

Product Codes Making the Connection....

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Consumer Safety Officer, 510(k) Staff
FDA Office of Evaluation, CDRH**

Public Law 94-295
94th Congress

An Act

To amend the Federal Food, Drug, and Cosmetic Act to provide for the safety and effectiveness of medical devices intended for human use, and for other purposes.

May 28, 1976
[S. 510]

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

Medical Device
Amendments of
1976.
21 USC 301 note.

SHORT TITLE AND TABLE OF CONTENTS

SECTION 1. (a) This Act may be cited as the "Medical Device Amendments of 1976".

(b) Whenever in this Act (other than in section 3(a)(1)(B)) an amendment is expressed in terms of an amendment to a section or other provision, the reference shall be considered to be made to a section or other provision of the Federal Food, Drug, and Cosmetic Act.

21 USC 301.

TABLE OF CONTENTS

Sec. 1. Short title and table of contents.

Sec. 2. Regulation of medical devices.

"Sec. 513. Classification of devices intended for human use.

- "(a) Device classes.
- "(b) Classification; classification panels.
- "(c) Classification panel organization and operation.
- "(d) Classification.
- "(e) Classification changes.
- "(f) Initial classification of certain devices.
- "(g) Information.
- "(h) Definitions.

"Sec. 514. Performance standards.

- "(a) Provisions of standards.
- "(b) Initiation of a proceeding for a performance standard.
- "(c) Invitation for standards.
- "(d) Acceptance of certain existing standards.
- "(e) Acceptance of offer to develop standard.
- "(f) Development of standard by Secretary after publication of subsection (c) notice.
- "(g) Establishment of a standard.

"Sec. 515. Premarket approval.

- "(a) General requirement.
- "(b) Regulation to require premarket approval.
- "(c) Application for premarket approval.
- "(d) Action on an application for premarket approval.
- "(e) Withdrawal of approval of application.
- "(f) Product development protocol.
- "(g) Review.
- "(h) Service of orders.

"Sec. 516. Banned devices.

- "(a) General rule.
- "(b) Special effective date.

"Sec. 517. Judicial review.

- "(a) Application of section.
- "(b) Additional data, views, and arguments.
- "(c) Standard for review.
- "(d) Finality of judgments.



Code of Federal Regulations (CFR)

**The May 28, 1976, Medical Device
Amendments required and led to:**

**The classification of
approximately 1,700 generic
device types.**

Code of Federal Regulations (CFR)

