Product Codes
Making the Connection….

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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

Code of Federal Regulations (CFR)

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

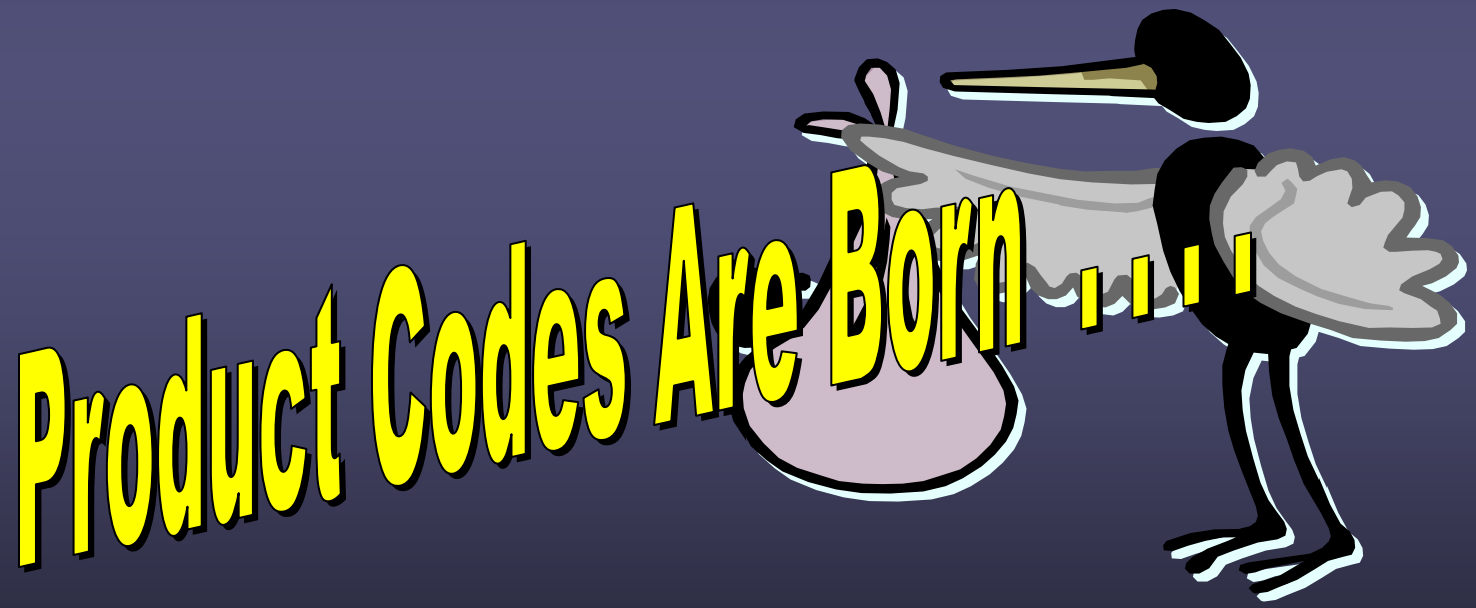
The classification of approximately 1,700 generic device types.

