

# FDA Product Codes & GMDN

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# Medical Device Amendments to Federal Food, Drug, & Cosmetic Act May 28, 1976

- Defined a device (201(h) of the Act)
- Required classification of devices
- Led to classification of approximately 1,700 generic types of devices and grouped into 19 medical specialties
- Required premarket review of devices



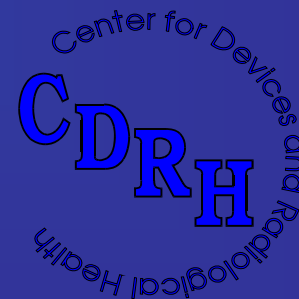
# Regulatory Classes

- Three Regulatory Classes (risk based level of control necessary to assure safety and effectiveness)
  - Class I – General Controls
  - Class II – General Controls & Special Controls
  - Class III – General Controls and Premarket Approval



# Regulatory Classes (cont.)

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



# Where Do Product Codes Fit In?

- 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
- Individual devices are classified by premarket review
- New uses or new technologies are assigned new product codes (most product codes are put under a classification regulation)

# 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*



# Product Codes (cont.)

- If more than one class in a regulation, then there is more than one product code – Example:

21 CFR 870.1875 – Stethoscope

– LDE

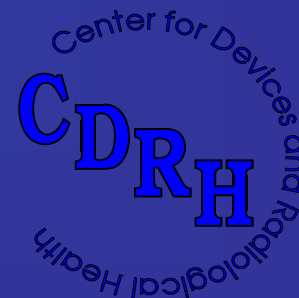
Manual Stethoscope

Class I exempt from 510(k), subject to the limitations of exemption (21 CFR 870.9)

– DQD

Electronic Stethoscope

Class II non-exempt/510(k) required



# Product Codes



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

# FDA Product Codes and GMDN

- 1) How will FDA databases handle GMDN codes?
- 2) Will FDA include GMDN codes on decision letters?
- 3) How/where will we explain GMDN codes in relation to FDA product codes?
- 4) How will GMDN codes affect FDA classification of devices?
- 5) How will FDA finance obtaining GMDN codes and access to the GMDN database?
- 6) How quickly can FDA obtain a new GMDN code?
- 7) FDA is currently working to obtain comment/define the plan.