产品编码
建立联系....

朱莉·“布兰迪”·斯图尔特
中心产品编码协调员
消费者安全官员，510(k) 工作人员
食品和药品管理局评估办公室
医疗器械和放射健康中心

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.

1976年5月28日

医疗器械修正案

公法 94-295

TABLE OF CONTENTS

联邦法规(CFR)

1978年5月28日的医疗器械修正案要求并导致:

1700种通用器械的分类。

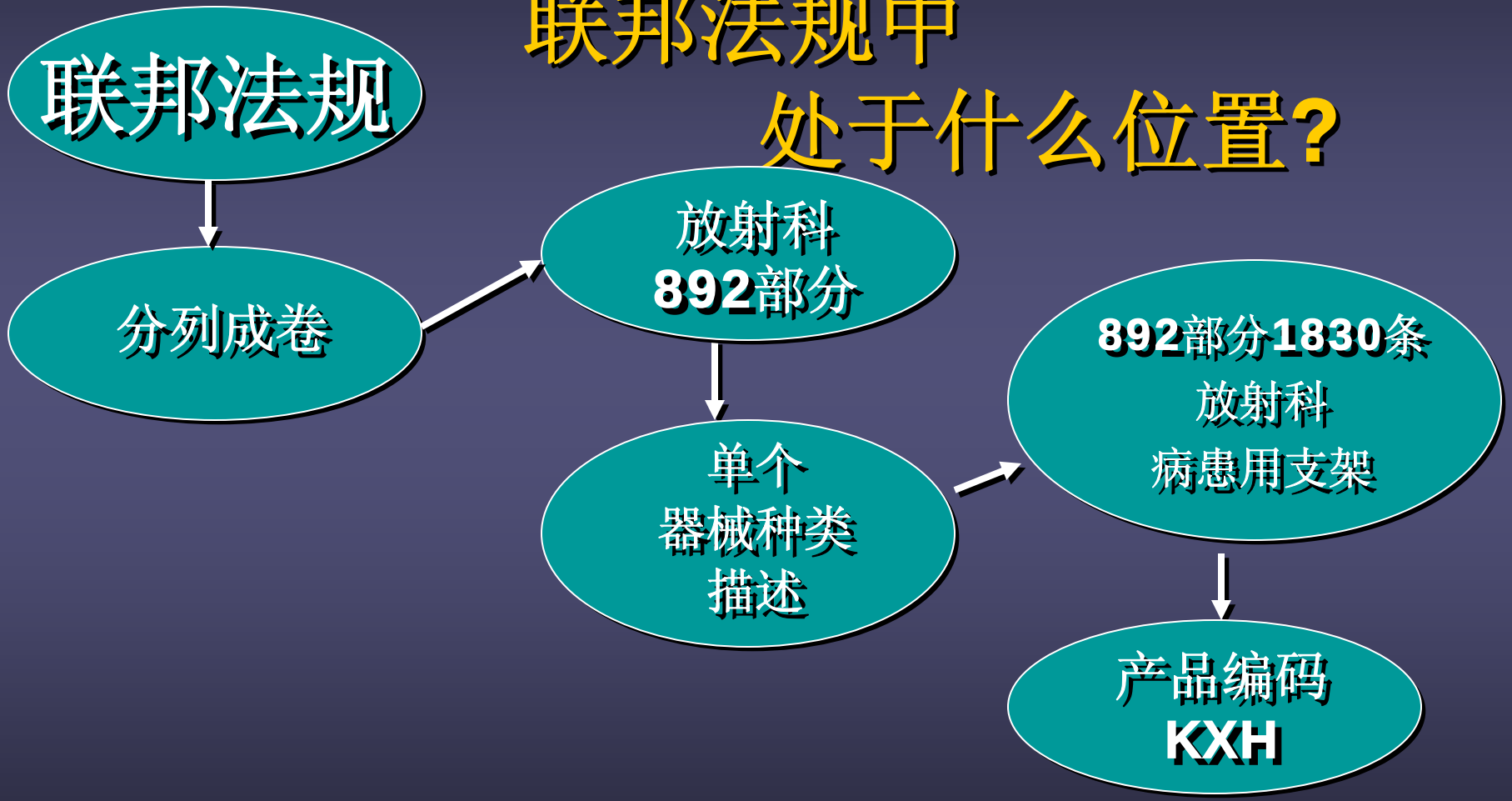
联邦法规(CFR)
第21卷第862部分-第892部分

联邦法规(CFR)
第21卷第862部分-第892部分

规定描述了1976年5月28日前存在的器械种类 (修正案前器械)。

1976年5月28日
医疗器械
修正案
公法 **94-295**

产品编码在联邦法规中处于什么位置?



