When to Submit (or not) a 510(k), That is the Question!
AMDM/FDA-OIVD Workshop
April 2011




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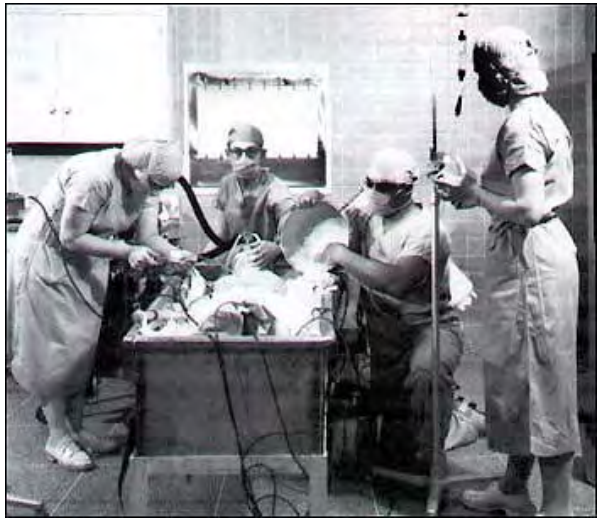
FDA

The 510(k) program was established more than 30 years ago

- **Introduced as part of the Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act in 1976**

- **Devices were much simpler**
  - **The electronics revolution and trend towards miniaturization had not yet begun**
  - **There was no Internet**
  - **There were few combination products**

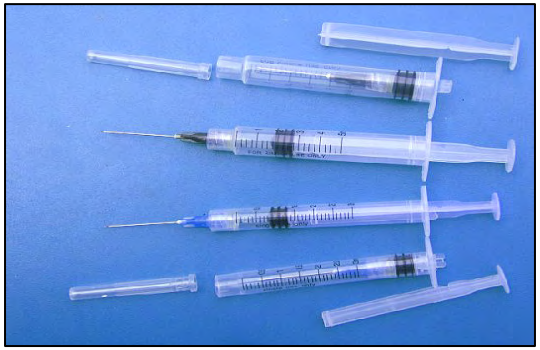


Much has changed over time…

- **In devices themselves…**

Yesterday

- Simple barrel, rod, plunger devices



Today

- Mechanical systems reduce needle sticks
- Retractable needles
- Projectile rigid cover

… and in device regulation.

“The Poison Squad”

Harvey Washington Wiley, M.D., (third from right) and the Division of Chemistry Staff in 1883

Federal Food and Drugs Act of 1906 (The "Wiley Act")

FDA U.S. Food and Drug Administration — Department of Health and Human Services

FDA Home Page | Search FDA Site | FDA A-Z Index | Contact FDA

FEDERAL FOOD AND DRUGS ACT OF 1906 (THE "WILEY ACT")

PUBLIC LAW NUMBER 59-384
34 STAT. 768 (1906)
21 U.S.C. Sec 1-15 (1934)
(REPEALED IN 1938 BY 21 U.S.C. Sec 329 (a))

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CDRH Center for Devices and Radiological Health

Federal Food, Drug, and Cosmetic Act

- **1938**
  - **President Roosevelt signed the Food, Drug, and Cosmetic Act which superseded the "Wiley Act", and introduced "safety" as criterion for premarket approvals of drugs.**
- **1962**
  - **"Effectiveness" was added.**

FDA Undercover

- **Illegal sales of amphetamines and barbiturates occupied more regulatory concern at FDA than all other drug problems combined from the 1940s to the 1960s. Interdiction in some venues required undercover tactics, as indicated here by these two inspectors posing as truck drivers.**

Medical Device Amendments of 1976

- **Enacted on May 28, 1976, to ensure safety and effectiveness of medical devices, including diagnostic products**
  - **Some products must have premarket approval by FDA; others must meet performance standards prior to marketing.**
- **Defined a device (201(h) of the Act)**
- **Required risk-based classification of devices**

Definition of “Device”

- **The term “device” means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is –**
  - **(1) recognized in the official National Formulary, or the U.S. Pharmacopoeia, or any supplement to them,**
  - **(2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or**
  - **(3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.**

Pre- vs. Post-Amendment Devices

- **MDA divided medical devices based on when they were introduced into commercial distribution*:**
  - **Pre-amendment devices (pre-May 28, 1976**
  - **Post-amendment devices (post-May 28, 1976)**

***Commercial distribution and Pre-amendment Status are determined by CDRH's Office of Compliance.**

(http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ComplianceActivities/ucm072746.htm)

Device Classification

- As per section 513 of FFD&C Act, FDA classified all legally marketed pre-amendment devices by generic type.
- Device Type – 21 CFR 860.3(i)
  - Generic type of device means a grouping of devices that do not differ significantly in purpose, design, materials, energy source, function, or any other feature related to safety and effectiveness, and for which similar regulatory controls are sufficient to provide reasonable assurance of safety and effectiveness.

Device Classification – Based on Risk

- **Section 513(a)(2) of the FFD&C Act requires FDA to determine safety and effectiveness of a device by weighing any probable benefit to health from the use of the device against any probable risk of injury or illness from the use.**

The 510(k) Program "A Well Oiled Machine"

- Regulatory pathway by which most medical devices go to market in US
- Used by some foreign countries for review of devices in their country
- Valid scientific evidence required for review of 510(k)s (21 CFR 860.7)

The 510(k) Program
"A Well Oiled Machine"

- Most new indications for use and most new technologies go to market via the 510(k) path
- Approximately 10% of 510(k)s have clinical data
- Many pre-Investigational Device Exemption Applications (pre-IDEs) are for 510(k)s
- Many IDEs are for 510(k)s

The 510(k) Program "A Well Oiled Machine"

- In 510(k), what is new today is old tomorrow! We may not need as much data after the first few 510(k)s for a new indication for use or a new technology.

