# How is My Medical Device Classified?

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Hello, my name is Commander Kimberly Piermatteo of the United States Public Health Service and I am a Consumer Safety Officer within the Center for Devices and Radiological Health's Division of Industry and Consumer Education at FDA. Welcome to CDRH learn, CDRH's resource for multimedia industry education. This CDRH Learn module addresses the question "how is my medical device classified?" Once you determine that your product would be regulated as a medical device the next step is to determine how your medical device is classified and what regulatory requirements apply to your device.

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After watching this module, I hope you will gain a better understanding of how to classify your medical device and identify the applicable regulatory requirements for your device. I also encourage you to watch the companion CDRH Learn module which walks through a case study on how to classify a medical device using the various methods discussed in this module.

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I will address the following four learning objectives during this module. First, I'll discuss how the FDA classifies medical devices. Next, I'll discuss the different regulatory requirements for medical devices based on their class. Then I'll briefly go over different classifications methods you may use to help you determine the class of your medical device. And, lastly, I'll identify ways for you to request additional assistance if needed.

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Let's first review the different medical device classes and the regulatory requirements that apply to each class.

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The FDA regulates medical devices based on risk, that is, the risk the device poses to the patient and/or user. The risk is a major factor in determining which class it is assigned. Subsequently, the class of the device then determines the extent of regulatory controls that are necessary to provide reasonable assurance of a device's safety and effectiveness.

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The FDA classifies all medical devices into one of three regulatory classes. Medical devices may be classified as class I, class II or class III. As I discuss each class of medical devices, I will fill in the middle columns of this table looking at the columns titled device risk and potential harm, as well as applicable regulatory controls and submission types or exemption for each device class.

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The risk of the device determines whether the device will be considered Class I, II or III. Within the table provided on this slide, I have filled in the risk and potential harm columns for each device class. Class I devices are considered to be the lowest risk and present minimal potential for harm to the patient or user. Class II devices are considered moderate risk and present a higher risk than class one devices. Class III devices are considered the highest risk devices and these devices may sustain or support life, be implanted or present the potential for unreasonable risk of illness or injury.

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Next in the table I'm going to discuss regulatory controls. However, I'd like to define what regulatory controls are first before I fill in the table.

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Regulatory controls are referred to as either general, special or premarket approval controls. They may apply to a particular device type and are generally broad, but they may be device specific. Regulatory controls describe the appropriate level of regulatory oversight necessary to ensure reasonable assurance of a device's safety and effectiveness. More information on regulatory controls can be found on the link provided at the bottom of this slide.

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Referring back to the classes of medical devices table, regulatory control increases from Class I to Class III. Devices in all three classes are subject to general controls, unless exempted by the regulations. In addition to complying with general controls, Class II devices may also be subject to special controls. Class III devices must comply with general controls as well as Premarket Approval controls.

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This slide provides examples of some general controls, which apply to all medical device classes. A few examples of general controls from the table provided on this slide include requirements for companies to register their establishments and list the medical devices they market with the FDA; as well as the requirement to manufacture their devices in accordance with Good Manufacturing Practices; and the requirement to label their devices in accordance with the FDA's labeling regulations. If a device is exempted from a specific general control, such an exemption would be stated in the classification regulation for that particular device.

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Class II devices may also be subject to special controls, which would be identified by the FDA and may include special labeling requirements, or design characteristics or specifications, or compliance with a particular performance standard or testing. There may also be a Special Controls guidance document for a particular device type outlining any of these.

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Class III devices are typically life supporting or life sustaining, therefore, due to the level of risk associated with Class III devices, general and special controls alone are insufficient to assure the safety and effectiveness of Class III devices. These devices must obtain Premarket Approval prior to marketing. A Premarket Approval Application, or a PMA, is the most stringent type of device marketing application. PMA requirements are outlined within the code of federal regulations or CFR, under section 814 specifically. Examples of Class III devices that require PMA are intraocular lenses and mechanical heart valves.

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The next column in the classes of medical devices table discusses the applicable submission type for each class or if there is not an applicable submission type, whether there may be an exemption. Most Class I devices are exempt from the Premarket Notification or 510(k) requirements. Most Class II devices require Premarket Notification or 510(k) clearance prior to marketing. There are some Class II devices which are 510(k) exempt, as long as the device complies with FDA defined special controls. And lastly, Class III devices require Premarket Approval prior to marketing. For more information on exemptions and any limitations to those exemptions, you may refer to the webpage titled, Class I and II exemptions.

A link to this webpage is provided at the end of this module on the resources slides. Links to the FDA's webpages on 510(k) and PMA are also provided on the resources slides at the end of this module.

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When I discuss the device class and the extent of regulatory requirements, I think it is important to mention FDA product codes. FDA product codes are three letter codes used to identify and track similar devices. If you are able to determine the appropriate FDA product code for your device, you can then easily determine the applicable regulatory requirements. Product codes can be found by searching the FDA's public product classification database. On this slide, I've provided a screen shot of this database as well as a link to this database.

