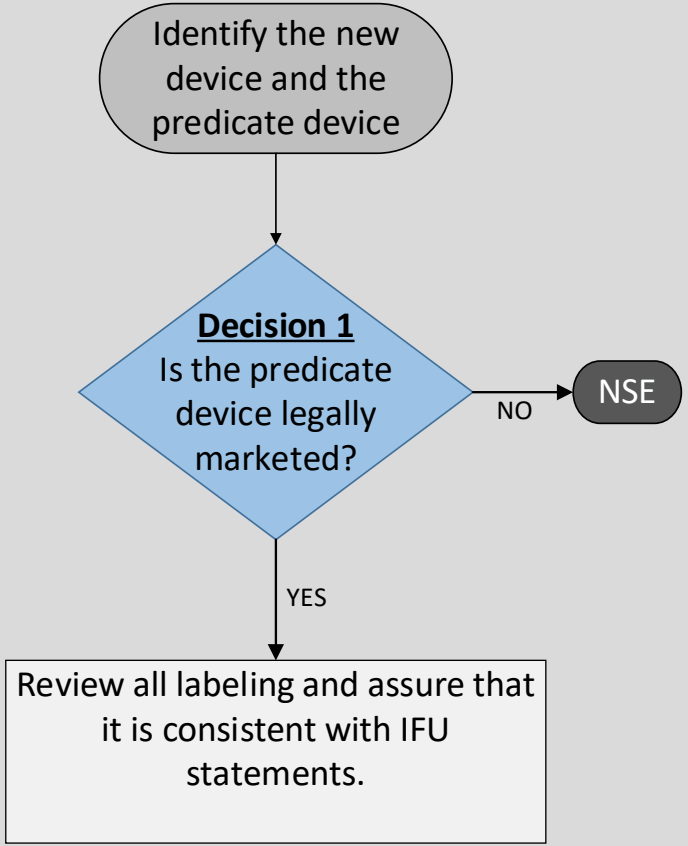


Guidance: Evaluating Substantial Equivalence in Premarket Notifications

- Flowchart not intended to be used as a stand-alone document
- Decision questions are answered in order
- Walk through with primary predicate

Is Predicate Device Legally Marketed?

- Cleared 510(k)
- Granted De Novo
- Preamendments
- Reclassified from Class III to Class I or II



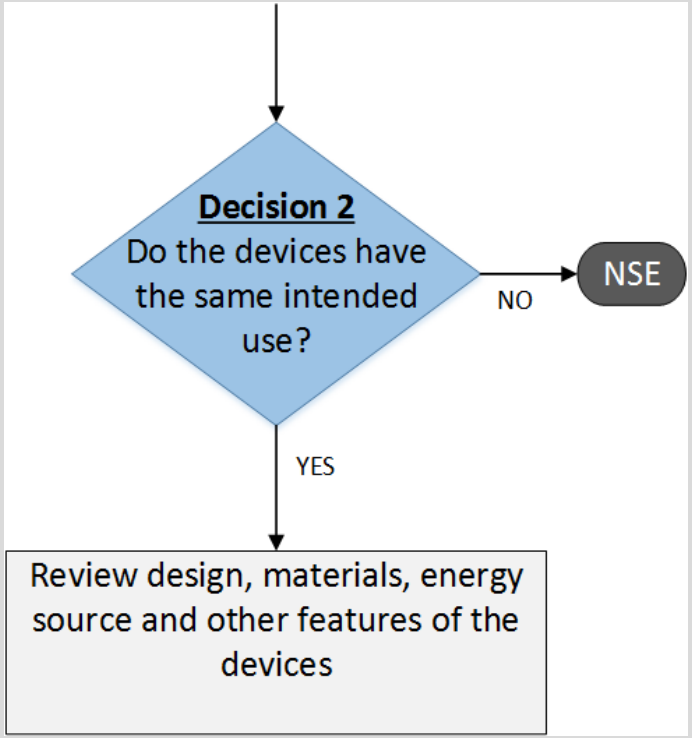
Do devices have same intended use?

