

OIVD 510(k) WORKSHOP

**“When to Submit a 510(k) or Not
.... That is the Question”.**

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The 510(k) Program

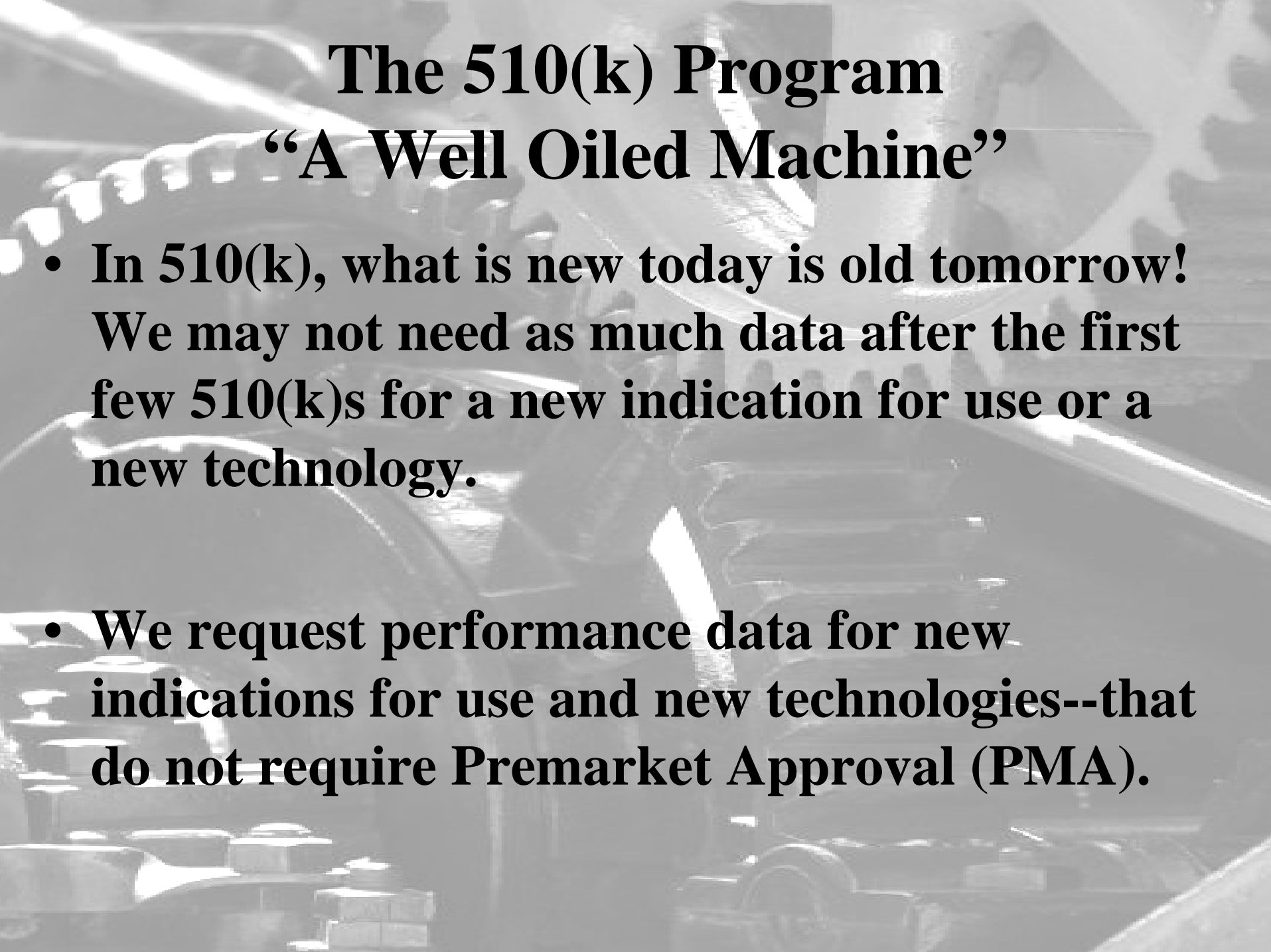
“A Well Oiled Machine”

- **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

“A Well Oiled Machine”

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

What Is A 510(k)