21 CFR Parts 862-892

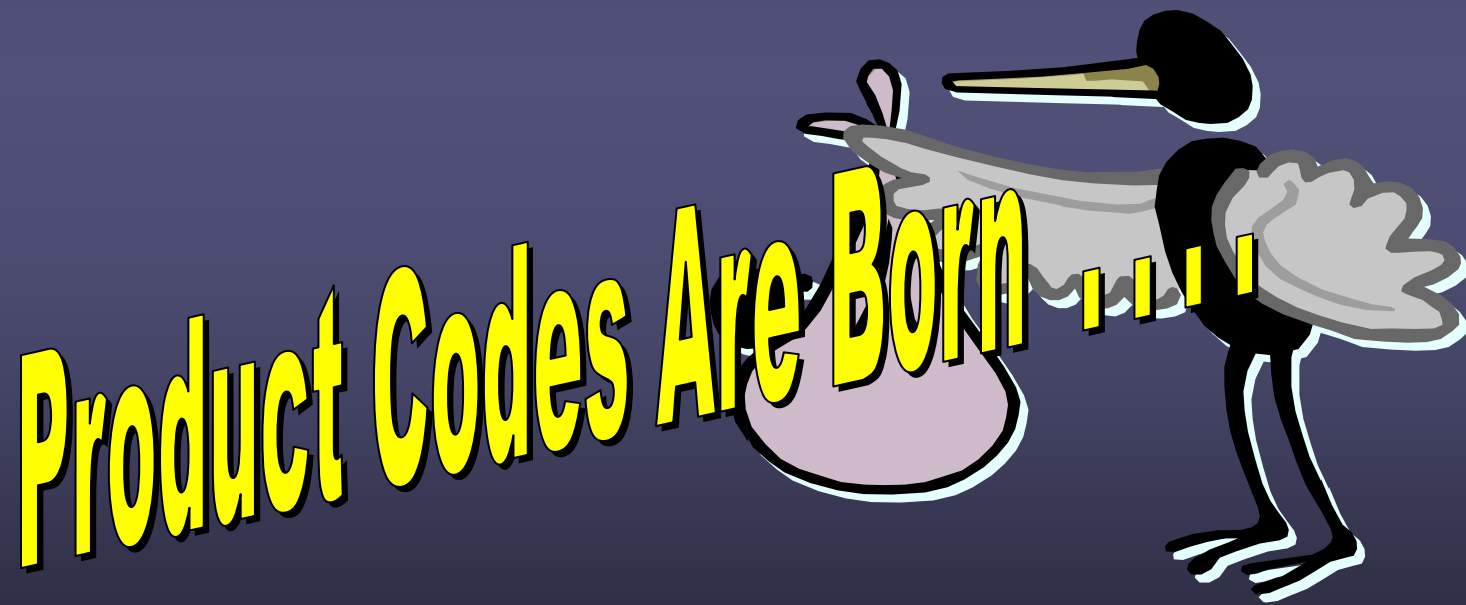


Code of Federal Regulations (CFR)