- We request performance data for new indications for use and new technologies--that do not require Premarket Approval (PMA).

- The 510(k) Program allows for innovation and flexibility, to provide for reasonable assurance of the S&E of devices.

Why 510(k)?

- The 510(k) process is meant to:
  - Classify post amendment* devices
  - Find a device substantially equivalent; or
  - Find a new device not substantially equivalent automatically placing device type into class III resulting in:
    - Requirement for PMA;
    - Eligibility for de novo; or
    - Requiring reclassification before marketing

**Post amendment – Post May 28, 1976 Medical Device Amendments to FF,D,&C Act*

Regulatory Classes: I, II, and III

- **Three regulatory Classes – based on the level of control necessary to provide reasonable assurance of safety and effectiveness:**
  - **Class I – General Controls**
  - **Class II – General Controls & Special Controls**
  - **Class III – General Controls and Premarket Approval**

Description of Classes I, II, and III

- **Class I:**

1. **Devices for which general controls and special controls are insufficient to provide reasonable assurance the safety and effectiveness of such devices, but devices:**
   - **are not life-sustaining or life-supporting;**
   - **are not of substantial importance in preventing impairment of human health; and**
   - **do not present a potential unreasonable risk of illness or injury; and**
2. **Devices for which general controls are sufficient to provide reasonable assurance of the safety and effectiveness of such devices.**

Description of Classes I, II, and III

- **General Controls include:**
  - **Prohibition against adulterated or misbranded devices**
  - **Premarket notification (510(k)) requirements**
  - **Banned devices**
  - **Good Manufacturing Practices**
  - **Registration of manufacturing facilities**
  - **Listing of device types**
  - **Record keeping**
  - **Repair, replacement, refund**

Description of Classes I, II, and III

- **Class II:**

  1. **Devices which cannot be classified into Class I because general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of such devices, but...**
  2. **For which there is sufficient information to establish special controls to provide such assurance.**

Description of Classes I, II, and III

- **<u>Special Controls include</u>:**
  - **Guidance**
  - **Performance standards**
    - **Discretionary, voluntary national or international standard, recognized by rulemaking**
  - **Postmarket surveillance**
  - **Patient registries**
  - **Other**

Description of Classes I, II and III

- **Class III:**

  1. **Devices for which insufficient information exists to determine that general and special controls are sufficient to provide reasonable assurance of the safety and effectiveness of such devices; and**
  2. **Such devices:**
     - **Are life-sustaining or life-supporting;**
     - **Are of substantial importance in preventing impairment of human health; or**
     - **Present unreasonable risk of illness or injury.**

Classification Regulations

- **Classification regulations describe the device type as it existed prior to May 28, 1976**
- **New uses or technologies may be found through the product codes.**

Regulatory Classes

- **Class determines type of premarket submission required by FDA**

Class I or II Exempt	**Subject to limitations on exemptions covered under 21 CFR xxx.9 (e.g., 862.9 to 892.9)**
Class I or II Non Exempt	**510(k) Required**
Class III	**PMA***

***510(k) for preamendment devices until 515(b) calls for PMA or the device type is reclassified**

Classification of Post-Amendment Devices

- **Section 510(k) of FFD&C Act:**

  Each person who is required to register under this section and who proposes to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a device intended for human use shall, at least ninety days before making such introduction or delivery, report to the Secretary or person who is accredited under section 523(a) (in such form and manner as the Secretary shall by regulation prescribe)—

  (1) the class in which the device is classified under section 513 or if such person determines that the device is not classified under such section, a statement of that determination and the basis for such person's determination that the device is or is not so classified, and

  (2) action taken by such person to comply with requirements under section 514 or 515 which are applicable to the device.

Classification of Post-Amendment Devices

- **The 510(k) process is used to classify individual post-amendment devices:**
  - **Either find a device substantially equivalent to a predicate; or**
  - **Find a new device that must be placed automatically into class III and require PMA, de novo, or reclassification before marketing in U.S.**

Classification Regulations

Classification regulations for individual device types found in 21 CFR Parts 862-892

Example:

PART 870 -- CARDIOVASCULAR DEVICES

Regulation 870.1875

Stethoscope.

(a) ***Manual stethoscope*** **–(1)*Identification.* A manual stethoscope is a mechanical device used to project the sounds associated with the heart, arteries, and veins and other internal organs. (2)*Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in 870.9.**

(b) ***Electronic stethoscope*** **--(1)*Identification.* An electronic stethoscope is an electrically amplified device used to project the sounds associated with the heart, arteries, and veins and other internal organs.(2)*Classification.* Class II (performance standards).**

Classification Regulations & Product Codes

21 CFR 870.1875

Stethoscope

Pro Code: LDE
Manual Stethoscope
Class 1 510(k) Exempt

Pro Code: DQD
Electronic Stethoscope
Class 2 510(k) Required

Pro Code: OCR
Lung Sound Monitor
Class 2 510(k) Required

What is Substantial Equivalence?

- **1976 Congressional Record**

  "The term 'substantially equivalent' is not intended to be so narrow as to refer only to devices that are identical to marketed devices nor so broad as to refer to devices which are intended to be used for the same purposes as marketed products. The committee believes that the term should be construed narrowly where necessary to assure the safety and effectiveness of a device but not narrowly where differences between a new device and a marketed device do not relate to safety and effectiveness."

What is a Predicate?

- **21 CFR Part 807.92(a)(3)***

  An identification of the legally marketed device to which the submitter claims equivalence. A legally marketed device to which a new device may be compared for a determination regarding substantial equivalence is a device that was legally marketed prior to May 28, 1976, or a device which has been reclassified from class III to class II or I (the predicate), or a device which has been found to be substantially equivalent through the 510(k) premarket notification process.

