

510(k) Overview

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Medical Device Amendments of 1976 to the FF,D,&C Act

- **May 28, 1976**
- **Defined a device (201(h) of the Act)**
- **Required classification of device types legally on the market at that time**
- **Led to classification of approximately 1,700 different generic types of devices and grouped them into 19 medical specialties**
- **Required premarket review of devices**



What is a 510(k)

- Premarket Notification
- Section 510(k) of Federal Food, Drug, & Cosmetic Act
- 21 CFR 807 Subpart E
- Marketing Clearance Application
- Allows FDA to Determine Substantial Equivalence (SE)
- “The” classification process for a device



What a 510(k) Is Not

- A Form
- Establishment Registration
- Device Listing
- Premarket Approval (PMA)



510(k) & Classification

A 510(k) is the classification process for individual post-amendment devices by:

- Finding the device substantially equivalent (SE) or
- Finding the device not substantially equivalent (NSE)



Pre-amendment vs. Post-amendment

The F F, D, & C Act divided the arena of medical devices depending on when the devices were introduced into commercial distribution:

- Pre-amendments Devices (pre-May 28, 1976)
 - Exempted (with conditions) from marketing clearance

VS.

- Post-amendments Devices (post-May 28, 1976)
 - Requires marketing clearance



What is a Predicate?

21CFR 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;



What is a 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.



Regulatory Classes

Three Regulatory Classes (level of control based on risk):

Class I – General Controls

Class II – General Controls &
Special Controls

Class III – General Controls and
Premarket Approval



Classification

- Classification regulations for individual device types are found in 21 CFR Parts 862-892
- Regulations describe the device type as it existed **Prior** to May 28, 1976
- New indications for use or new technologies are assigned new product codes



Classification (cont.)

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

Example:

Part 872 – Dental Devices

138 Device Types, e.g.,:

Sec. 872.4760 Bone plate. (a) *Identification*. A bone plate is a metal device intended to stabilize fractured bone structures in the oral cavity. The bone segments are attached to the plate with screws to prevent movement of the segments.

(b) *Classification*. Class II.



Substantially Equivalent (SE) Ltr



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

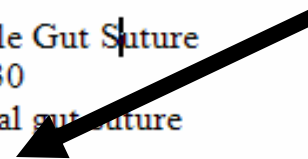
Company ABC
c/o John Doe
123 Street Name
Somewhere, ST 99999

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

Dear Mr. Doe:

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

Classification
Regulation appears
on all SE Letters
and are available on
the Internet



510(k) Exempt Devices

- Preamendments Devices
- Unfinished Devices
- Devices Exempt by Statute or by regulation from 510(k)
739 Class I (93%), 74 Class II (8%)
- Finished Devices not Sold in U.S.
- Devices Covered Under Another 510(k), e.g., Private Labeled Device
- Custom Devices
- Veterinary Devices



Limitations of Exemption from 510(k) - Class I & II

- Found in “.9” of Classification Chapters
- Four Limitations
- If the device has an intended use that is different from the intended use of a legally marketed device in that generic type



Limitations of Exemptions from 510(k)- Class I & II (cont.)

- Operates using a different fundamental scientific technology than that used by a legally marketed device in that generic type
- Specific limitations for in vitro diagnostic devices
- Device specific limitations as specified in a classification regulation



Regulatory Class

- Class determines type of premarket submission required by FDA
 - Class I or II 510(k) Exempt
 - Subject to limitations on exemptions covered under 21 CFR xxx.9 (e.g., 862.9 to 892.9)
 - Class I or II Non 510(k) Exempt
 - 510(k) Required
 - Class III
 - PMA (510(k) for pre-amendment devices until 515(b) calls for PMA or the device type is reclassified)



510(k) Submission Required When?

- Introducing a device to the market for the first time
- Change in indications for use for a previously cleared device
- Making significant modification to a previously cleared device



Who Must Submit a 510(k)?

- Manufacturers
- Specifications Developers
- Repackagers who change device or its labeling
- Relabelers who change the labeling- e.g., instructions for use
- Anyone who both manufactures & distributes



Who is Not Required to Submit a 510(k)?

Private Label Distributor who ONLY adds
company name & wording such as:

“Distributed by _____” or

“Manufactured for _____”



Not Required to Submit (cont.)