Code of Federal Regulations (CFR)
21 CFR Parts 862-892

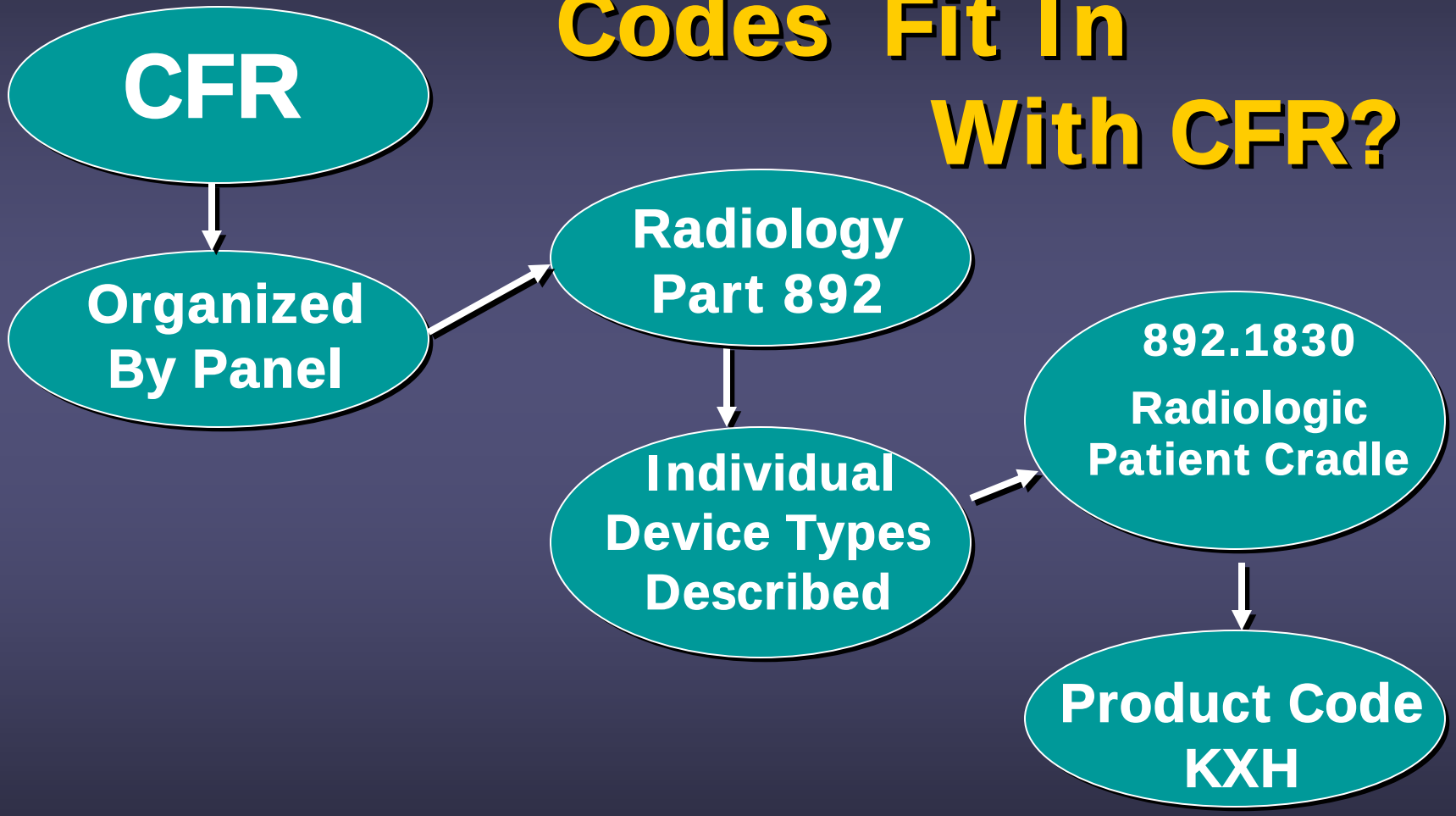
Code of Federal Regulations (CFR)
21 CFR Parts 862-892

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?



