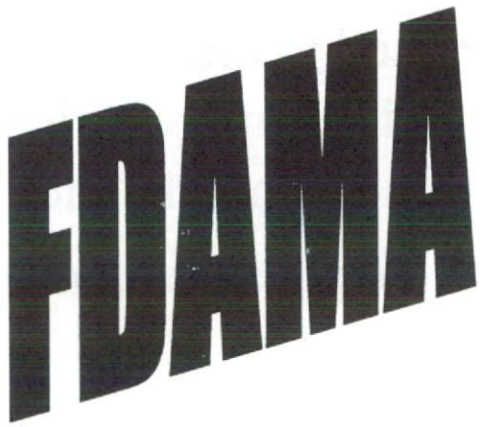
Food & Drug Modernization Act (FDAMA)

- **1997**
  - Redefined 510(k) Exemption Criteria for Class I
  - Added Class II Exemption Criteria
  - De Novo
  - SE w/Limitations
  - Class II Petitions for Exemption



Definition of Device (201(h) of the Act)

- 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 United States Pharmacopeia, 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 on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

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.

Preamendments vs. Postamendments Devices

- The act divided the arena of medical devices into either:
  - Preamendments Devices (pre-May 28, 1976) or
  - Postamendments Devices (post-May 28, 1976)
- Depending on when the devices were introduced into commercial distribution

❖ *Commercial distribution and Preamendment Status are determined by the Office of Compliance (www.fda.gov/cdrh/comp/preamend.html)*

The Code of Federal Regulations (CFR)

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

  www.fda.gov/cdrh/devadvice/365.html

Regulatory Classes

Regulatory Class Determines Type of
Premarket submission (510(k))/PMA) Submission Required

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

Description of Classes

Class I

1. Devices for which general controls are sufficient to provide reasonable assurance of the safety and effectiveness of such devices.

Description of Classes (cont.)

- **General controls include:**
  - prohibition against adulterated or misbranded devices
  - premarket notification (510(k)) requirements
  - banned devices
  - GMPs
  - Registration of manufacturing facilities
  - listing of device types
  - record keeping
  - repair, replacement, refund

Description of Classes (cont.)

2.Devices for which general controls and special controls are insufficient to provide reasonable assurance 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

Description of Classes (cont.)

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 (cont.)

Special Controls include:

- Performance Standards (discretionary, voluntary national or international standard, recognized by rulemaking);
- Guidance Document;
- Postmarket Surveillance;
- Patient Registries;
- Other

Description of Classes (cont.)

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;
- substantial importance in preventing impairment of human health; or
- present unreasonable risk of illness or injury.

What is a 510(k)

- Premarket Notification
- Section 510(k) of F,D, & C Act
- 21 CFR 807 Subpart E
- Marketing Clearance Application
- Allows FDA to Determine Substantial Equivalence (SE)
- "The" classification process

What a 510(k) Is Not

- A Form
- Establishment Registration (FDA-2891)
- Device Listing (FDA-2892)
- Premarket Approval (PMA)
- Product Development Protocol (PDP)
- Automatic Class III Designation-
  (De Novo)

Classification & Premarket Notification (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) 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

Product Codes

- Found on all 510(k)/PMA clearance/approval letters
- Ultimately classify the device
- Used to search for a predicate device
- Used in assigning inspections
- Used to search Medical Device Reports (MDRs) in public database
- Used to search listings in public database

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

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

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)

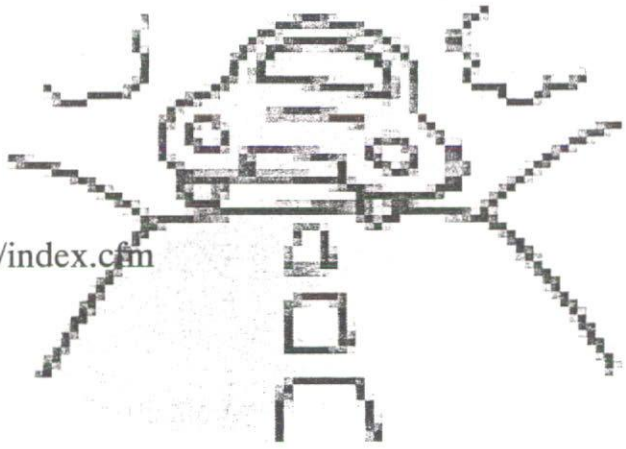
Regulations & Product Codes

- 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***

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



Information Highway

- CDRH Publicly Searchable Databases
  www.fda.gov/cdrh/databases.html

This website contains over 15 publicly searchable FDA Databases.