***Regulation written in 1990.**

So 510(k) is…

- Premarket Notification
- Section 510(k) of FFD&C Act
- 21 CFR 807 Subpart E
- Determination regarding marketing clearance
- A process that allows FDA to make a determination regarding Substantial Equivalence (SE)
- The classification process for an individual device
- 1986 Guidance on the CDRH Premarket Notification Review Program
  - http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm081383.htm

The Premarket Notification (510(k)) Process is Used to…

- Identify new devices that must be placed automatically into class III and undergo premarket approval or reclassification before they are marketed
- For example:
  - A new device that is Not Substantially Equivalent (NSE) is in class III, whereas a new device that is Substantially Equivalent (SE) is in the same regulatory class as the device it is found equivalent to (class I or II)

Major Legislative Milestones

- **Safe Medical Devices Act (SMDA) – 1990**
  - **513(i) – Defined Substantial Equivalence**
  - **513(a)(1)(B) – Special Controls**

Major Legislative Milestones

- **Food & Drug Modernization Act (FDAMA) – 1997**
  - **Redefined 510(k) Exemption Criteria for Class I**
  - **Added Class II Exemption Criteria**
  - **Codified Third Party Review of 510(k)s**
  - **Added SE with Limitations**
  - **Added the Least Burdensome Provision**
  - **Added Evaluation of Automatic Class III Designation (De Novo)**
  - **Added Recognition of Standards**
  - **Added Class II Petitions for Exemption**

A 510(k) is required when…

- Introducing device to the market for the first time
- Changing a device's indications for use
- Making significant modification to device that could affect safety or effectiveness

Modifications

- **Changes in Indications for Use**
- **Modifications that could significantly enhance (or decrease) safety or effectiveness**
  - **E.g., change in design, materials, chemical composition, energy source, or manufacturing process**
- **1997 Guidance: "Deciding When to Submit a 510(k) for Change to an Existing Device"**
  - **http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080235.htm**

510(k) Exempt Devices

- **Some device types are exempt from the 510(k) requirements of the FFD&C Act:**
  - **Pre-amendments devices (legal pre-1976)**
  - **Unfinished devices**
  - **Devices exempt by statute or regulation from 510(k)**
    - **Class I (93%), Class II (8%) subject to limitations**
  - **Finished devices not sold in U.S.**
  - **Devices covered under another 510(k), e.g., private labeled device**
  - **Custom devices**
  - **General purpose articles**
  - **Veterinary devices**

A Device Must be Compared to…

- A legally marketed device (a predicate*) that does not require a PMA, i.e.:
  - A pre-amendment device*
  - A device found by FDA to be Substantially Equivalent (SE)
  - A reclassified device*
  - A device classified by a de novo petition

*21 CFR 807.92(a)(3)

Substantially Equivalent (SE)?

- **If SE → Device may be marketed without a PMA**

- **If NSE → PMA, PDP, HDE application or de novo petition required**

A Device is SE if…

- **In comparison to a predicate device, it:**
  - **Has the same intended use, and**
  - **Has the same technological characteristics as the predicate device,**

    or…

    (cont'd)

A Device is SE if…

- In comparison to a predicate device it:
  - Has the same intended use, and
  - Has different technological characteristics and the information in the 510(k):
    - Does not raise different questions of safety and effectiveness, and
    - Information submitted demonstrates, including appropriate clinical or scientific data, it is at least as safe and effective as the predicate
- Approximately 85% have been determined to be SE

New Technological Features

- **Technological differences may include:**
  - **Modifications in design, materials, or energy sources, for example:**
    - **changes in the power levels of electrical surgical instruments**
    - **use of new reagents in in vitro diagnostic devices**
    - **use of new materials in orthopedic implants**
    - **use of new battery designs in implanted pacemakers**

A Device is NSE if…

- There is no predicate device; or
- It has a new intended use; or
- It has different technological characteristics compared to the predicate device and it raises a different type question of safety and effectiveness; or
- It does not demonstrate that it is at least as safe and effective as the predicate.

Not Substantially Equivalent

- **Approximately 3% – 4% have been determined NSE (remaining ~10% are withdrawn or not-a-device).**
- **Data is looked at last in the 510(k) regulatory process.**
- **FDA usually asks for additional information at least once prior to determining the device is NSE for lack of data.**

The Administrative Element

- Each 510(k) is received in our mailroom, entered into our database, routed to the appropriate Division/Branch, and then assigned to a reviewer.
- The reviewer first screens the 510(k) for minimum necessary content, then determines if consults from other Offices will be needed for the review.
- … Let the review begin!