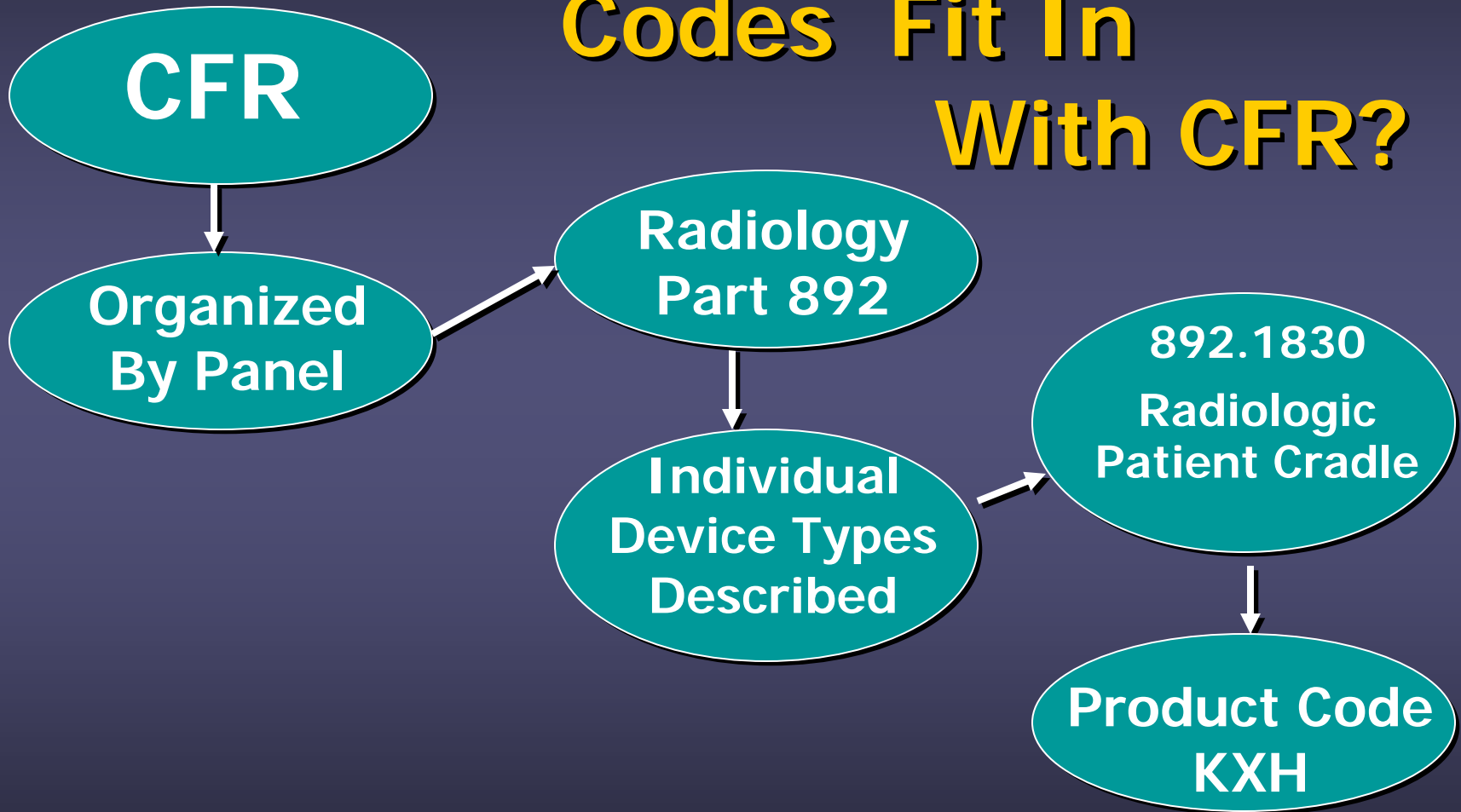
21 CFR Parts 862-892

**Regulations describe the
device types as they
existed prior to May 28,
1976 (Pre-amendment)**

May 28, 1976
Medical Device
Amendments
Public Law 94-295



How Do Product Codes Fit In With CFR?





[510\(k\)](#) | [Registration & Listing](#) | [Adverse Events](#) | [PMA](#) | [Classification](#) | [CLIA](#)
[CFR Title 21](#) | [Advisory Committees](#) | [Assembler](#) | [Recalls](#) | [Guidance](#) | [Standards](#)

New Search	Back To Search Results
Product Classification Database	
Device	Cradle, Patient, Radiologic
Regulation Description	Radiologic patient cradle.
Regulation Medical Specialty	Radiology
Review Panel	Radiology
Product Code	KXH
Submission Type	510(k) Exempt
Regulation Number	892.1830
Device Class	1
GMP Exempt?	No
Note: FDA has exempted almost all class I devices (with the exception of Reserved Devices) from the premarket notification	

Classification Today & Product Codes

Individual devices are classified by premarket review i.e., 510(k), PMA

New indications for use or new technologies are assigned new product codes that are placed under the original regulation

Preamendment Device Type Described in CFR

872.6865 – Powered Toothbrush

A powered toothbrush is an AC-powered or battery-powered device that consists of a handle containing a motor that provides mechanical movement to a brush intended to be applied to the teeth. The device is intended to remove adherent plaque and food debris from the teeth to reduce tooth decay.

Classification: Class 1 Exempt

Product Code Information: JEQ Powered Toothbrush
Regulation: 876.6865 Class 1 Exempt

Substantially Equivalent

New Device Type: Ionic Powered Toothbrush

New Technology Required 510(k)

