Medical Device Classification

The Food and Drug Administration (FDA) has established classifications for approximately 1,700 different generic types of devices and grouped them into 16 medical specialties referred to as panels. Each of these generic types of devices is assigned to one of three regulatory classes based on the level of control necessary to assure the safety and effectiveness of the device. The three classes and the requirements which apply to them are:

Device Class and Regulatory Controls

1. Class I General Controls
   - With Exemptions
   - Without Exemptions

2. Class II General Controls and Special Controls
   - With Exemptions
   - Without Exemptions

3. Class III General Controls and Premarket Approval

The class to which your device is assigned determines, among other things, the type of premarketing submission/application required for FDA clearance to market. If your device is classified as Class I or II, and if it is not exempt, a 510k will be required for marketing. All devices classified as exempt are subject to the limitations on exemptions. Limitations of device exemptions are covered under 21 CFR xxx.9, where xxx refers to Parts 862-892. For Class III devices, a premarket approval application (PMA) will be required unless your device is a preamendments device (on the market prior to the passage of the medical device amendments in 1976, or substantially equivalent to such a device) and PMA's...
have not been called for. In that case, a 510k will be the route to market.

Device classification depends on the intended use of the device and also upon indications for use. For example, a scalpel's intended use is to cut tissue. A subset of intended use arises when a more specialized indication is added in the device's labeling such as, "for making incisions in the cornea". Indications for use can be found in the device's labeling, but may also be conveyed orally during sale of the product. A discussion of the meaning of intended use is contained in Premarket Notification Review Program K86-3.

In addition, classification is risk based, that is, the risk the device poses to the patient and/or the user is a major factor in the class it is assigned. Class I includes devices with the lowest risk and Class III includes those with the greatest risk.

As indicated above, all classes of devices are subject to General Controls. General Controls are the baseline requirements of the Food, Drug and Cosmetic (FD&C) Act that apply to all medical devices, Class I, II, and III.

How to Determine Classification

To find the classification of your device, as well as whether any exemptions may exist, you need to find the regulation number that is the classification regulation for your device. There are two methods for accomplishing this: go directly to the classification database and search for a part of the device name, or, if you know the device panel (medical specialty) to which your device belongs, go directly to the listing for that panel and identify your device and the corresponding regulation.

Device Panels
If you already know the appropriate panel you can go directly to the CFR and find the classification for your device by reading through the list of classified devices, otherwise, you can use the product code classification database. In most cases this database will identify the classification regulation in the CFR.

Each classification panel in the CFR begins with a list of devices classified in that panel. Each classified device has a 7-digit number associated with it, e.g., 21 CFR 880.2920 - Clinical Mercury Thermometer. Once you find your device in the panel's beginning list, go to the section indicated: in this example, 21 CFR 880.2920. It describes the device and says it is Class II. Similarly, in the Classification Database under "thermometer", you'll see several entries for various types of thermometers. The three letter product code, FLK in the database for Clinical Mercury Thermometer, is also the classification number which is used on the Medical Device Listing form.

Once you have identified the correct classification regulation go to device panels and find correct classification regulation or go to the CFR Search page. Some Class I devices are exempt from the
premarket notification and/or parts of the good manufacturing practices regulations. Approximately 572 or 74% of the Class I devices are exempt from the premarket notification process. These exemptions are listed in the classification regulations of 21 CFR and also have been collected together in the Medical Device Exemptions document.

Sources:

FDA:  
http://www.fda.gov/default.htm

Classification Databases:  


Premarket Notification Review Program K86-3:  
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm081383.htm

Device Panel:  
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/ucm051530.htm

CFR - Code of Federal Regulations Title 21:  

Medical Device Exemptions:  