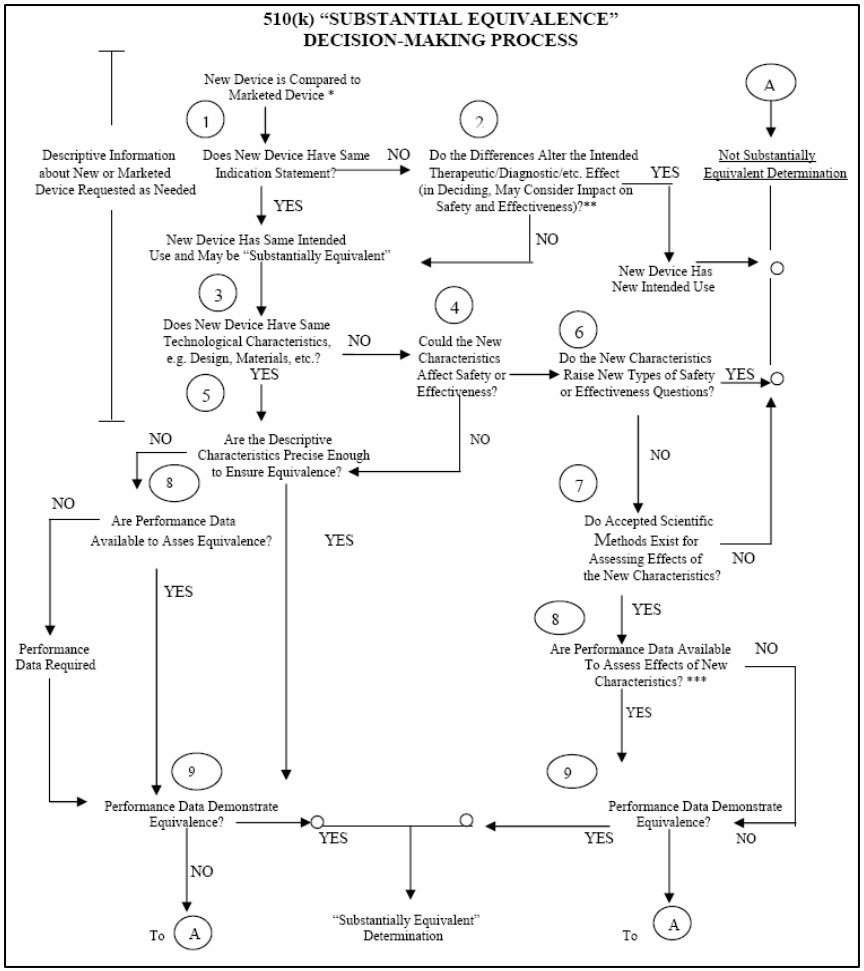
Timeframes

- **Under the Medical Device User Fee Amendments of 2007 (MDUFA), FDA is subject to the following performance goals:**
  - **FDA will issue a decision for 90% of 510(k) submissions within 90 days.**
  - **FDA will issue a decision for 98% of 510(k) submissions within 150 days.**

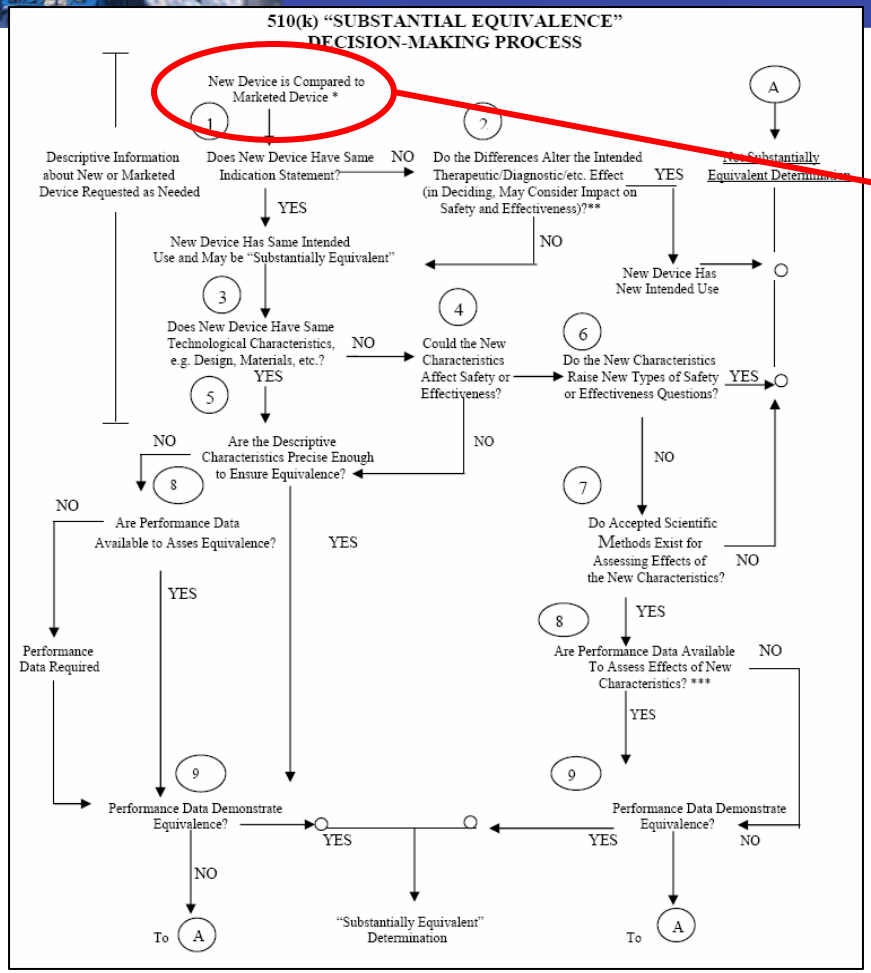
Options when Reviewing Information

- **FDA may request Additional Information (AI), if needed to make a determination.**
  - **May be made by standard mail, fax, email, or phone.**
- **A review may result in any of the following determinations:**
  - **Substantially Equivalent (SE)**
  - **Substantially Equivalent (SE) with Limitations**
  - **Not Substantially Equivalent (NSE)**