510(k) Found Substantially

Equivalent to Preamendment Device

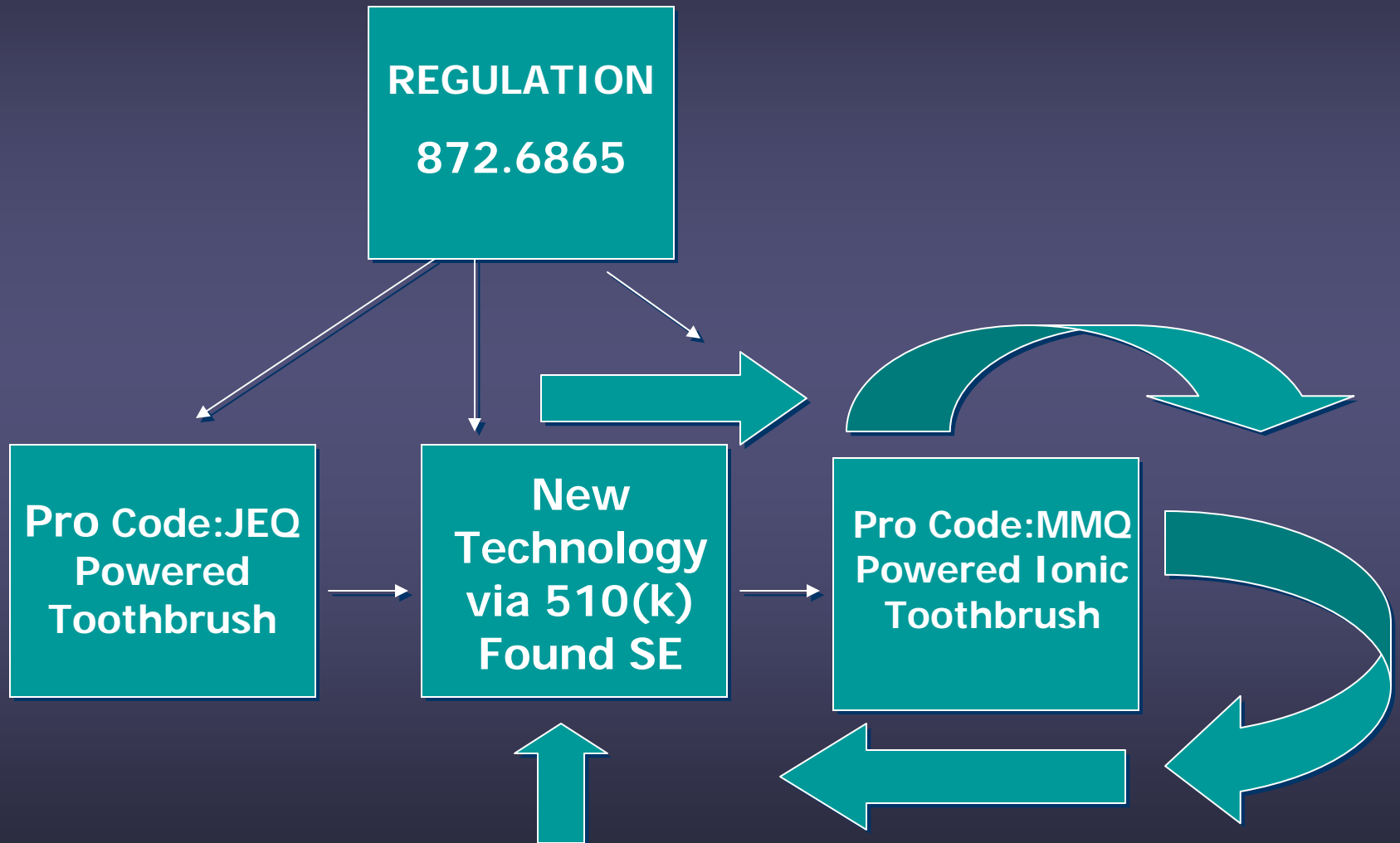
Product Code Information:

MMQ Powered Ionic toothbrush

Regulation: 876.6865

Class 1 Exempt

Substantially Equivalent (SE)



Why Are Product Codes Important To Me?

**Ultimately classify the device Found on all
510(k) & PMA Letters**

Tools:

- **Required for Registration & Listing**
- **Used to Search for a Predicate**
- **Used to Search & Report Adverse Events**
- **Used Identify Third Party Eligible Device
Types**
- **Required When Importing & Exporting
Devices**

Why Are Product Codes Important To Me?

Product Codes
Ultimately Classify
Your Device

Found on all 510(k)
and PMA Letters





DEPARTMENT OF HEALTH & HUMAN SERVICES

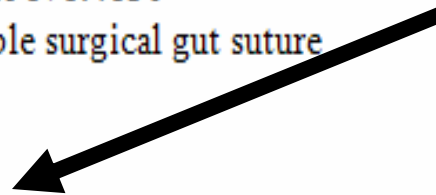
Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

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

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

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

Registration and Listing

A firm can **ONLY** list with
the product code found on their 510(k)
or PMA Clearance/Approval Letter

Unless registering with a

Class 1 Exempt Device

Class 2 Exempt Device

Search For Predicates



U.S. Food and Drug Administration



Department of Health and Human Services

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www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm

Search 510(k) Database [Help](#) [Download File](#) [More About 510\(k\)](#)

510K Number	<input type="text" value="K"/>	Type	<input type="text"/>
Model	<input type="text"/>	Cleared/Approved/UL Products	<input type="checkbox"/>
Applicant Name	<input type="text"/>	Third Party Reviewed	<input type="checkbox"/>
Device Name	<input type="text"/>	Expedited Review	<input type="text"/>
Panel	<input type="text"/>	Product Code	<input type="text"/>
Decision	<input type="text"/>		
Decision Date	<input type="text"/>	to	<input type="text"/>
Sort by	Decision Date (descending) <input type="text"/>		