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Another point I'd like to make is within the CFR, the FDA has classified various device types based on risk. Each regulation number may have one or more associated product codes which are classified differently and have different regulatory requirements. For example, the regulation number 21 CFR 870.1875 has four different product codes under this one regulation number. As displayed in the table, a manual stethoscope is considered to be Class I and 510(k) exempt under the product code LDE, whereas an electronic stethoscope, which falls under the same regulation number, has a different product code, is considered Class II and is not 510(k) exempt. The point to remember here is that when classifying a medical device, it is very important to drill down all the way to the appropriate FDA product code, and not just to the class or regulation number. Determining the appropriate product code will help you determine the extent of regulatory requirements for your device.

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To complete the classes of medical devices table, the last column provides you some insight into the percentage of devices in each class. Out of all the regulated medical devices, roughly 35% are considered to be Class I, 53% are considered Class II and 9% are considered Class III. As noted by the asterisk, roughly 3% of devices are unclassified. An unclassified device is a device which was in commercial distribution, prior to the medical device amendments of 1976, and for which has not yet been classified into Class I, II or III.

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Next, I'm going to discuss three classification determination methods. These methods are not the only methods available to you, but ones which I find helpful when determining how a medical device may be classified. During this module I will briefly discuss these methods. I encourage you to watch the companion CDRH Learn module within which I cover each of these methods in more details using a specific case study.

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The three methods I find useful when determining the classification of a medical device are: one, to directly search for the appropriate product classification; two, to search for a similar device by its clearance or approval; and third, to search for a similar device by device listing.

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The first method I recommend is to search directly for an appropriate product classification in the FDA's public Product Classification database. A link to this database is provided on this slide. You can search this database to identify an appropriate FDA product code which then based on the product code you

can review the regulatory requirements for that particular device type. This method is the most common and often used.

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The second method is useful if you know of a similar device already being marketed. You can work backwards by determining how the similar device has been classified based on its 510(k) clearance or PMA approval and then determine if the same classification applies to your proposed device. For this method you would only be able to search for devices which received 510(k) clearance or Premarket approval. Since most Class I devices and some Class II devices are exempt from 510(k) clearance and do not require PMA approval, you would not be able to find these devices and determine how they are classified using this method.

One note I'd like to make is - if a device has been classified but it did not receive 510(k) clearance or PMA approval, it may have obtained marketing authorization through a De Novo. The De Novo pathway provides a possible route to classify novel devices of low to moderate risk. If you think a similar device was the first new, novel device type, then this first marketing authorization would not be found in the 510(k) clearance database. You would need to search the De Novo database to find this first classified device under the newly created regulation. Links to all three public databases have been provided on this slide and on the resources slides at the end of this module.

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The third method I recommend is to search for a similar device by device listing. This method is useful when determining how a currently marketed device is classified because establishment registration and device listing are a general control, meaning all medical device establishments currently marketing a device in the United States must be registered with FDA and list their devices.

So, if you know of a similar device currently being marketed you can search for it by its listing and see if the same product classification applies to your device. A link to the FDA's public Establishment Registration and Device Listing database is provided on this slide.

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If you are unable to determine the appropriate product classification for your proposed device, you may consider requesting additional assistance from the FDA.

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For informal assistance, you may contact the Division of Industry and Consumer Education or DICE. DICE staff can provide further guidance on conducting any of the three search methods discussed in this module. DICE staff may be reached at the phone number or email provided on this slide. Please note, responses to such informal assistance are not classification decisions and do not constitute FDA clearance or approval for commercial distribution.

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If you would like to request a formal product classification from the FDA, you should consider submitting a 513(g) Request. Section 513(g) of the Federal Food, Drug and Cosmetic Act, or the FD&C Act, provides a means for obtaining the agency's views about the product classification and regulatory requirements that may be applicable to a particular device.

For instructions on how to submit a 513(g) Request, refer to the FDA guidance document titled FDA and Industry Procedures for Section 513(g) Requests for Information under the Federal Food, Drug and Cosmetic Act. A link to this guidance is provided on this slide.

Keep in mind a response to a 513(g) Request does not constitute FDA clearance or approval for commercial distribution, meaning if FDA's response to a 513(g) Request states a 510(k) clearance for the described device is required, a 510(k) clearance must be obtained prior to marketing.

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In summary, medical devices are classified based on risk, and the risk of the device determines the extent of regulatory controls. When determining the applicable class and regulatory requirements for a device, searching the FDA public databases can be helpful.

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Additional resources and links are provided on the…

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next few slides. I will not cover them in detail…

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but they are provided for your reference as needed.

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CDRH provides multiple opportunities for industry education. On this slide, I have provided you links to CDRH Learn which consists of numerous learning modules covering a wide range of medical device topics; as well as Device Advice, which is a text-based resource and lastly, you may contact the Division of Industry and Consumer Education or DICE by phone or email with questions.

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For this module, my call to action for you is, to evaluate the risk of your device to determine the appropriate class and regulatory controls necessary to ensure its safety and effectiveness. As well as become familiar with the three methods for determining classification which can be instrumental when determining how your medical device may be classified. If you would like more details on the three methods discussed, be sure to watch the companion CDRH Learn module titled, Case Study - How is My Medical Device Classified.

Thank you for watching and I hope you found this module to be useful.

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