- Premarket Notification
- Section 510(k) of FF,D,&C Act
- 21 CFR 807 Subpart E
- Marketing Clearance Submission
- Allows FDA to Determine Substantial Equivalence (SE)
- “The” classification process for devices

What A 510(k) Is Not

- A Form
- Establishment Registration
- Device Listing
- Premarket Approval (PMA)
- Product Development Protocol (PDP)
- Evaluation of Automatic Class III Designation (de novo)

Classification & 510(k)

- The 510(k) process is meant to:
 - Classify postamendment devices
 - Find a device substantially equivalent; or
 - Find a new device not substantially equivalent (one that must be placed automatically into class III and require PMA, de novo, or reclassification before marketing)

510(k) Submission Required When?

- Introducing a device to the market for the first time
- Change in intended use for a marketed device
- Making significant modification to a marketed 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
- Reprocessors of single-use devices whose exemption from 510(k) requirements has been terminated

9/25/06 FR:

www.fda.gov/OHRMS/DOCKETS/98fr/06-8166.htm

- 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 device and does not alter labeling or change device

510(k) Exempt Devices

- Preamendments Devices
- Unfinished Devices
- Devices Exempt by Statute or 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
- General Purpose Articles
- Veterinary Devices

Class I Exemptions- **(Section 510(l) of FD&C Act)**

- All Class I Devices are Exempt Except-
 - Those intended for a use which is of substantial importance in preventing impairment of human health, or
 - Those that present a potential unreasonable risk of illness or injury

Class II Exemptions- **(Section 510(m) of the FD&C Act)**

- Class II devices that do not require 510(k)s to provide reasonable assurance of safety and effectiveness
- 75 device classifications exempt*
- * *Subject to the Limitations on Exemptions*

www.fda.gov/cdrh/modact/frclass2.html

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

- Found in “.9” of Classification Chapters
- Four Limitations:
 - 1) 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.)

- 2) Operates using a different fundamental scientific technology than that used by a legally marketed device in that generic type

- 3) Specific limitations for in vitro diagnostic devices, such as:
 - For assessing the risk of cardiovascular diseases
 - For use in diabetes management
 - For noninvasive testing as defined in 812.3(k)
 - For near patient testing (point of care)

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

- 4) Device specific limitations as specified in a classification regulation

Modifications

(21 CFR 807.81(a)(3))

- Changes in Indications for Use
- Modifications that 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

Deciding When to Submit a 510(k) for a Change to an Existing Device

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

Blue Book Memorandum

#K97-1 Notice of Availability:

February 21, 1997 - 62 FR 8024

Hints for Using the Guidance

- Guidance Does Not Establish Regulatory Requirements, i.e., Does Not Bind FDA or Industry
- For Modification Resulting From Recalls, Refer to “510(k) Requirements for Firm-Initiated Recalls”
www.fda.gov/cdrh/ode/k951.html
- Understand Roles
 - Industry - Decision-maker
 - FDA - Arbiter

Hints (cont.)

- Document Does Not Supplant Device/Situation Specific Guidance
- Read the Narrative; Do Not Go Directly to the Flowcharts
- Understand the Definitions; Do Not Make Assumptions
- In Using the Guidance, Comparison Should be to Your Own “Unmodified Device, Whereas 510(k) Submission May Compare to Any Legally Marketed Device

Hints (cont.)

- Assess Individual Changes; Consider all Reasonably Foreseeable Effects of Each Change
- Do Not Overlook the Cumulative Effect(s) of a Series of Incremental Changes
- Go All the Way Through the Flowcharts, i.e., Don't Stop at the First Decision Point
- Establish a process for evaluation of modifications
- Document Decision-making

Modifications to Devices Requiring 510(k) (cont.)

- When is the device new?
- When is the device modified?
- Is the proposed modification “significant?”
- “Could” it significantly affect safety or effectiveness?
- When does FDA say no 510(k) is required?