The 510(k) Flowchart: Overview

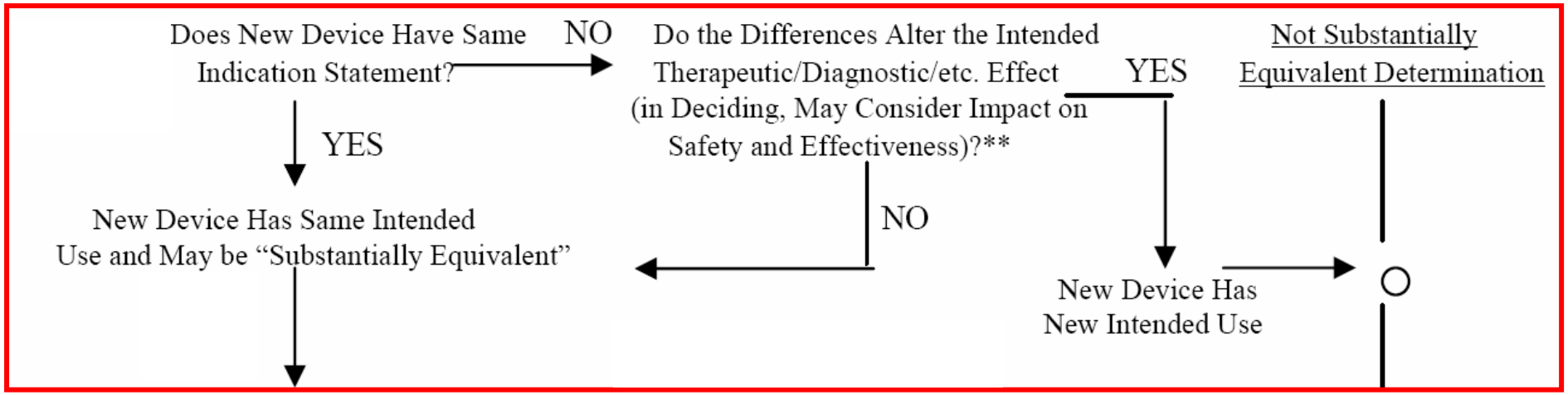


The 510(k) Flowchart: Predicates

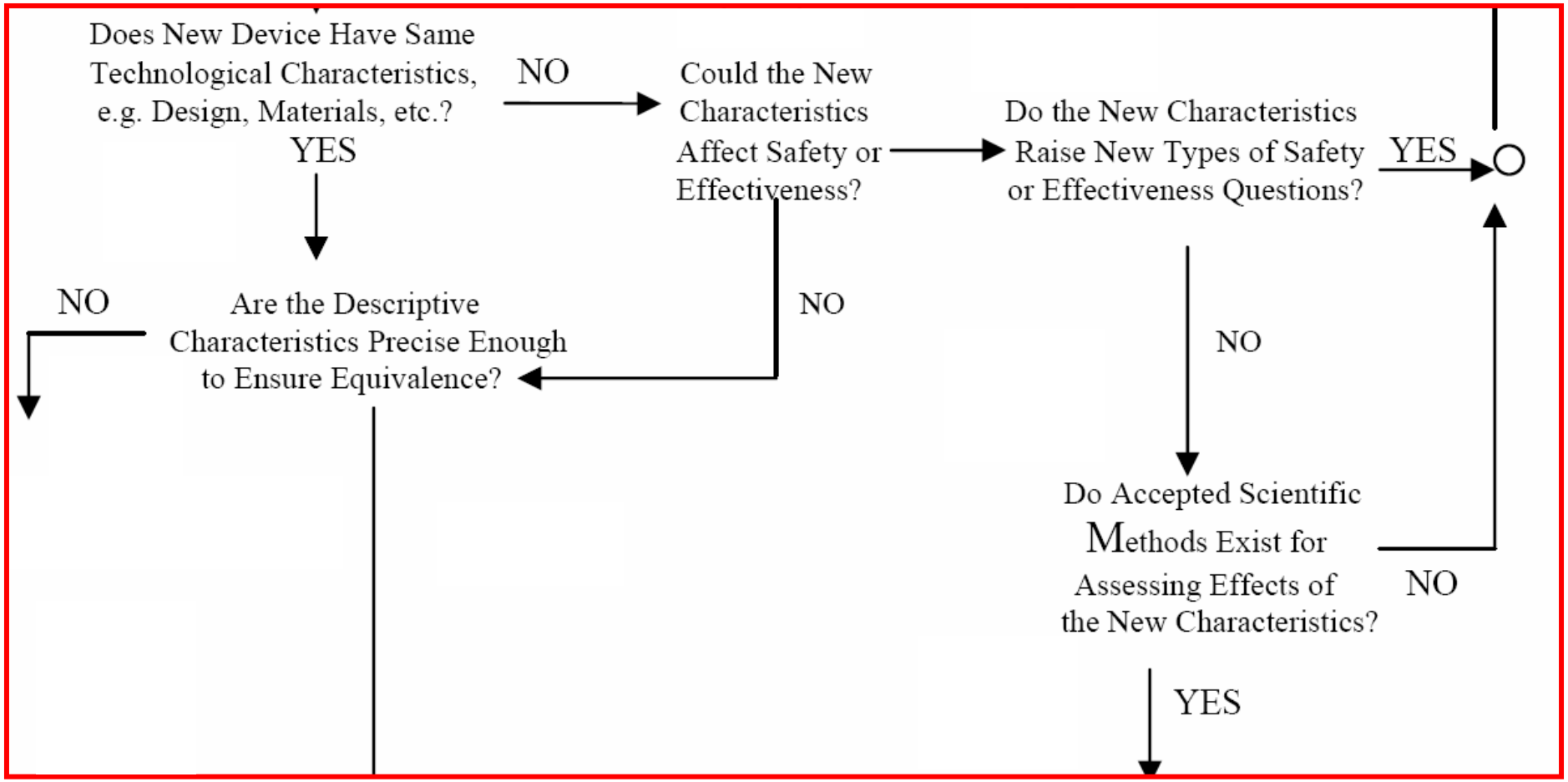


New Device is Compared to Marketed Device

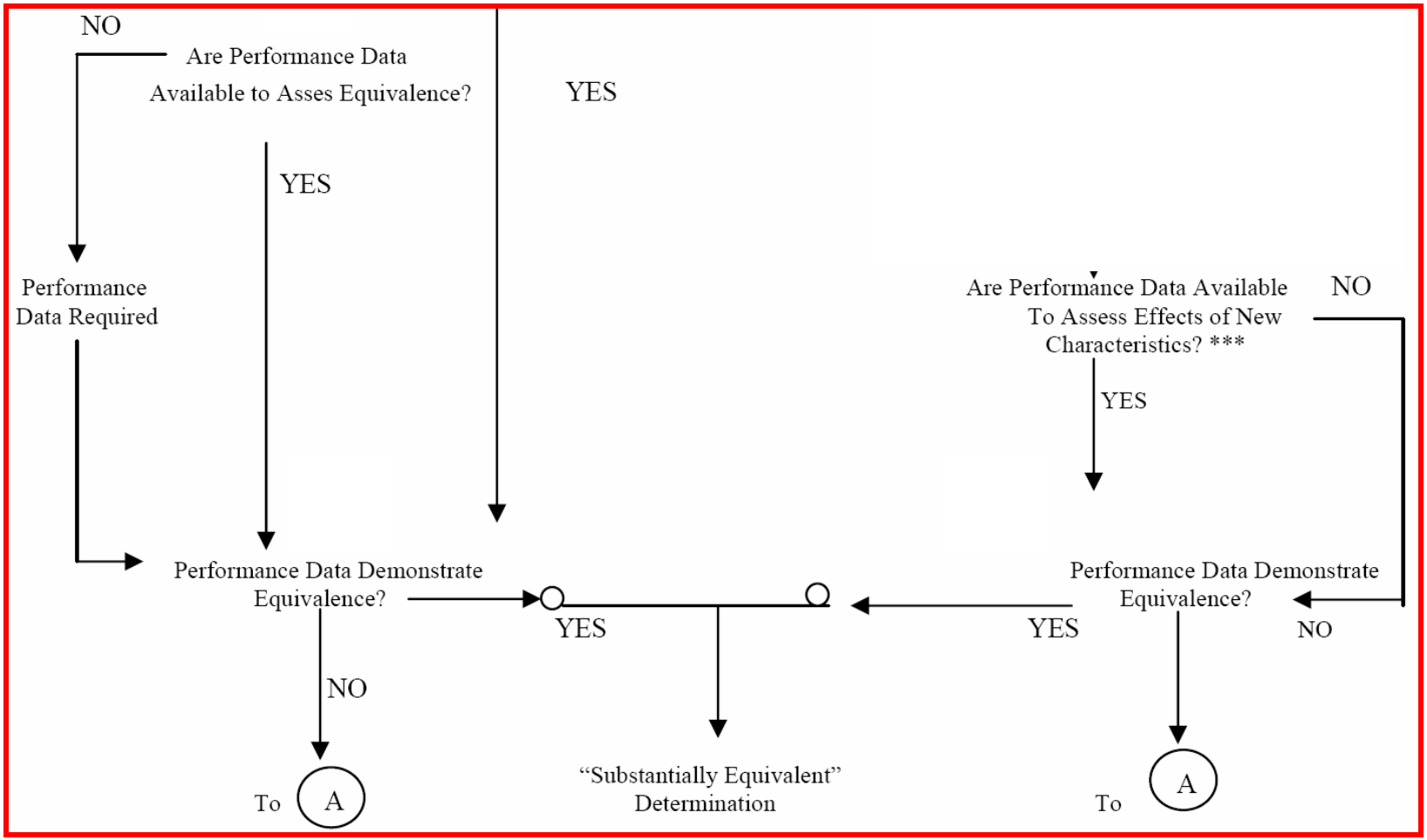
The 510(k) Flowchart: Intended Use



The 510(k) Flowchart: Technology



The 510(k) Flowchart: Performance



The Review

- The information requested by FDA varies based on the device type, indications for use, technology, etc.
  - Descriptive Characteristics
  - Bench Testing
  - Animal Testing
  - Clinical Studies

The Review

- Horizontal Standards and Guidance
  - Biocompatibility
  - Sterilization
  - Software
  - Electrical Safety
  - Electromagnetic Compatibility

The Review

- **Vertical Standards and Guidance**
  - **Indicates information needed for specific types of devices.**
  - **Information requested under a vertical standard or guidance may supersede that requested under a horizontal standard or guidance.**

Device-Specific Examples

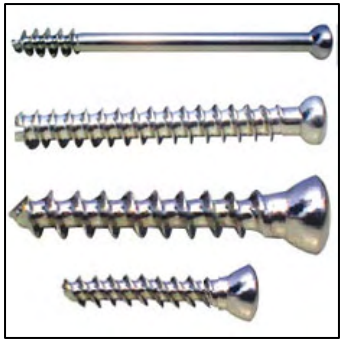
- **Non-Invasive Blood Pressure Devices:**
  - **Voluntary consensus standard exists**
  - **Clinical data are required**

Device-Specific Examples

- **Pulse Oximeters:**
  - **Voluntary consensus standard exists**
  - **Clinical data are required**
  - **Neonatal indications rely on adult data**

Device-Specific Examples

- **Bone Plates and Screws:**
  - **Voluntary consensus standard exists**
  - **Level of evidence required ranges:**
    - **Descriptive characteristics alone are sufficient (rarely)**
    - **Bench testing is sufficient (typically)**
    - **Animal or cadaver studies are required (sometimes)**
    - **Clinical testing is required (rarely)**



Device Clearance

- After a device is cleared, the following materials are added to FDA's online public database:
  - Indications for Use Form
  - 510(k) Summary or 510(k) Statement
    - "510(k) Summary" is written by sponsor
    - "510(K) Statement" refers to language specified by regulation
  - FDA's Substantial Equivalence (SE) Letter