FDA U.S. Food and Drug Administration

Department of Health and Human Services

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

FDA Home Page | CDRH Home Page | Search | A-Z Index

CDRH SuperSearch

510(k) | Registration & Listing | Adverse Events | PMA | Classification | CLIA

CFR Title 21 | Advisory Committees | Assembler | Recalls | Guidance | Standards

产品编码：KXH

New Search

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

目前的分类和产品编码

各种器械通过上市前审议分类，如510(k)、上市前批准（PMA）

新指定用途和新技术被设定新的产品编码，置于最初的规定之下

联邦法规描述的修正案前器械种类

872部分6865条 – 电动牙刷

电动牙刷由交流电或电池提供动力。该器械包括内装马达的手柄，以机械方式驱动一个刷子，旨在用于牙齿上。该器械的目的是从牙齿上去除牙菌斑和食物残渣，以减少牙齿腐蚀。

分类：第一类免除

产品编码信息：**JEQ**电动牙刷

相关规定：**876部分6865** 条 第一类免除

显著等同

新器械种类：离子电动牙刷

需要提交510(k)的新技术

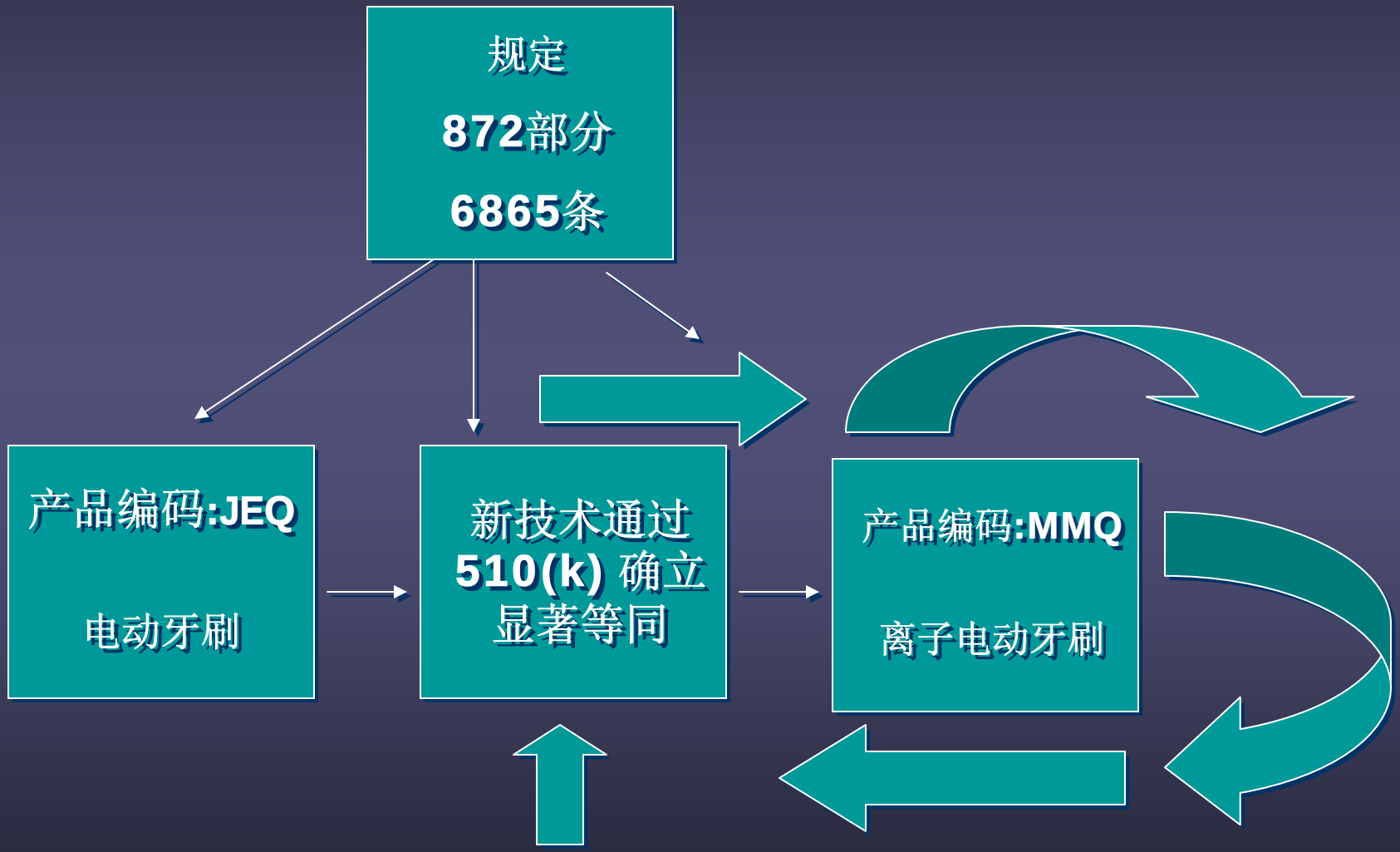
510(k) 认定和修正案前器械

存在显著等同

产品编码信息：
MMQ 离子电动牙刷

相关规定：876部分第6865条
第一类器械免除

显著等同(SE)


规定
872部分
6865条
产品编码:JEQ
电动牙刷
新技术通过
510(k) 确立
显著等同
产品编码:MMQ
离子电动牙刷

产品编码对我来说为什么重要?

最终用来为**510(k)** 和上市前批准文件中的所有器械分类。

作为一种工具，产品编码:

- 用于器械登记和注册
- 用于搜索参照器械
- 用于搜索和通报不利事件
- 用于确定符合第三方审议标准的器械
- 用于器械进出口

产品编码对我来说为什么重要?

产品编码最终用于对所有510(k)和上市前批准文件中的器械进行分类

DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

显著等同(SE)信函:

Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

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

产品编码出现在所有显著等同信函上，并可以在互联网上获得

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

登记和注册

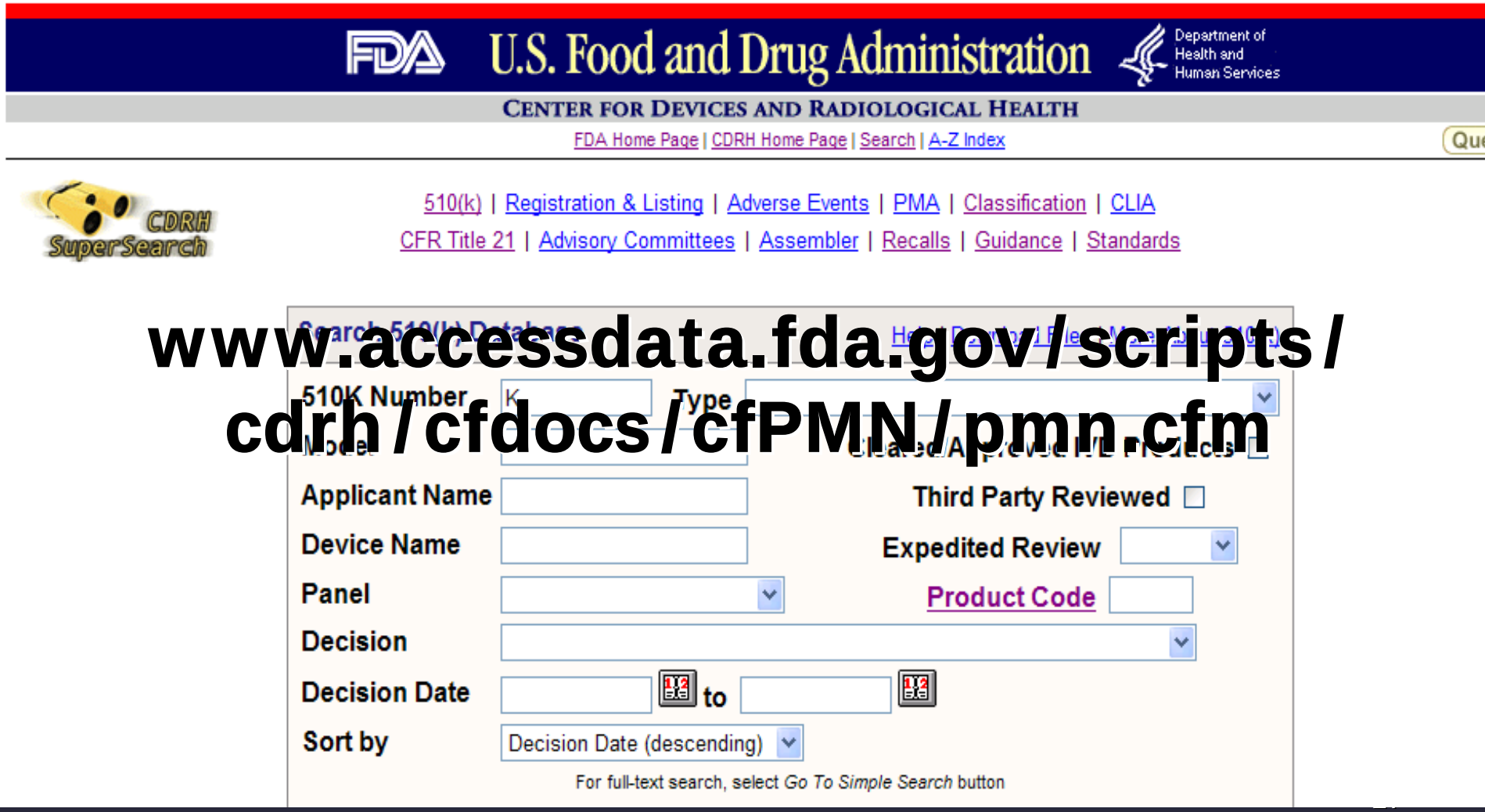
一家公司只能使用510(k)或者上市前批准申请获准文件上的产品编码注册

除非是为下列器械登记注册 . . . . . .

第一类免除器械

第二类免除器械

搜索参照器械



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

不利事件通报

FDA U.S. Food and Drug Administration — Department of Health and Human Services

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- MAUDE data represents reports of adverse events involving medical devices. The data consists of voluntary reports since June 1993, user facility reports since 1991, di reports since 1993, and manufacturer reports since August 1996. MAUDE may not include reports made according to exemptions, variances, or alternative reporting requi 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 r regarding devic[illegible] n(s) provided by th requester.