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

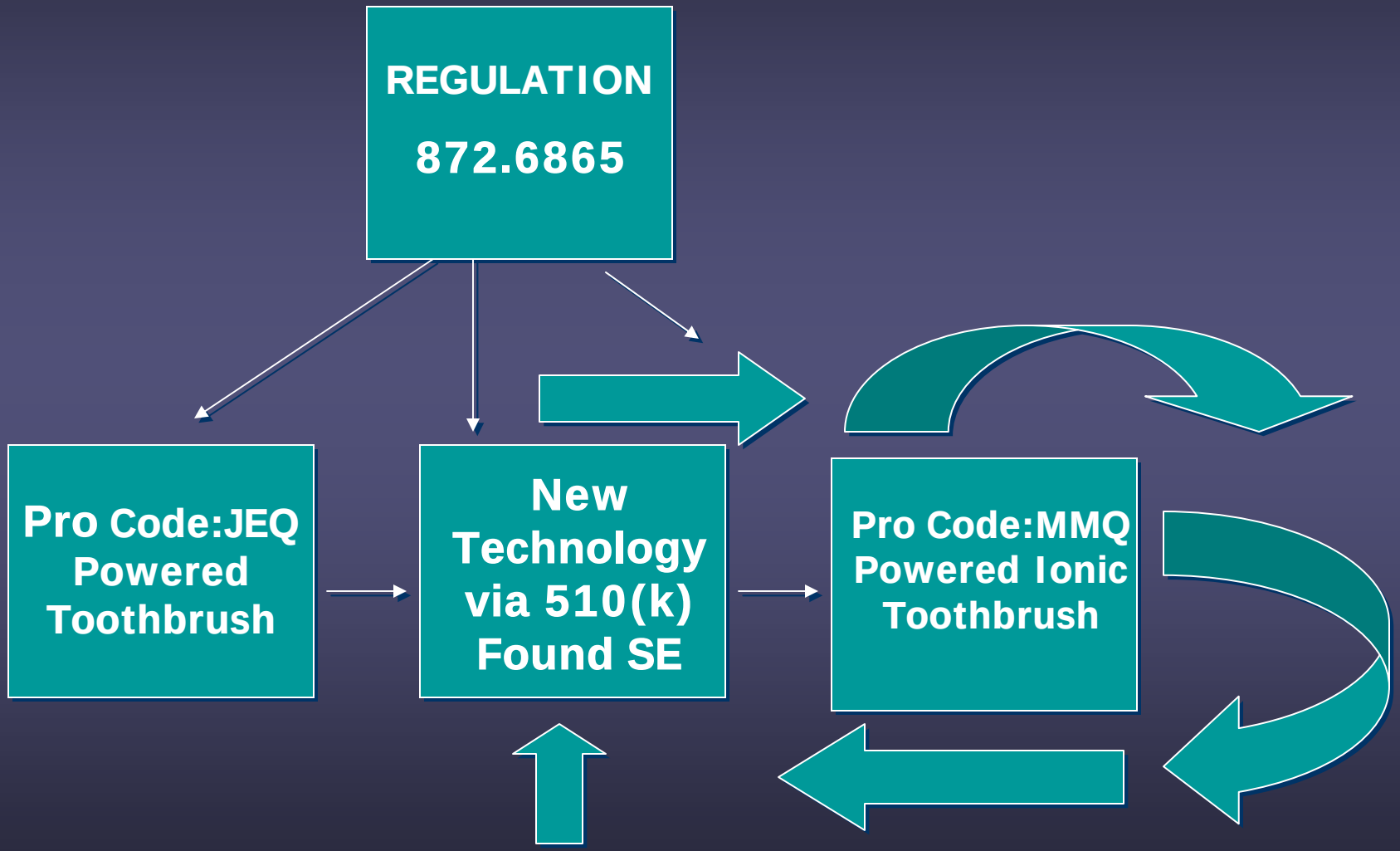
New Technology Required 510(k)