- Repackager who does not alter labeling
- Distributor or Importer who furthers marketing of the legally marketed device and does not alter labeling or change device



Information Requested in 510(k) (21 CFR § 807.87)

- Submitter's name, address, phone & fax, contact person, rep/consultant name
- Device Regulation (Classification) Name, CFR number, device class, product code
- Common/usual name & trade/proprietary name & model number



Information Requested in 510(k) (21 CFR § 807.87)

- Indications for Use Statement
- Truthful and Accurate Statement
- Proposed labeling
- Adherence to voluntary standard and standard form
- Financial Certification or Disclosure Statement or both



Information Requested (cont.)

(21 CFR § 807.87)

- Identification of marketed device(s) to which equivalence is claimed
- Compliance with section 514 Special Controls
- Proposed labels, labeling, including any promotional material



Information Requested (cont.)

(21 CFR § 807.87)

- Photographs, engineering drawings
- Substantially equivalent statement & comparison with predicate
- Statement of similarities and/or differences with predicate device
- Data for changes for modified devices



Information Requested (cont.)

(21 CFR § 807.87)

- 510(k) MUST include either:

510(k) Statement (21 CFR 807.93)		510(k) Summary (21 CFR 807.92)
510(k) Holder provides copy of 510(k) deleting trade secret & commercial confidential information to anyone within 30 days	OR	FDA provides 510(k) summary, as provided by 510(k) Holder, to any requester and is available on our website

Information Requested (cont.) (21 CFR § 807.87)

- Class III 510(k) must include:
 - Certification & literature search has been conducted, and
 - Summary of adverse S & E data with citation to the literature

**Content and Format (21 CFR § 807.94)*



Information Requested (cont.)

(21 CFR § 807.87)

- Performance Data (bench, animal, and/or clinical)
- Sterilization, Software & Hardware Information, if any
- Address information requested in specific guidance documents



Clinical Data in 510(k)

- Approximately 10% of all 510(k)s
- Important difference with the predicate device, e.g., new indication for use or new technology
- Must be collected under Investigational Device Exemption Regulations (21 CFR Part 812)



A 510(k) Must Contain:

- Proposed labeling sufficient to describe the device's indications for use
- A description of how the device is similar to or different from other devices of comparable type (predicate device)
- Any other information the Center needs to determine whether the device is SE



FDA Requests Additional Information-

- Administratively incomplete submissions
- When information/performance data are required to demonstrate equivalence