Modifications That Do Require a 510(k)

- New Indications for Use
- New Fundamental Scientific Technologies

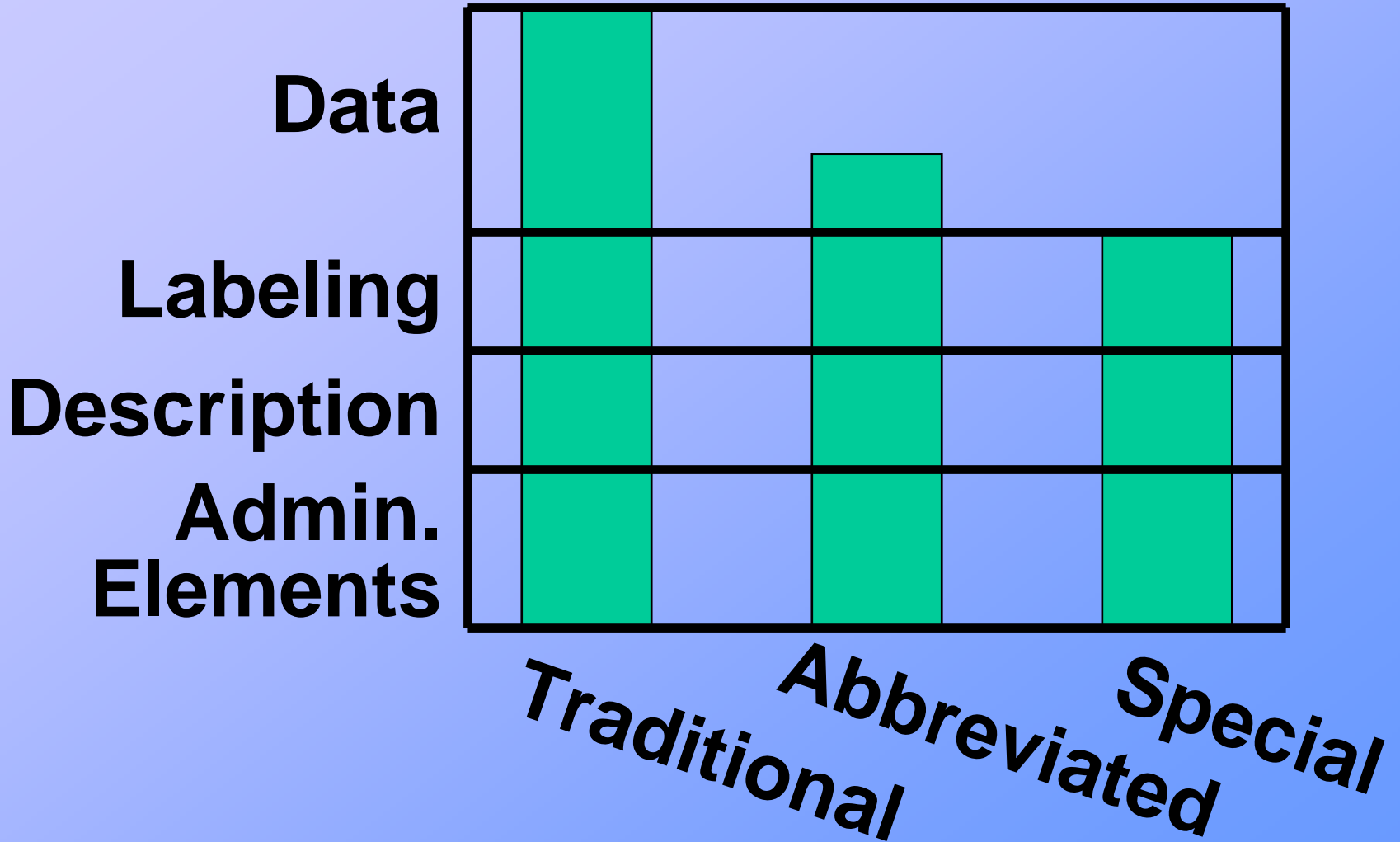
Modifications That Do Not Require a 510(k)

- Addition of a trade name
- Additional sizes within the specifications
- Change from one traditional sterilization to another
- Deleting Indications
- Changing Warnings or Precautions

The 510(k) Paradigm

- Special 510(k)s
- Abbreviated 510(k)s
- Traditional 510(k)s

510(k) Content



When Can a Modification be a Special 510(k)?

- Manufacturer Modifies own Legally Marketed Class I, II, or III Device and Determines that a 510(k) is Required
- Modification Does not Affect Intended Use or Basic Fundamental Scientific Technology

What Can Be a Special 510(k)?