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

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

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

Registration and Listing

A firm can ONLY list with

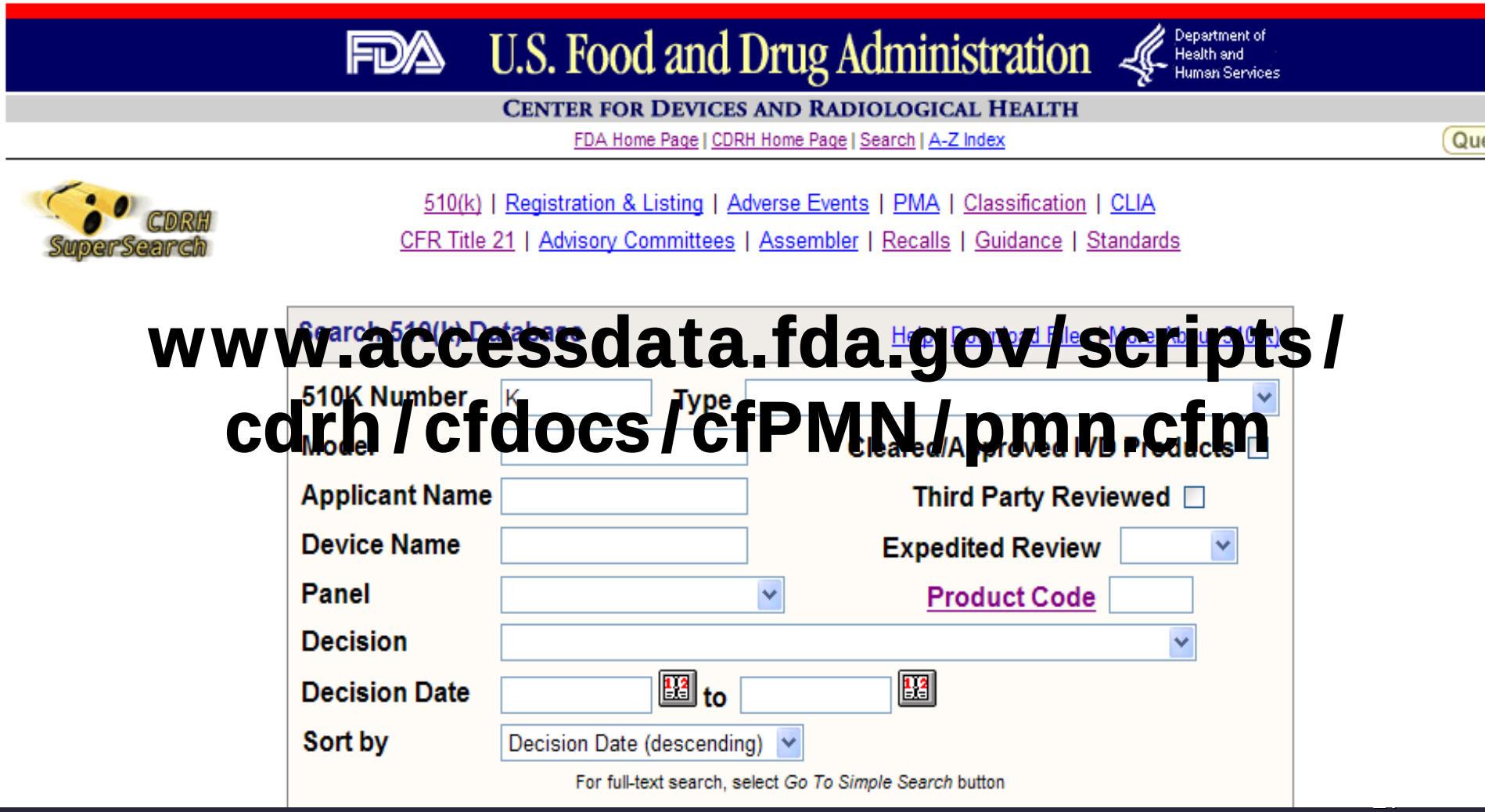
the product code found on their 510(k) or PMA Clearance/Approval Letter

Unless registering with a . . . . . .