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

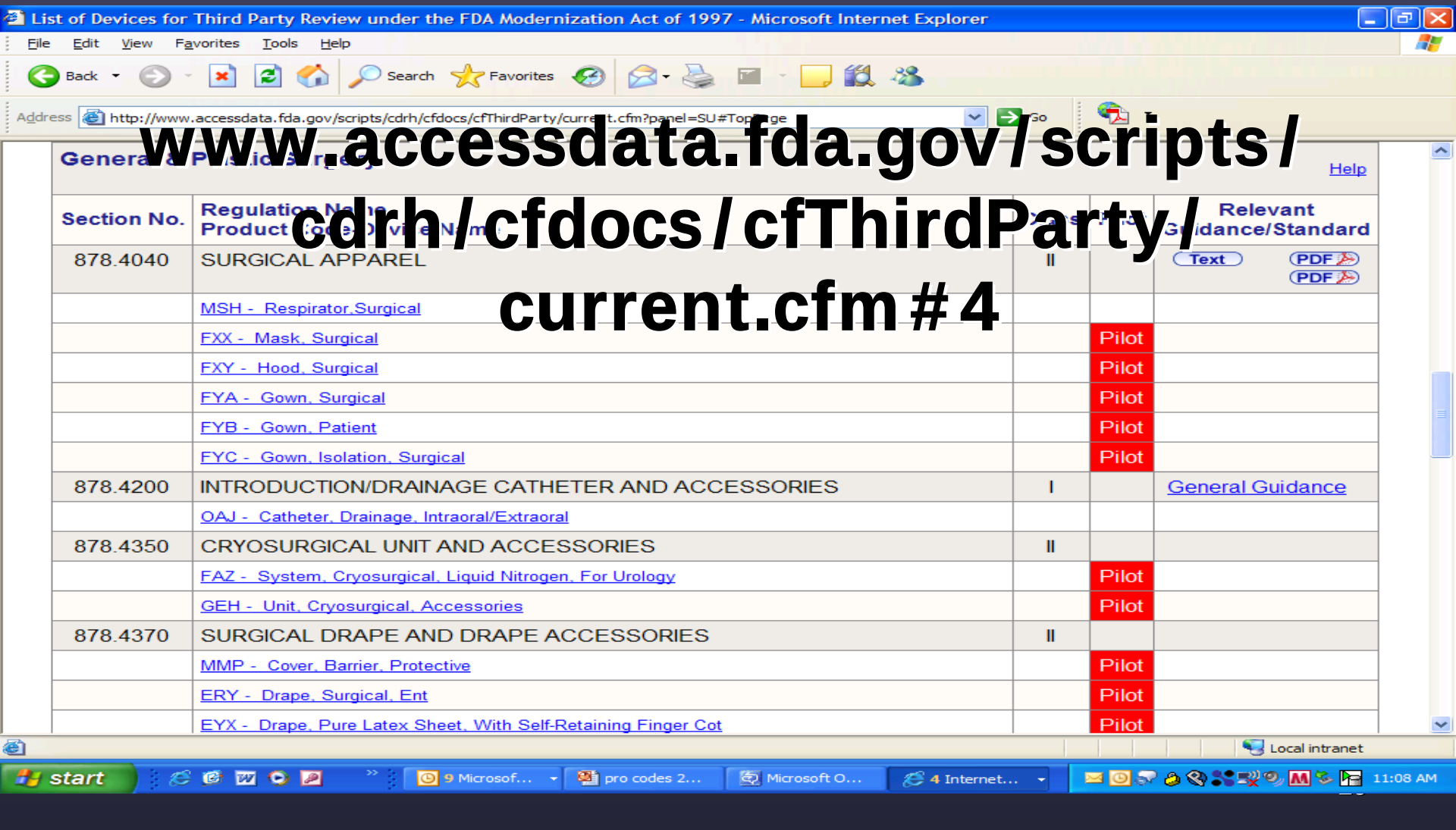
Enter *one* or a *combination* of the MAUDE Search Values and select *Search*

Product Problem			
Product Class			
Brand Name		**510K Number**	K
Manufacturer		**PMA Number**	P
Event Type		**Product Code**	

Date Report Received by FDA *(mm/dd/yyyy)* 01/01/2008 **to** 08/29/2008

For full-text search, select *Go To Simple Search* button

搜索符合第三方审批标准的器械种类



分类数据库

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

产品编码相关内容

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	

分类数据库

提供:

通往标准的链接;

通往相关指导文件的链接;

产品编码定义以及指定用途;

详细说明; 以及

第三方审批资格

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电话：240-276-4020

信息高速公路

食品和药物管理局主页： www.fda.gov
器械咨询： www.fda.gov/cdrh/devadice
搜索美国联邦注册：
www.accessdata.fda.gov/scripts/oc/ohrms/index.cfm
美国联邦法规 （CFR）：
www.fda.gov/cdrh/devadvice/365.html
美国联邦食品、药品和化妆品法：
www.fda.gov/opacom/laws/fdcact/fdctoc.htm

信息高速公路

医疗器械和放射健康中心
公开检索数据库：
www.fda.gov/cdrh/databases.html

这个网站包含了超过15个FDA
公开检索数据库

510k 显著等同决策过程

指导 & 流程图

www.fda.gov/cdrh/k863.html