CDRH Learn

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The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)s]

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Background

- **Date of publication:** December 2011

- **Draft Guidance:** not for implementation

Purpose

- updates and merges two existing guidance documents:
  - "Guidance on the CDRH Premarket Notification Review Program, 510(k) Book Memorandum K86-3" (published June 1986)
  - "The New 510(k) Paradigm – Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications" (published March 1998)
- reflects changes, clarifications and updates to 510(k) Program over the past few years
- guidance is culmination of those efforts

Purpose

- provides clarity, transparency, consistency, and predictability in the 510(k) decision-making process
- addresses each critical decision point in the substantial equivalence evaluation of a 510(k)
- addresses elements identified in the January 2011 510(k) Implementation Plan

Definitions

- **510(k):** premarket notification; the type of medical device application used to obtain market clearance for Class I and II medical devices (that are not exempt)

- **predicate device:** a legally marketed device that is used for comparison to a new device for the purpose of determining substantial equivalence

- **substantial equivalence:** demonstration that a new device, as compared to a predicate device, has the same intended use, same technological characteristics or differences that don't raise different questions

Definitions

- **reference device:** a legally marketed device that is not a "predicate device" but is otherwise used to address certain performance characteristics of a new device

- **intended use:** the general purpose of a device, or what the device does

- **indications for use:** describes the disease/condition the device will diagnose, treat, prevent, cure, or mitigate, including a description of the target patient population

Scope of Guidance

- Scope:
  - all medical devices regulated under the 510(k) Program by CDRH and CBER
  - all key 510(k) Program areas (e.g., Traditional, Special, and Abbreviated)
- Device Areas Impacted: all device areas

Development Process

- Description of Contributing Team:
  - guidance development team formed in Spring 2011
  - contributors from all impacted program areas in CDRH and CBER
  - team worked in sub-teams to address each key area of 510(k) Program

- FDA Centers involved: CDRH and CBER

Development Process

- **Chronology of Key Milestones**:
  - August 2010: 510(k) Implementation Report published and identified this project
  - February 2011: 510(k) Guidance Working Group formed
  - December 2011: Draft Guidance published

Development Process

- **Public Stakeholder Contribution:**
  - feedback solicited and received over past two years via:
    - official comments received to public dockets in response to 510(k) reports
    - stakeholder workshops
    - informal comments
- **FDA Centers issuing policy:**
  - CDRH and CBER

Content of Guidance

- addresses each critical decision point in SE evaluation:
  - appropriate use of multiple predicates
    - introduces a new term “reference device”
  - general principles for determining “new intended use”
  - process for determining “different questions of safety and effectiveness” due to different technological characteristics
  - request for performance data, especially clinical data
  - use of a verified 510(k) summary
- updates the Special 510(k) and Abbreviated 510(k) Programs

Content of Guidance

- updates the SE Flowchart
- addresses various categories of NSE determinations
- addresses eligibility of NSE devices for *de novo* program

Impact (if finalized)

- Impact on Manufacturers:
  - impact when a 510(k) is needed
  - impact the content/format of the 510(k) summary
- Impact on Consumers:
  - may impact the availability of new medical devices
- Impact on FDA Review Staff:
  - education and training in consistent use and implementation

Policy Impact

- Revision of existing policy

- What is the same:
  - the decision-making points of the 510(k) Flowchart
  - the existence and use of the three main 510(k) Programs (i.e., Traditional, Special, Abbreviated)
  - the statute and regulations that pertains to the 510(k) Program

Policy Impact

- What is new/different:
  - the wording and flow of the 510(k) Flowchart
  - a template structure for the 510(k) Summary
  - the concept that the 510(k) Summary is verified
  - additional qualifications to the eligibility of a Special 510(k)

Similarities Between Flowcharts

Both flowcharts ask:

- for identification/comparison to predicate device as first step
- if new and predicate devices have same intended use
- if new and predicate devices have same technological characteristics
- for review of scientific methods for evaluating new/different characteristics
- for evaluation of data
- if data demonstrate equivalence

Clarifications Between Flowcharts

- Indications/Intended Use
  - current flowchart asks if new device has same indication statement
  - proposed flowchart asks about intended use, which encompasses indications for use
- Proposed flowchart
  - specifies review of all labeling to ensure consistency with indication statement, and high level review of data sources (bench, animal, clinical)
  - clarifies when to proceed to review of technological characteristics
  - clarifies when to review data

Clarifications

- Questions of S&E
  - current flowchart asks if new types of safety & effectiveness questions are raised
  - proposed flowchart asks if different safety & effectiveness questions are raised (tracks language in Statute)
- Scientific Methods
  - current flowchart asks if scientific methods exist
  - proposed flowchart asks if scientific methods are acceptable

Conclusion

- guidance reflects culmination of significant multi-year effort
- represents the keystone updated policy on the 510(k) Program
- issued during period in which CDRH is issuing a number of far-reaching policies
- request and welcome significant amount of review of this draft guidance

Next Steps

- draft guidance will be open for 120-day official comment period to solicit feedback from all stakeholders
- upon closure of comment period, FDA will address comments, make any revisions as needed, and move to finalize guidance
- FDA will develop training for FDA staff and stakeholders on use of guidance

FDA Contact for Assistance

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CDRH Learn:

www.fda.gov/Training/CDRHLearn/default.htm