Class 1 Exempt Device

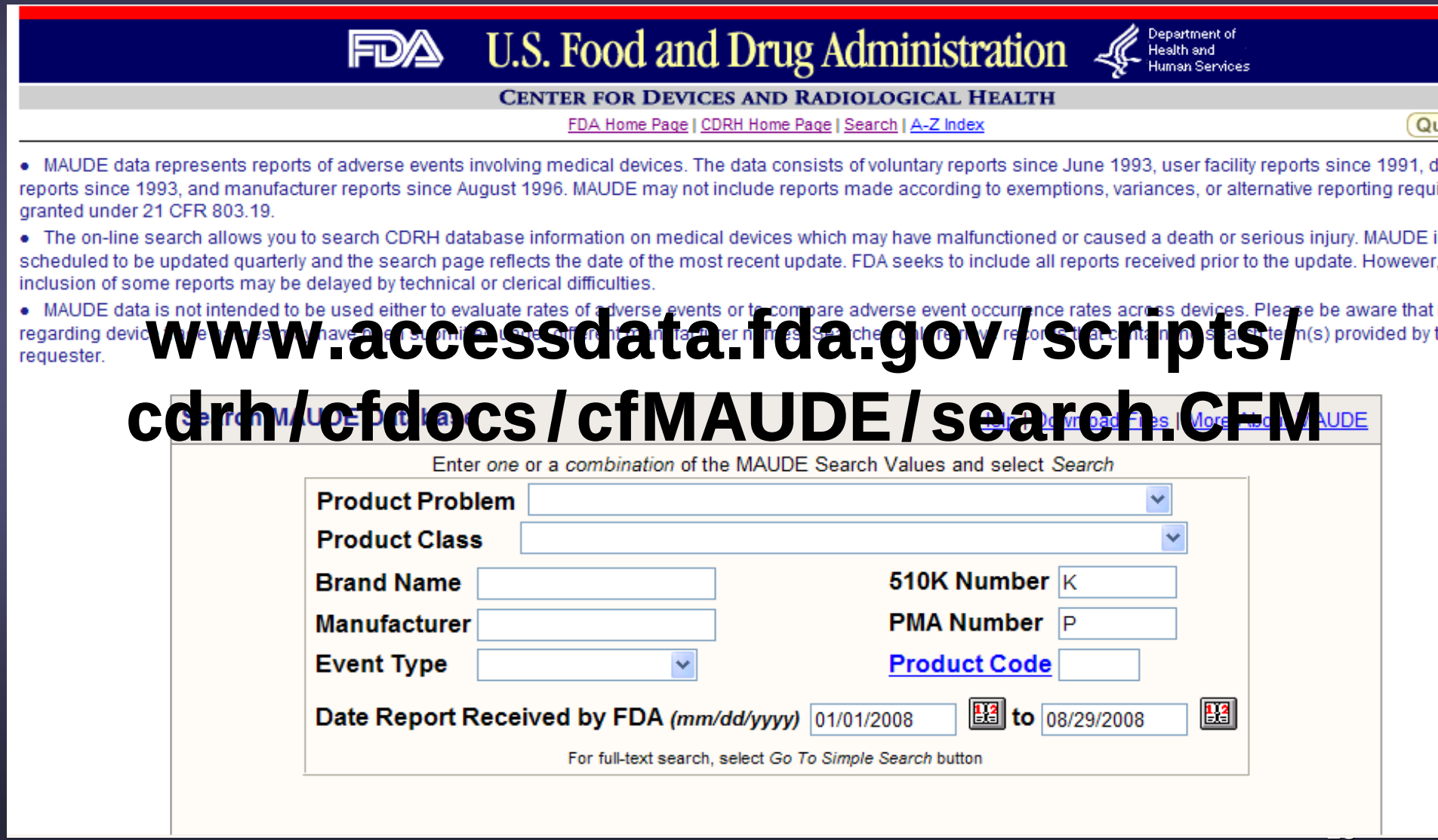
Class 2 Exempt Device

Search For Predicates

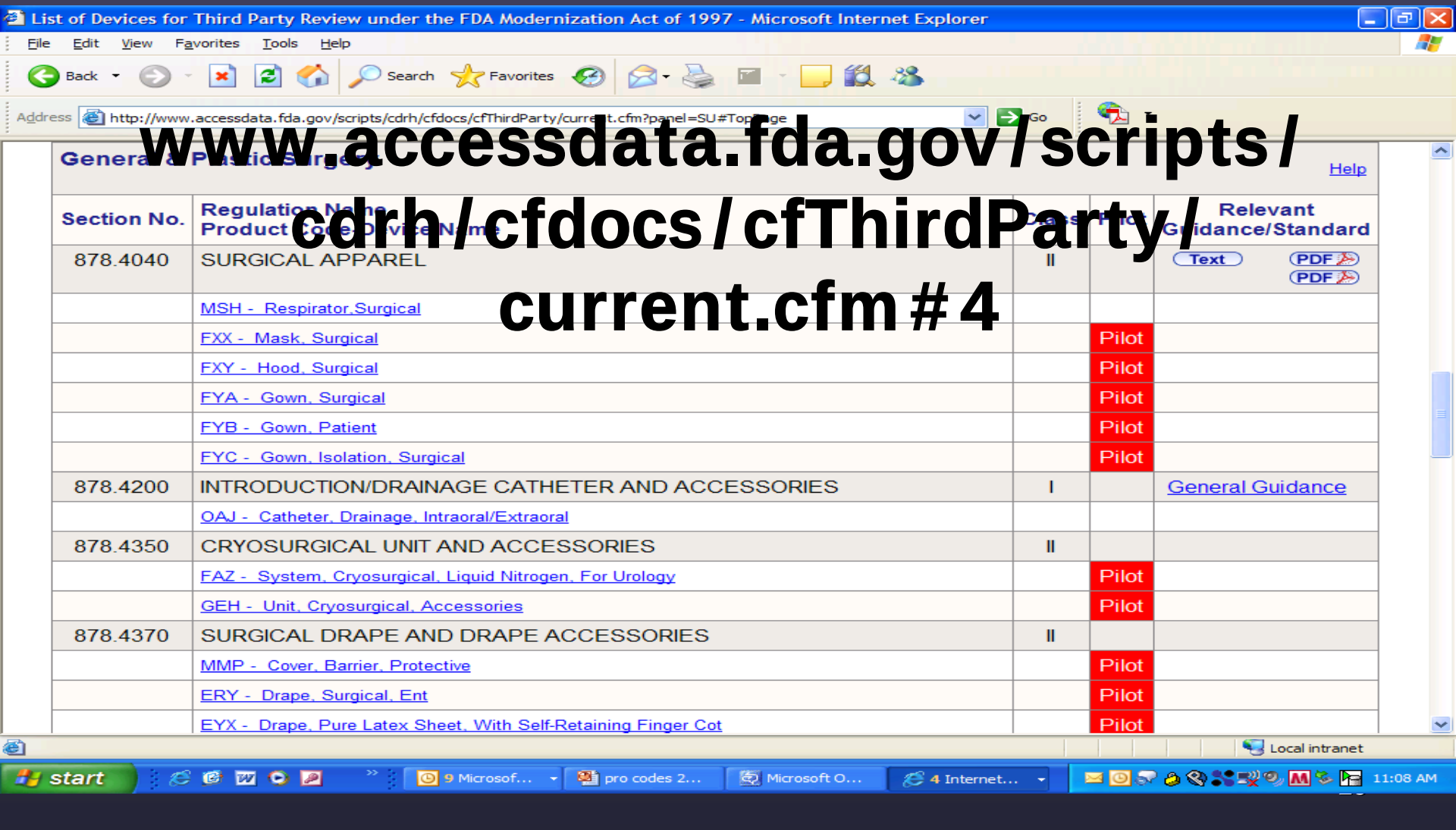


www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm

Adverse Event Reporting



Search For Third Party Eligible Device Types



Classification Database

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

Product Code Descriptions

New Search | Back To Search Results

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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240-276-4020