- Fingertip control to voice activation
- IV catheter, single to double lumen
- Increase in balloon length & diameter, change in manufacturing
- Addition of a radiopaque material
- Change in stent material, used in type device previously

What Can Be a Special 510(k)? (cont.)

- Manual operating switch to a pressure operating switch
- Reagent reformulated to achieve extended reconstituted stability
- Change in power source
- Etc., etc.

What Cannot Be a Special?

- Cannot declare conformity with design controls
- Change in intended use
- Change is fundamental scientific technology
- New surfactant, not used in the type device previously
- Addition of a new analyte

“Abbreviated 510(k)”

- Manufacturer Intends to Market New “*reserved*” Class I/Class II or Select Class III device
- Device is Subject to Special Controls/FDA Guidance or Recognized Standard(s)
- Manufacturer uses Special Controls/FDA Guidance or Conforms to Standard(s)

When Can a Modification be an Abbreviated 510(k)?

A: ALWAYS, if there is a standard or guidance

Q: **When Can a Modification be Reviewed by a Third Party?**

A: ALWAYS, if the device is eligible and no clinicals are needed

What is the Gray Zone?

- Indications vs. Claims?
- Changes in Materials?
- Sterilization Changes?

What is the Gray Zone? (cont.)

- What about implied indications for use?
- When does a device exempt from 510(k) require a new 510(k) for a modification?
- How/When do you submit a 510(k) for a modification to a reamendments device?

What Should You Do in the Gray Zone?

- Submit a 510(k)?
- Submit an Add-to-File?
- Submit a 513(g)?
- Document Your Files?
- Submit a Special 510(k)?
- Telephone CDRH?
- Email CDRH?

Product Codes

- Regulations describe the device type as it existed **prior** to May 28, 1976
- Individual devices are classified by premarket review i.e., 510(k), PMA
- New uses or new technologies are assigned new product codes (most product codes are put under a classification regulation)

Product Codes

- Ultimately classify the device
- Found on all 510(k) and PMA clearance/approval letters
- Used to Search for a Predicate
- Used in Assigning Inspections
- Used to Search MDRs in public database
- Used to Search Listings in public database

CDRH only releases product codes for cleared/approved device types or those for export use only

Product Codes

- 21 CFR 870.1875 – Stethoscope
 - DQD
Electronic Stethoscope
Class II Non Exempt
 - LDE
Manual Stethoscope
Class I Exempt, subject to the limitations in 870.9
- ❖ *If more than one class in a regulation, then must have more than one product code*

Substantially Equivalent (SE) Letter



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

Information Highway

- Classification Database

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

This database assists users when determining a device's classification, product code, regulation, and exemption status. In addition, this database has direct links to pertinent regulations, standards, and guidance documents.

Finished Device

820.3(1) – Quality System Regulation

- 820.3(1) *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 and 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 finished component sold to an end user are subject to 510(k) requirements.

Enforcement Discretion

Enforcement Discretion is when FDA makes the decision to *not* enforce *a* regulatory requirement. Unlike exemption from a regulation, enforcement discretion may apply to only one aspect of a regulatory requirement:

EXAMPLE: FDA does not require 510(k) clearance for *convenience kits* of a type consisting of components that have been cleared through the 510(k) process, and where the assembler/manufacture is able to reasonably conclude that any further processing of the kit and its components does not significantly affect the safety or effectiveness should be noted that while *FDA exercises enforcement discretion with respect to 510(k) requirements, assemblers/manufacturers of convenience kits are still required to comply with other general controls including registration, listing, prohibition against misbranding, and good manufacturing practices.*

Enforcement Discretion

vs.

