Product Codes
Making the Connection....

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Consumer Safety Officer, 510(k) Staff
FDA Office of Evaluation, CDRH
PUBLIC LAW 94–295—MAY 28, 1976

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.

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

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.

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.
The May 28, 1976, Medical Device Amendments required and led to:
The classification of approximately 1,700 generic device types.
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

Product Codes Are Born
How Do Product Codes Fit In With CFR?

CFR
Organized By Panel
Radiology Part 892
Individual Device Types Described
892.1830 Radiologic Patient Cradle
Product Code KXH
<table>
<thead>
<tr>
<th>Device</th>
<th>Cradle, Patient, Radiologic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regulation Description</td>
<td>Radiologic patient cradle.</td>
</tr>
<tr>
<td>Regulation Medical Specialty</td>
<td>Radiology</td>
</tr>
<tr>
<td>Review Panel</td>
<td>Radiology</td>
</tr>
<tr>
<td>Product Code</td>
<td>KXH</td>
</tr>
<tr>
<td>Submission Type</td>
<td>510(k) Exempt</td>
</tr>
<tr>
<td>Regulation Number</td>
<td>892.1830</td>
</tr>
<tr>
<td>Device Class</td>
<td>1</td>
</tr>
<tr>
<td>GMP Exempt?</td>
<td>No</td>
</tr>
</tbody>
</table>

**Note:** FDA has exempted almost all class I devices (with the exception of [Reserved Devices](#)) from the premarket notification process.
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)

REGULATION 872.6865

Pro Code:JEQ Powered Toothbrush

New Technology via 510(k) Found SE

Pro Code:MMQ Powered Ionic Toothbrush
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 to 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

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
Adverse Event Reporting

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

- MAUDE data represents reports of adverse events involving medical devices. The data consists of voluntary reports since June 1993, user facility reports since 1991, direct 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 MAUDE does not have a summary of data that may be used in the search for adverse reports that contain the same term(s) provided by the requester.
## Search For Third Party Eligible Device Types

Visit the website [www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfThirdParty/current.cfm#4](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfThirdParty/current.cfm#4) to search for third-party eligible device types.

### General & Public Surgery

<table>
<thead>
<tr>
<th>Section No.</th>
<th>Regulation Name</th>
<th>Product Code</th>
<th>Eligibility</th>
<th>Relevant Guidance/Standard</th>
</tr>
</thead>
<tbody>
<tr>
<td>878.4040</td>
<td>SURGICAL APPAREL</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>MSH - Respirator Surgical</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>FXX - Mask, Surgical</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>FXY - Hood, Surgical</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>FYA - Gown, Surgical</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>FYB - Gown, Patient</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>FYC - Gown, Isolation, Surgical</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>878.4200</td>
<td>INTRODUCTION/DRAINAGE CATHETER AND ACCESSORIES</td>
<td></td>
<td>General Guidance</td>
<td></td>
</tr>
<tr>
<td></td>
<td>OAJ - Catheter, Drainage, intraoral/extraoral</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>878.4350</td>
<td>CRYOSURGICAL UNIT AND ACCESSORIES</td>
<td></td>
<td>Pilot</td>
<td></td>
</tr>
<tr>
<td></td>
<td>FAZ - System, Cryosurgical, Liquid Nitrogen, For Urology</td>
<td></td>
<td>Pilot</td>
<td></td>
</tr>
<tr>
<td></td>
<td>GEH - Unit, Cryosurgical, Accessories</td>
<td></td>
<td>Pilot</td>
<td></td>
</tr>
<tr>
<td>878.4370</td>
<td>SURGICAL DRAPE AND DRAPE ACCESSORIES</td>
<td></td>
<td>Pilot</td>
<td></td>
</tr>
<tr>
<td></td>
<td>MMP - Cover, Barrier, Protective</td>
<td></td>
<td>Pilot</td>
<td></td>
</tr>
<tr>
<td></td>
<td>ERY - Drape, Surgical, Ent</td>
<td></td>
<td>Pilot</td>
<td></td>
</tr>
<tr>
<td></td>
<td>FXY - Drape, Pure Latex Sheet, With Self-Retaining Finger Cot</td>
<td></td>
<td>Pilot</td>
<td></td>
</tr>
</tbody>
</table>
## Classification Database

The Classification Database is a resource provided by the U.S. Food and Drug Administration (FDA), specifically within the Center for Devices and Radiological Health (CDRH). It allows users to search for product classifications and is accessible through the URL `www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm`.

The database interface includes several search options, such as:
- **Device**: Enter the name of the device.
- **Product Code**: Enter the product code.
- **Review Panel**: Select a panel.
- **Regulation Number**: Enter the regulation number.
- **Sort By**: Select sorting criteria (Device Name, Device Class).

For a full-text search, users can select the `Go To Simple Search` button. The database is updated on 08/06/2008.
# Product Code Descriptions

## Product Classification Database

<table>
<thead>
<tr>
<th>Device</th>
<th>Elisa, Antibody, West Nile Virus</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regulation Description</td>
<td>West Nile virus serological reagents.</td>
</tr>
<tr>
<td>Definition</td>
<td>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.</td>
</tr>
<tr>
<td>Regulation Medical Specialty</td>
<td>Microbiology</td>
</tr>
<tr>
<td>Review Panel</td>
<td>Microbiology</td>
</tr>
<tr>
<td>Product Code</td>
<td>NOP</td>
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<tr>
<td>Submission Type</td>
<td>510(k)</td>
</tr>
<tr>
<td>Regulation Number</td>
<td>866.3940</td>
</tr>
<tr>
<td>Device Class</td>
<td>2</td>
</tr>
<tr>
<td>GMP Exempt?</td>
<td>No</td>
</tr>
<tr>
<td>Guidance Document</td>
<td></td>
</tr>
</tbody>
</table>

New Search | Back To Search Results
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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