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

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Suggested Pre-requisite

The 510(k) Program

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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

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

Search Database

Device: non-invasive blood pressure

Search
<table>
<thead>
<tr>
<th>Device</th>
<th>System, Measurement, Blood-Pressure, Non-Invasive</th>
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<tbody>
<tr>
<td>Regulation Description</td>
<td>Noninvasive blood pressure measurement system.</td>
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<td>Regulation Medical Specialty</td>
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<td>Review Panel</td>
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<td>Product Code</td>
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<td>Premarket Review</td>
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<td>Division of Cardiovascular Devices (OCD)</td>
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<td>Cardiac Diagnostics Devices Branch (CDB)</td>
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<td>Regulation Number</td>
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<tr>
<td>Device Class</td>
<td>Total Product Life Cycle (TPLC)</td>
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<tr>
<td>TPLC Product Code</td>
<td>Report</td>
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<tr>
<td>Exempt?</td>
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<td>Recognized Consensus Standards</td>
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<tr>
<td>ISO 80601-1:2005 Edition 1.0 2013-07</td>
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<td>International Organization for Standardization (ISO)</td>
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<td>Non-invasive sphygmomanometers - Part 2: Clinical validation of automated measurement type</td>
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<tr>
<td>3-123 IEC 60601-2-30 Edition 1.0 2013-07</td>
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<td>Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers</td>
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<td>Health informatics - Personal health device communication - Part 10407: Device Specialization - Blood pressure monitor</td>
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<tr>
<td>Implant Device?</td>
<td>No</td>
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<tr>
<td>Life-Sustaining Support Device?</td>
<td>No</td>
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<tr>
<td>Third Party Review</td>
<td>No</td>
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<tr>
<td>Eligible for Accredited Persons Program</td>
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<td>Center For Measurement Standards Of Industrial</td>
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<td>Regulatory Technology Services, Inc</td>
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<tr>
<td>Third Party Review Group, LLC</td>
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<tr>
<td>Tuv Sud America Inc</td>
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</table>
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

**Decision 1**
Is the predicate device legally marketed?

- Yes: Review all labeling and assure that it is consistent with IFU statements.
- No: NSE
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 \(\rightarrow\) new intended use

General/Specific Intended Use-Guidance for 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

**Decision 3**
Do the devices have the same technological characteristics?

- **YES**
  - SE

- **NO**
  - Determine what questions of safety and effectiveness the different technological characteristics raise.
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)

Review the proposed scientific methods for evaluating new/different characteristics’ effects on safety and effectiveness.
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