Exemption from 510(k)

- **Exempt – Exempt from 510(k) requirements by regulation or statute**
- **Enforcement Discretion – FDA makes decision not to enforce a regulatory requirement, e.g., 510(k) requirements**

Licensing of 510(k)s

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

General Purpose Article 807.65(c)

- Sec. 807.65 Exemptions for device establishments.
 - The following classes of persons are exempt from registration in accordance with 807.20 under the provisions of section 510(g)(1), (g)(2), and (g)(3) of the act, or because the Commissioner of Food and Drugs has found, under section 510(g)(5) of the act, that such registration is not necessary for the protection of the public health. The exemptions in paragraphs (d), (e), (f), and (i) of this section are limited to those classes of persons located in any State as defined in section 201(a)(1) of the act. (a) A manufacturer of raw materials or components to be used in the manufacture or assembly of a device who would otherwise not be required to register under the provisions of this part. (b) A manufacturer of devices to be used solely for veterinary purposes. *(c) A manufacturer of general purpose articles such as chemical reagents or laboratory equipment whose uses are generally known by persons trained in their use and which are not labeled or promoted for medical uses.*

General Purpose Article 807.65(c)

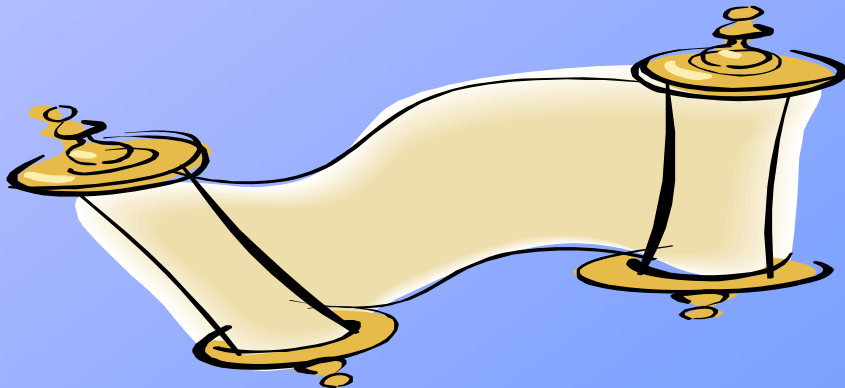
- Exempt from Registration and Listing
- Exempt from premarket requirements i.e., 510(k), PMA
- Subject to enforcement action

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 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 any specific device types
- or
- Recommend a format for
 - Special 510(k)s
 - PMAs
 - IDEs

A person is shown from the chest down, wearing a white lab coat, working on a complex electronic circuit board. The person's hands are positioned over the board, which is covered in various components and traces. The background is a warm, golden glow, suggesting a laboratory or industrial setting. The overall image is semi-transparent, allowing the text to be overlaid clearly.

The 510(k) Program

“A Fine Tuned, Well Oiled Machine”

Since 1976 FDA has reviewed 510(k)s for over 150,000 devices, each possessing incremental changes over its predicates, with FDA providing appropriate regulatory and scientific evaluation to increase access to new technologies and at the same time, protecting the public health.

Information Highway

- **FDA Homepage:**
www.fda.gov/
- **Device Advice:**
www.fda.gov/cdrh/devadvice/
- **Search Federal Register:**
www.accessdata.fda.gov/scripts/oc/ohrms/index.cfm
- **Code of Federal Regulations (CFR)**
www.fda.gov/cdrh/devadvice/365.html
- **Federal Food, Drug, and Cosmetic Act**
www.fda.gov/opacom/laws/fdcact/fdctoc.htm



FAQs

- **Q: I am thinking about sending in a new 510(k) because I had to change the vendor for a reagent. Can I just keep the study results showing no performance change in my file?**
- **Q: Studies in my 510(k) used the standard described in EP6. I modified the protocol slightly to fit the investigator's preference. I plan to submit only the data, related to that standard, in an Abbreviated 510(k). Is that appropriate?**

FAQs

- **Q: I have clearance for a glucose meter and a separate clearance for glucose strips. I plan to modify both the meter and the strip and clear them as a new glucose system. Can I submit a Special 510(k)?**
- **Q: I have a new device that determines whether a person will loose 10 Lbs. if they stop exercising for a week. Is this device a candidate for de novo? If so, what is the process?**

FAQs

- **Q: I have a test that is cleared for use in a central laboratory and I want to modify it to be used in a point of care setting. Can I submit this as a Special 510(k) or can I just keep the data supporting no change in performance in my files?**
- **Q: I have a test cleared using serum. I want to also allow urine as a sample. Can I submit a Special 510(k)?**
- **Q: I plan to modify my device because of a patient problem that may lead to a recall. Since this is a modification, can I submit a Special 510(k)?**



Thank You!