Intended Use

- general purpose of device or its function
- includes indications for use

Indications for Use (IFU)

- describes disease or condition the device will diagnose, treat, prevent, cure, or mitigate
- patient population



Example 1: New Intended Use and New Indications for Use

Blood Pressure Cuff

- **Predicate IFU:** Professional and home use to manually measure systolic and diastolic pressure
- **Proposed IFU:** Home use for automated diagnosis of heart attack or stroke

Different indications for use raise a safety and effectiveness issue not raised by predicate device→ new intended use

General/Specific Intended Use-Guidance for Industry:
www.fda.gov/regulatory-information/search-fda-guidance-documents/generalspecific-intended-use-guidance-industry

Example 2: Same Intended Use and New Indications for Use

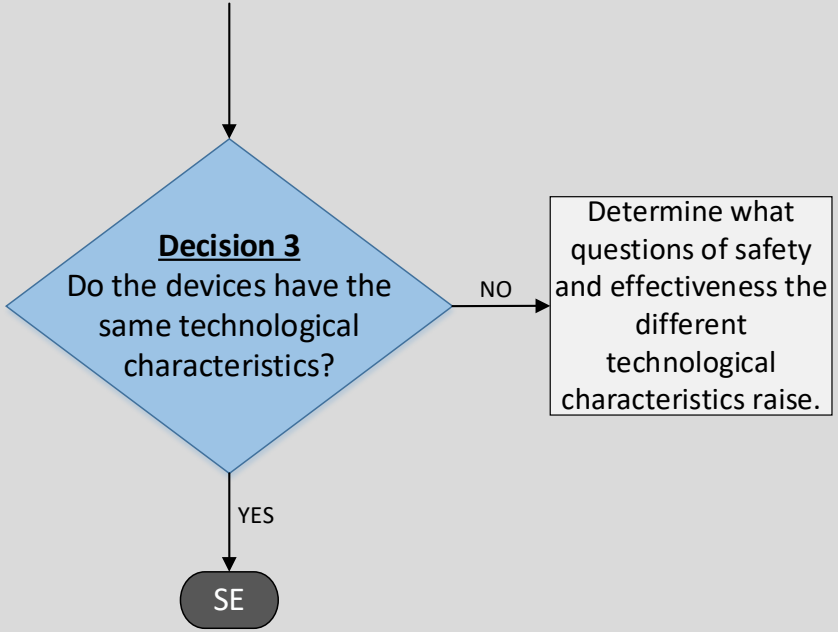
Catheter

- **Predicate IFU:** Access femoral artery
- **Proposed IFU:** Access subclavian artery

- Intended use for both is to access an artery
- IFU only changes location of access
- No new risks or questions of safety or effectiveness

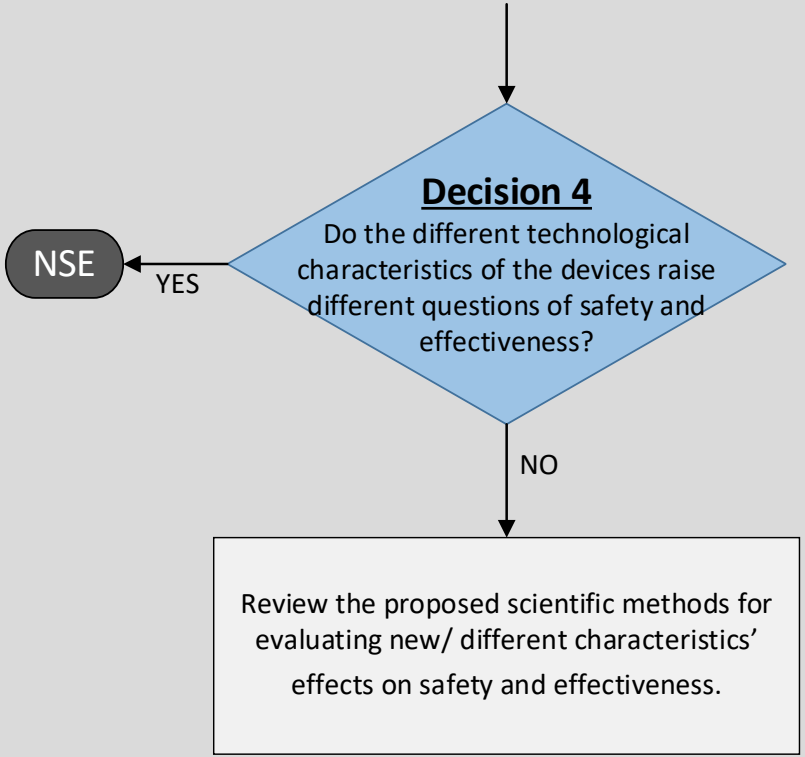
Do devices have same technological characteristics (TC)?

