Device Classification - Is Your Device a Medical Device?

New product development within any organization utilizes many resources to determine the efficacy of a product. Will it meet the customers’ needs? Are there competing products? Will the product sell? Developing products that have a purpose in improving lives, additional resources are needed to determine the classification of the product. The Food and Drug Administration, FDA, is a valuable source of information in that determination. It only makes sense to take advantage of a source like the FDA to determine if your product meets the definition of a ‘device’. If it does, there are FDA requirements that apply. First, see the definition below.

Medical Device Definition

Medical devices range from simple tongue depressors and bedpans to complex programmable pacemakers with microchip technology and laser surgical devices. In addition, medical devices include in vitro diagnostic products, such as general purpose lab equipment, reagents, and test kits, which may include monoclonal antibody technology. Certain electronic radiation emitting products with medical application and claims meet the definition of medical device. Examples include diagnostic ultrasound products, x-ray machines and medical lasers. If a product is labeled, promoted or used in a manner that meets the following definition in section 201(h) of the Federal Food Drug & Cosmetic (FD&C) Act it will be regulated by the Food and Drug Administration (FDA) as a medical device and is subject to premarketing and postmarketing regulatory controls. A device is:

- "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article,
including a component part, or accessory which is:

- recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
- intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
- intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes."

This definition provides a clear distinction between a medical device and other FDA regulated products such as drugs. If the primary intended use of the product is achieved through chemical action or by being metabolized by the body, the product is usually a drug. Human drugs are regulated by FDA's Center for Drug Evaluation and Research (CDER). Biological products which include blood and blood products, and blood banking equipment are regulated by FDA's Center for Biologics Evaluation and Research (CBER). FDA's Center for Veterinary Medicine (CVM) regulates products used with animals. If your product is not a medical device but regulated by another Center in the FDA, each component of the FDA has an office to assist with questions about the products they regulate. In cases where it is not clear whether a product is a medical device there are procedures in place to use DSMICA Staff Directory to assist you in making a determination.

**Steps to Determine if a Product is a Medical Device**

**Step One:**
Access: CDRH Classification Database.


The classification database contains products we consider devices and the associated codes developed by the FDA to support its regulatory and administrative processes. If you find a name that describes your product, in all but a few instances, it is a device regulated by the FDA.

Search the product classification database at CDRH Classification Database. If you use the advance search form, it is recommended that you enter only one word or search term for "device" in the search criteria. You may narrow your search by completing other search criteria; however, this may also limit your results.

The following is an example of the partial results you will receive from your search.

**Product Classification Database**

<table>
<thead>
<tr>
<th>Device</th>
<th>Condom</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regulation Description</td>
<td>Condom.</td>
</tr>
<tr>
<td>Regulation Medical Specialty</td>
<td>Obstetrics/Gynecology</td>
</tr>
<tr>
<td>Review Panel</td>
<td>Obstetrics/Gynecology</td>
</tr>
<tr>
<td>Product Code</td>
<td>HIS</td>
</tr>
<tr>
<td>Submission Type</td>
<td>510(k)</td>
</tr>
<tr>
<td>Regulation Number</td>
<td>884.5300</td>
</tr>
<tr>
<td>Device Class</td>
<td>2</td>
</tr>
<tr>
<td>GMP Exempt?</td>
<td>No</td>
</tr>
</tbody>
</table>

Copy or print this information from the search results for future reference.
Then click the back button in your web browser twice to return to this page and continue with Step Two.

**Step Two:**

**Access: Contacts For Device / Not A Device Decision**

If the preceding information does not result in your determining whether your product is a device as defined by section 201(h) of the Federal Food, Drug and Cosmetic Act, you may contact Mr. Bryan H. Benesch, Device Determination Officer, Office of Compliance, at (301) 796-5506, send him a fax at (301) 847-8136, or e-mail him at bryan.benesch@fda.hhs.gov.

**Information Sources to help in determining if you have a medical device**

**Links:**

**FDA:**
[http://www.fda.gov/default.htm](http://www.fda.gov/default.htm)

**Classification Databases:**

**Federal Food, Drug, and Cosmetic Act (FD&C Act):**