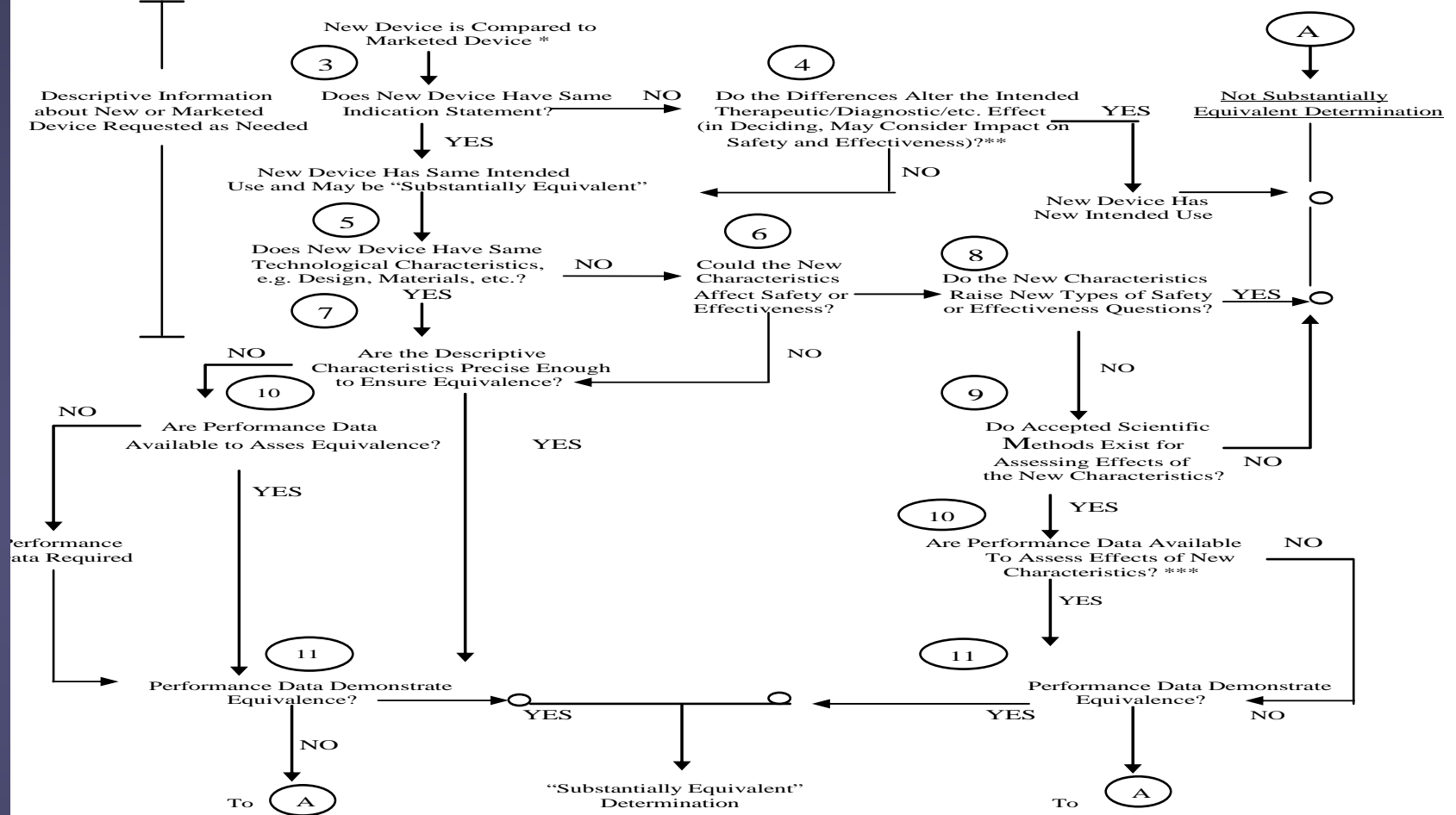


Request for Additional Data (cont.)

- Reviewer requests by telephone, email or letter
- Clock stops by letter only
- Submit to Document Mail Center
- 30 days to submit
- May request extension of time



510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

*** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

Establish Equivalence to:

- A legally marketed device (a predicate*) that does not require a PMA, i.e., a:
 - Preamendments device*
 - A device found by FDA to be Substantially Equivalent (SE), or
 - A reclassified device*

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



Device is Substantially Equivalent (SE)

- If:
 - In Comparison to a legally marketed device, it:
 - Has the same intended use, and
 - Has the same technological characteristics as the predicate device,

Or



Substantially Equivalent (SE)

- Has the same intended use, and
- Has different technological characteristics and the information in the 510(k):
 - Does not raise new questions of safety and effectiveness, and
 - Demonstrates it is at least as safe and effective as the predicate



FDA finds the device Substantially Equivalent (SE)?

- NO \Rightarrow PMA, Application or De Novo
- YES \Rightarrow To Market



Not Substantially Equivalent (NSE)

- There is no predicate device
- Has a NEW intended use
- Has different technological characteristics compared to the predicate device and raises a new type question of safety and effectiveness

**All examples above required no review of data and will require PMA or De Novo*



Not Substantially Equivalent (NSE)

- Does not demonstrate that it is at least as safe and effective as the predicate

**The example above required review of data and is eligible for a new 510(k) with new data*



Not Substantially Equivalent (NSE)

- Approximately 3% are found NSE
- 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



510(k) & Classification

- Finding the device not substantially equivalent (NSE)
 - automatically places device into class III and requires:
 - PMA; or
 - Reclassification before marketing



Modifications

- Changes in indications for use
- Modifications that could significantly enhance (or decrease) safety or effectiveness
 - change in design, materials, chemical composition, energy source, or manufacturing process
- Guidance: *"Deciding When to Submit a 510(k) for Change to an Existing Device"*

www.fda.gov/cdrh/ode/510kmod.html



Licensing of 510(k)s

- A firm may not BOTH manufacture and distribute a device without their own 510(k)
- (21 CFR 807.85(b)(2))



Finished Device

820.3(l) – Quality System Regulation

- 820.3(l) *Finished device* means any device or accessory to any device that is suitable for use or capable of functioning, whether or not it is packaged, labeled, or sterilized.
- Finished device in final form for sale to an end user is subject to 510(k) requirements



“Unfinished Device” for purposes of 510(k)

- If not in final form, **OR** in final form but **NOT** for sale to an end user, is not subject to the 510(k) requirements



Accessories & Components

- Component (820.3(c)) - *Component* means any raw material, substance, piece, part, software, firmware, labeling, or assembly which is intended to be included as part of the finished, packaged, and labeled device.
- Accessory—"extras" (not defined in the regulations)
- Accessories/components to a device take on the same classification as the "parent" device unless they are separately classified
- A finished accessory or a finished component sold to an end user, is subject to 510(k) requirements.



Confidentiality of Information

21 CFR § 807.95



Misbranding by Reference to 510(k)

21 CFR § 807.97



510(k) Overview

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