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.

添付資料－15

Unique Device Identification and the US FDA

Background and History

- 1999 – IOM publishes report "To Err is Human: Building a Safer Health System"
- 2004 - FDA issues final rule requiring bar codes of NDC numbers on drugs and biological products to help reduce medication errors
- Devices specifically excluded from bar code rule because devices lack a unique numbering scheme
- 2005 - FDA receives letters from Congress and a consortium of hospital groups asking that we revisit the issue of bar coding medical devices.

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Realities of the Device World

- Diverse industry
  - 28,000+ firms (many are small < 20 employees)
  - Global marketplace – international harmonization
  - Varied approaches by regulators
- Diverse population (of devices):
  - 100,000+ brands/models of devices
  - Vary in size, complexity, packaging and use
  - High volume, low volume
  - Kits; components; systems
  - Reprocessed devices; SUDs

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FDA believes that UDI can...

- Reduce device related medical errors - identify compatibility and interoperability issues:
  - right device for right patient (latex allergy)
  - right accessory for right device
  - MRI compatibility
- Improve identification of specific device in adverse event reports and provide more "denominator" data
- Facilitate more effective device recalls – identify and locate recalled devices in a timely fashion

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UDI can also…

- Facilitate the population of device use information in Electronic Medical Record Systems (HIT)
- Provide ancillary benefits for a wide variety of stakeholders:
  - Improve materials management and associated healthcare cost savings
  - Help track devices and identify counterfeit devices
  - Identify similar or substantially equivalent devices to avoid shortage
  - Emergency preparedness – national, military

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Federal Register Notice

- 11 August 2006 – request comments to help FDA understand how the use of a unique device identification system may improve patient safety.
- Public Meeting – 25 October 2006 – focused on:
  - Benefits and costs of a UDI system
  - Design and implementation of UDI system
  - Data repository – design, maintenance, use
  - Automatic identification technologies
- Docket closed 9 November 2006
- Notice focuses on 3 broad areas

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Combination of 3 Distinct Ideas

1. Development of a standardized system of unique device identifiers (UDI)
2. Placing UDI in human readable and AutoID on device, its labeling, or both
3. Creation of the UDI Database – for each UDI, it contains the Minimum Data Set:
   - UDI, and the information used to create it, and
   - Information for Safe Use (e.g., indications, latex)

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1st Develop UDI System

- Manufacturer chooses standard – GS1 or HIBCC (not NHRIC or NDC)
- UDI = Concatenate Device ID + Production ID
- Device ID = Who makes it and what is it (manufacturer, make, model) – specific device
- Production ID = Serial number or lot number and expiration date
- Quantity as needed – device would have same DID regardless of how it's packaged.

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2nd Put UDI on Device

- Put the UDI on the device, its label, or both
- At the current "unit of use"
- The UDI would be human readable
- Encode in Automatic Identification (AutoID)
- Remain technology neutral (open source)
- AutoID options include:
  - Linear and 2-dimensional barcode
  - RFID
  - Direct Part Marking (DPM) – for reusable or sterilizable instruments

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3rd Develop UDI Database

Minimum Data Set (MDS) – based on DID, may be different for different devices types; includes:

1. Device Identification:
   - Manufacturer, make, model
   - Unique attributes (size, quantity, software version)
2. Information for Safe Use includes:
   - Procode, GMDN code
   - Indications for use, contraindications
   - Allergens, compatibility, single use/reusable
   - Accessories needed, devices approved (parent/child)

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3rd Develop UDI Database

- Dynamic record – over device lifetime
- Submitted via HL7 SPL standard (bulk) or dedicated website (single)
- Checked for incomplete data and unique ID
- Maintained internally
- Publicly releasable used to populate DailyMed
- Production ID submitted periodically – not released, associated with DID

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Other UDI Issues

- Serialization – anti-counterfeiting
- Emergency preparedness issues
- GMDN
- Combination products, kits (w, w/o drugs) – pedigree issues
- Reprocessed devices; SUDs
- Legacy devices
- Triggers for a "new" DID
- Devices which currently do not have PIDs?

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Next Steps

We are now…

- Analyzing Comments
- Determining FDA's role and approach
- Assembling data on costs and benefits
- Understanding role of Auto ID technology

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Unique Device Identification

www.fda.gov/cdrh/ocd/udi/

Email: cdrhudi@fda.hhs.gov

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「製造販売規制を効率的に行うための
医療機器の体系的な分類の推進に関する研究」
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