For full-text search, select [Go To Simple Search](#) button

Adverse Event Reporting



U.S. Food and Drug Administration



Department of Health and Human Services

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Qu

- MAUDE data represents reports of adverse events involving medical devices. The data consists of voluntary reports since June 1993, user facility reports since 1991, device reports since 1993, and manufacturer reports since August 1996. MAUDE may not include reports made according to exemptions, variances, or alternative reporting requirements granted under 21 CFR 803.19.
- The on-line search allows you to search CDRH database information on medical devices which may have malfunctioned or caused a death or serious injury. MAUDE is scheduled to be updated quarterly and the search page reflects the date of the most recent update. FDA seeks to include all reports received prior to the update. However, inclusion of some reports may be delayed by technical or clerical difficulties.
- MAUDE data is not intended to be used either to evaluate rates of adverse events or to compare adverse event occurrence rates across devices. Please be aware that not all reports regarding device adverse events may have been submitted under different manufacturer names. Searches will return records that contain any search term(s) provided by the requester.

www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM

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Enter one or a combination of the MAUDE Search Values and select Search

Product Problem	<input type="text"/>	<input type="button" value="v"/>
Product Class	<input type="text"/>	<input type="button" value="v"/>
Brand Name	<input type="text"/>	510K Number <input type="text" value="K"/>
Manufacturer	<input type="text"/>	PMA Number <input type="text" value="P"/>
Event Type	<input type="text"/>	<input type="button" value="v"/> Product Code <input type="text"/>
Date Report Received by FDA (mm/dd/yyyy)	<input type="text" value="01/01/2008"/>	<input type="button" value="to"/> <input type="text" value="08/29/2008"/>

For full-text search, select [Go To Simple Search](#) button

Search For Third Party Eligible Device Types

List of Devices for Third Party Review under the FDA Modernization Act of 1997 - Microsoft Internet Explorer

Address: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfThirdParty/current.cfm?panel=SU#TopPage>

www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfThirdParty/current.cfm#4

Section No.	Regulation Name Product Code Device Name	Class	Third Party	Relevant Guidance/Standard
878.4040	SURGICAL APPAREL	II		Text PDF PDF
	MSH - Respirator, Surgical			
	FXX - Mask, Surgical		Pilot	
	FXY - Hood, Surgical		Pilot	
	FYA - Gown, Surgical		Pilot	
	FYB - Gown, Patient		Pilot	
	FYC - Gown, Isolation, Surgical		Pilot	
878.4200	INTRODUCTION/DRAINAGE CATHETER AND ACCESSORIES	I		General Guidance
	OAJ - Catheter, Drainage, Intraoral/Extraoral			
878.4350	CRYOSURGICAL UNIT AND ACCESSORIES	II		
	FAZ - System, Cryosurgical, Liquid Nitrogen, For Urology		Pilot	
	GEH - Unit, Cryosurgical, Accessories		Pilot	
878.4370	SURGICAL DRAPE AND DRAPE ACCESSORIES	II		
	MMP - Cover, Barrier, Protective		Pilot	
	ERY - Drape, Surgical, Ent		Pilot	
	EYX - Drape, Pure Latex Sheet, With Self-Retaining Finger Cot		Pilot	

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Classification Database

FDA > CDRH > Product Classification Database Search - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Back Forward Stop Refresh Home Search Favorites

Address <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm> Go

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

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Device Product Code

Review Panel Submission Type

Regulation Number Ther. Priority

Sort By Device Class

For full-text search, select [Go To Simple Search](#) button

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Database Updated 08/06/2008

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start | 9 Microsof... | pro codes 2... | Microsoft O... | 5 Internet... | 11:16 AM

Product Code Descriptions

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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	

Classification Database Classification Database

Provides:

Links to Standards;

**Links to Associated Guidance
Documents;**

**Product Code Definitions and
Indications for Use Fields;**

Expanded Descriptions; and

Third Party Eligibility



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