- Device description can inform if TC are comparable
- “Yes” implies descriptive characteristics enough for SE
- Uncommon to determine SE on descriptive characteristics alone



Do different TC raise different questions of safety and effectiveness?

- **Different Question**
  - Not applicable to predicate
  - Poses unique safety or effectiveness concern for new device
- FDA responsible to identify different question
- If “Yes,” then Not Substantially Equivalent (NSE)



Example 3: New TC and No Different Questions

Syringe: Change in plastic composition

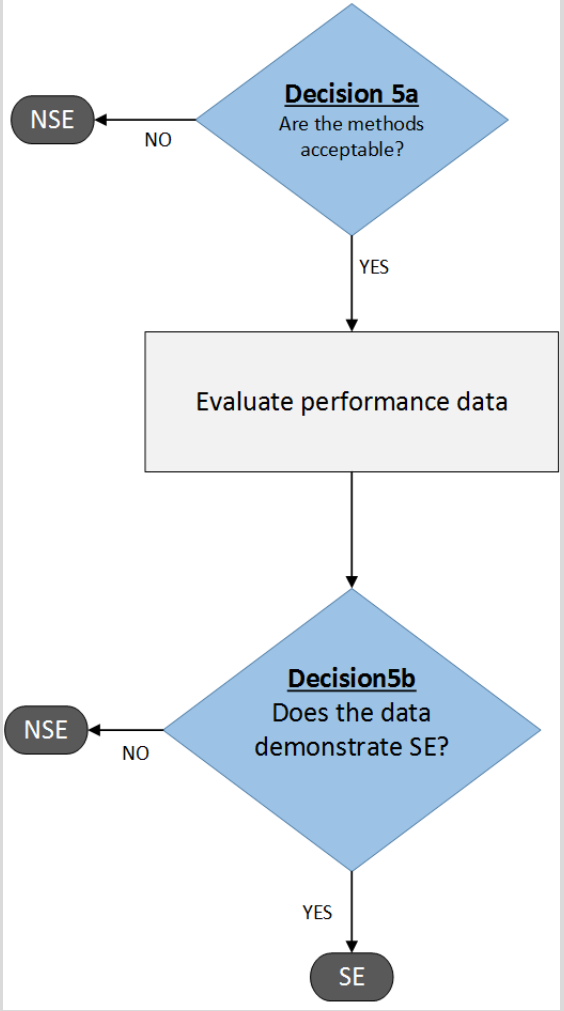
- Change in material raises same questions
  - biocompatibility
  - material properties

Example 4: New TC and Different Question

- **Electrosurgical Device:**
  - Change energy from radiofrequency to ultrasound
  - How is ultrasonic frequency controlled to avoid cavitation of cells?

Are methods acceptable and do data demonstrate substantial equivalence?

- If no different questions of safety and effectiveness:
  - can data evaluate differences?
- Are methods acceptable? (5a)
  - Rare to answer “No”
- Review data (5b)



After Device is Found Substantially Equivalent

- Applicant receives SE letter
- FDA adds information to public FDA 510(k) Database
  - Indications for Use form
  - 510(k) Summary
  - SE Letter
  - Decision summary (IVD products only)

Summary

- 510(k) Program allows for a comparison of a new device to a predicate device to support that the new device is ‘as safe and effective’

- 510(k) flowchart supports 510(k) review with specific questions to aid in determining whether a device is or is not substantially equivalent

Your Call to Action

1. Incorporate the basic principles of the 510(k) Program as you conduct your review

2. View other available resources on CDRH Learn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