510(k) Examples

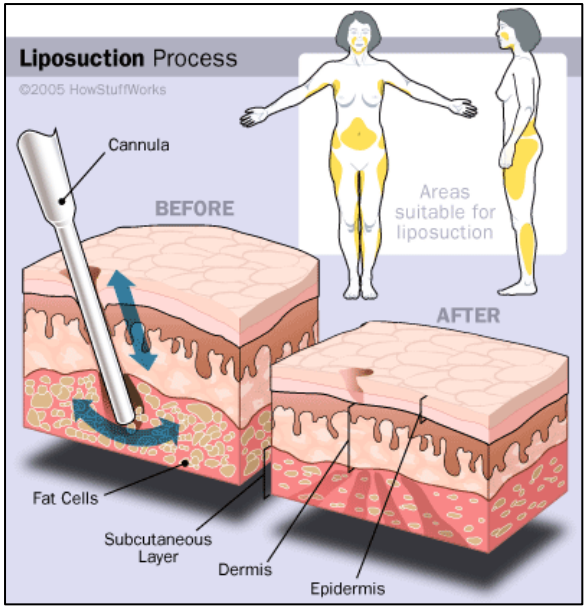
- **Straight Decision**
  - **E.g., Catheter: Original manufacturer not the original distributor now wants to be a distributor**
    - **510(k) for identical device**

510(k) Examples

- **<u>New Indication for Use</u> → <u>SAME Intended Use</u>**
  - **E.g., Blood Access Device: Femoral to Subclavian Access**

510(k) Examples

- **New Indication for Use → NEW Intended Use**
  - **E.g., Liposuction**



510(k) Examples

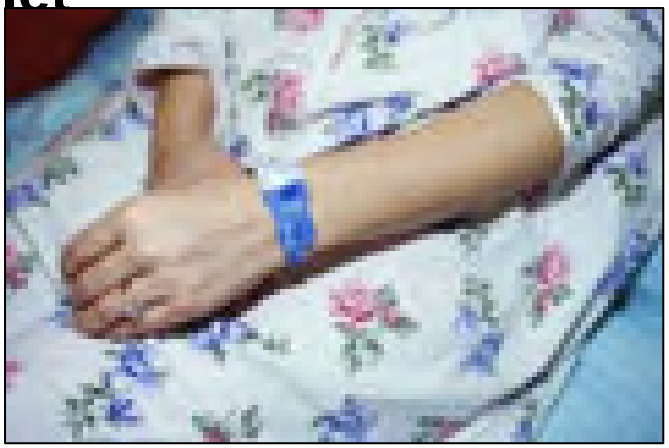
- **<u>New Technological</u> → <u>NO New Type of Question Characteristics</u>**
  - **E.g., Analog to Digital**

510(k) Examples

- **New Technological → NEW Type of Question Characteristics**
  - **E.g., Electrosurgical device to extracorporeal shockwave lithotripsy device**

De Novo Example

- **<u>Evaluation of Automatic Class III Designation "De Novo"- Section 513(f)(2) of the Act</u> (NSE for new technology that raised a new type question)**
  - **E.g., Veri Chip vs. ID Bracelet**



Why Are Product Codes Important?

- **Ultimately classify the device**
  - Found on all 510(k) and PMA Letters
- **Tools:**
  - Required for Registration & Listing
  - Used to Search for a Predicate
  - Used to Search and Report Adverse Events
  - Used Identify Third Party Eligible Device Types
  - Required When Importing & Exporting Devices

Substantially Equivalent (SE) Ltr

DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

Company ABC
c/o John Doe
123 Street Name
Somewhere, ST 99999

Re: K078522
Trade/Device Name: ABC Absorbable Gut Suture
Regulation Number: 21 CFR 878.4830
Regulation Name: Absorbable surgical gut suture
Regulatory Class: II
Product Code: GAK
Dated: May 1, 2007
Received: May 2, 2007

Product Codes are on all SE Letters and are available on the Internet

Dear Mr. Doe:

We have reviewed your Section 510(k) premarket notification of intent to market the

Classification Database

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

Classification Database

- **Public Database Contains:**
  - Classification Designation;
  - Premarket Submission Type Required;
  - Review Panel i.e., Radiology, Orthopedic;
  - GMP Exempt Status;
  - Standards;
  - Guidance Documents;
  - Definitions;
  - Indications for Use; and
  - Third Party Eligibility Status.

Product Code Descriptions

New Search | Back To Search Results

Product Classification Database

Device	Elisa, Antibody, West Nile Virus
Regulation Description	West Nile virus serological reagents.
Definition	The west nile virus elisa is intended for the detection of igg and igm antibodies to west nile virus. Specimens may be serum or cerebral spinal fluid from symptomatic patients.
Regulation Medical Specialty	Microbiology
Review Panel	Microbiology
Product Code	NOP
Submission Type	510(k)
Regulation Number	866.3940
Device Class	2
GMP Exempt?	No
Guidance Document	

Important 510(k) Content Points to Consider

Consider . . . .

- **Licensing of a 510(k)?**
  - A firm may not both manufacture and distribute a device without their own 510(k) (21 CFR 807.85(b)(2)).

- **Can you share a 510(k)? Sort of?**
  How? First…
  - Under 21 CFR § 807.85(b) as a private label distributor or re-packager of a legally marketed device
  - Cannot both manufacture and distribute without your own 510(k) (21 CFR 807.85(b))
  - Labeling requirements (§ 801.1(a),(c), and (e))

Guidance

Guidance for Industry and FDA Staff

Format for Traditional and Abbreviated 510(k)s

Last Update: November 17, 2005

www.fda.gov/cdrh/ode/guidance/1567.pdf

About Our Format Guidance

- Provides specific guidance on how to format an original submission for a Traditional or Abbreviated 510(k)
- Clearly defines common terms used in 510(k)
- Recommends formatted sections allowing FDA Reviewers to quickly locate information
- Provides valuable web sites and additional resources
- Compliments Summary of Technical Documentation (STED)

The Format Guidance Does NOT:

- Make recommendations for specific device types

or

- Recommend a format for
  - Special 510(k)s
  - PMAs
  - IDEs

510(k) Standards Form January 2008

www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf

Save As... | Print | Next Page | Reset Form

Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☐ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☐	☐
FDA Recognition number [3]	#	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☐	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☐
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☐
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☐
Is there an FDA guidance [6] that is associated with this standard?	☐	☐
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Standards Form - FAQs

- **Does this form need to be included with every 510(k) Submission?**
  - **This form needs to be included with any 510(k) where a firm chooses to use a standard in support of a substantial equivalence decision. If a standard is not referenced, they do not need to fill out and provide the form. Reviewers must document how a standard is used in support of substantial equivalence.**
  - **Firms now can use the Standards Form and state exactly what standard and, if the entire standard was not used, what parts of the standard were used in support of substantial equivalence.**

Standards Form – FAQs (cont)

- What authority was used for the form?
  - The form is an Office of Management and Budget (OMB)cleared form (OMB #0910-0120) for supplying data/information in a 510(k) as per 21 CFR 807.87.
- Was there a comment period prior to requiring use of the Standards Form in 510(k)s?
  - Yes. The 510(k) Standards Form was announced for comment in the Federal Register. No comments were received. The form was OMB cleared in August 2007. The Standards Form was implemented in January 2008.

Standards Form – FAQs (cont)

- Does this form serve as a declaration of conformity to a standard?
  - No. The form is not for a declaration of conformity. If a firm chooses to also make a declaration of conformity, then they should follow the guidance for making a declaration--in addition to the 510(k) Standards Form.
    - Guidance:

      http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070277.htm
- Does the 510(k) Standards Form increase the amount of information FDA requires in a 510(k)?
  - No. However, the 510(k) Standards Form replaces what a reviewer documented on use of standards in a 510(k).

Confidentiality of Information

21 CFR § 807.95

Misbranding by Reference to 510(k)

21 CFR § 807.97

Guidance Documents

- ODE Guidance Documents: 332
  - ODE Special Control Guidance Documents: 46
- OIVD Guidance Documents: 91
  - OIVD Special Control Guidance Documents: 23
- Online Publicly Searchable Database:
  www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfGGP/Search.cfm

Recognized Standards

CDRH has recognized approximately 800 Standards for use in premarket review

CDRH Learn

- New CDRH Tool for Industry Education
- www.fda.gov/cdrh/cdrhlearn
- Course List
  - Overview of Regulatory Requirements: Medical Devices
  - Quality System Regulation 21 CFR 820 Basic Introduction
  - Overview of the Premarket Notification Process – 510(k)
  - Product Codes Making the Connection…
  - 510(k) Format Guidance, Including Standards Form, and Extensions/Clinical Trial Form and 510(k)
  - 510(k) User Fees
  - 510(k) Third Party Review
  - "513(g)s"… Including 513(g) User Fees
  - How To Get Your Electronic Product on the U.S. Market

Next Steps

- Internal “Brainstorming” underway to improve and increase transparency of the 510(k) process
- FDA contracted Institute of Medicine (IOM) Study of the 510(k) Program (Study to conclude March 2011)
- FDA held Public Meeting on the 510(k) Program (Docket closed March 19, 2010)
- FDA Report to be completed May 31, 2010
- FDA Report out for comment June 2010

Summary: 510(k) Today

- **510(k) is the largest premarket program at FDA, addressing a great diversity of device types.**
- **50% of devices go to market as "510(k) exempt." Examples: adhesive bandages, hospital beds, non-powered breast pumps – all subject to limitations on exemption.**
- **There are 3,000-4,000 510(k) submissions per year, compared to 30-50 PMA applications.**
- **The program supported in part by user fees negotiated with industry and passed by law.**

Summary: 510(k) Today

- Most 510(k)s are class II devices.
- Many significant-risk devices to go market via 510(k) route, including implants and life-sustaining and life-supporting devices.
- Approximately 8% of 510(k)s are reviewed by third parties.
- A few 510(k) submissions receive expedited review.
  - E.g., battlefield use or important for quality of life.

Summary: 510(k) Today

- **Valid Scientific Evidence**
  - **Valid scientific evidence is required to be submitted in support of a 510(k) (21 CFR 860.7).**
  - **Evaluation is risk-based and data-driven, focusing on indications for use, technological characteristics, and performance.**
  - **Most 510(k) submissions include performance data (bench, animal, and/or clinical).**
  - **Approximately 10% of 510(k)s include clinical data.**

Summary: 510(k) Today

- **Premarket Tools**
  - **Many pre-Investigational Device Exemption Applications (pre-IDEs) are for 510(k)s.**
  - **Many IDEs are for 510(k)s.**
  - **510(k) reviews may include consults with other CDRH Offices such as OSEL and OSB, which together perform hundreds (500+) of 510(k) consults each year.**

Summary: 510(k) Today

- **Postmarket Tools**
  - **A manufacturer can be required to perform postmarket studies of certain class II devices cleared under 510(k).**
  - **A manufacturer can be required to track certain class II devices cleared under 510(k).**

Conclusion

- The 510(k) Program has evolved over time through statutory and regulatory changes, as well as through guidance.
- The current program is large and complex – there is more than just one type of 510(k).
- While we should not ignore the successes it has had, the 510(k) program should continue to be periodically reviewed and re-evaluated.


Thank You!