

CDRH Industry Basics: 513(g) Requests for Information

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Good afternoon, my name is Ifeanyi Uwemedimo and I am a device determination policy analyst in the Office of Regulatory Programs in CDRH. I am currently responsible for the device determination mailbox. Welcome to this presentation on 513(g) Requests for Information.

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You have a product and you're not sure whether the product is a medical device and, if yes, how FDA classifies it. What do you do? The purpose of this presentation is to provide information on how FDA addresses device determination and classification inquiries.

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During this presentation, I will describe how FDA addresses device determination inquiries. I will outline the 513(g) request process, and address when it is best to send an informal inquiry to the device determination mailbox, or submit a formal 513(g) request for information.

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Before we delve into how a device determination is made or what a 513(g) is, it's important to first understand how FDA defines medical device. So, what is a medical device? The complete definition of a medical device is provided in Section 201(h) of the Food Drug and Cosmetic Act, also known as the FD&C Act.

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Without reading the full definition, in summary, a medical device is a device that is intended to be used for a medical purpose and can affect the structure or function of the body. In other words, the device can be used to diagnose a disease or condition. It could also be used to cure, mitigate, treat or prevent a disease or condition.

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The first bullet on this slide is typically what distinguishes a medical device from a drug. It is important to note that a medical device does not achieve its primary intended purpose through chemical action. In other words, it does not require a chemical to be metabolized or processed in the body to impart the intended use. If a chemical action is required, the product is most often a drug and not a device. The term "device" generally does not include the software functions excluded under section 520(o).

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It's important to note that medical devices are also classified based on the level of risk. Low risk devices are classified as Class I, Moderate risk devices are Class II, and High risk devices are regulated as Class III devices. The risk level or class also helps to determine the type of premarket submission such as 510(k) or PMA that's required to determine device safety and effectiveness

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Class III devices require submission of a Premarket Approval Application, also known as PMA. PMAs are the most stringent pre-market submission and typically require clinical data. Most Class II devices require Premarket Notification or 510(k) submissions and these typically do not require clinical data. Less than 15% of 510(k) submissions received annually require clinical data. Lastly, the majority of Class I devices do not require a 510(k). However, there is a very small percentage that do require a 510(k).

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The De Novo classification pathway was established in 1997. While it's not mentioned in the pyramid on the previous slide, the De Novo pathway is an alternative pathway intended for novel low to moderate risk devices. When we say that a device is novel, it means that FDA has never seen or regulated a similar device. It's important to note that novel medical devices are automatically placed into Class III.

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There are a number of different medical device categories. I won't go through each one in detail. Device categories may include diagnostic devices, such as blood glucose monitors, and therapeutic devices, such as CPAP devices. We also have a category of devices known as general wellness products. These products are low risk devices intended to promote the general wellness of a patient. As technology continues to advance, these categories will continue to expand. We also included Mobile medical applications, also known as MMAs, that meet the definition of a medical device. For example, there are MMAs that can be used to monitor heart conditions.

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Now, that you understand how FDA defines a medical device and the different classifications, you are now in a better position to determine whether your product is a medical device.

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This slide shows the steps that can be taken to further address your device determination inquiry. To determine if a product is a medical device, it's important to understand the technology and intended use of the device.

The next step is to determine whether it meets FDA's definition of a medical device. In other words, is it intended to treat, diagnose, cure or mitigate a disease or condition?

When FDA makes a device determination, we use our existing databases, such as the product code, 510(k) and De Novo database to look for similar devices and existing regulations. These databases are available to the public, so you can also perform a similar search. However, once you have done your own research and you are still unsure about whether the product is a medical device, you can contact us. In the next few slides, we will go through the different mechanisms for obtaining feedback from us.

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There are two mechanisms for obtaining device determination feedback from FDA. The first option is the informal approach, where you can send an email to the device determination mailbox. The second option is the more formal approach, where you can submit a 513(g) Request to FDA. We will discuss these mechanisms in the next few slides.

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If you have a simple question that you believe can be addressed quickly, sending a device determination email inquiry is usually the best initial approach. To help us make a device determination, please include a brief device description, clear intended use, and a list of all labeling claims in your email. In the device description, it helps when the device mechanism of action is described. In other words, how does the device accomplish its intended use? If available, provide a list or picture of the labeling claims. This will help us better understand the device, especially when the technology is novel, and will also help us determine if they are medical in nature. The totality of this information is used to make a device determination.

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Here's an example of an email that would be appropriate to send to the device determination mailbox. I have a heat pack made of fabric that contains oats. The pack is heated in the microwave and can be reused. The heat pack is intended to provide pain relief and an increase in blood circulation. Is my product a medical device regulated by the FDA?

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FDA provides a brief informal device determination response, and if there is information we believe could be helpful, such as a safety communication or a guidance document, we may include that information as well. Before we provide our response to the heat pack, I want to note that we typically provide a response within 7 days, and if you don't hear back from us, we recommend reaching out again. We receive a large volume of emails and do our best to address them within a reasonable timeframe. There are situations where an inquiry is not truly simple, especially in situations where the product crosses different expertise and our subject matter experts need more time and information to provide an adequate response. In this situation, we would recommend submission of a 513(g) request.

An example of a complex question could be a question such as, “I have a virtual reality game that helps to treat Alzheimer’s.” While video gaming is not something we typically regulate, the Alzheimer claim is a medical claim that warrants further review particularly by our subject matter experts. In such a situation, a 513(g) Request would be recommended.

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As I mentioned in the previous slide, FDA’s response is often brief. Our response to the heat pack inquiry example indicates that the product is a medical device. This decision was based on the medical intended use pertaining to pain relief and increased blood circulation. I also want to note that the feedback we provide via email is not binding. Additionally, our response is not a classification decision and does not constitute FDA clearance or approval for commercial distribution of a product.

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The other option is a formal 513(g) Request for Information. So, what is a 513(g)? A 513(g) is a request for classification information and regulatory requirements for a particular product. 513(g) Requests are also referred to as 513(g)s, in short.

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Most 513(g) submissions typically do not exceed 15 pages. This slide lists the information we recommend including in a 513(g) in order to help us make a device determination and classification recommendation. This includes the cover letter, device description, the device intended use, and labeling claims. Please reference the guidance listed on this slide for additional information. In the next few slides we’ll discuss each of these.

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The cover letter is usually a page long and it should provide an overview of what is enclosed in the package. It should include the date of the request, company name, contact person, device name, contact information and the questions you have for FDA.

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The device description should be clear and brief, and as I previously mentioned, explaining how the device accomplishes its intended use is very helpful. A picture or schematic of the device helps us to conceptualize how the device works. In your description, please also include the patient population and the disease or condition the device is intended for.

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The intended use of the device is supposed to specify what the device is used for or its physiological purpose. For example, the device is intended to remove body fat.

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Labeling claims are usually promotional claims that are made beyond the intended use of the device. Assessment of these claims helps us to determine if a product is a medical device, the level of risk, and if performance data is required to support the claim. An example claim for a device is “the device removes 10% of body fat”. Such a claim would typically need to be supported by performance data.

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Questions associated with device determination, classification, and regulatory pathway are appropriate for a 513(g). Questions beyond that scope are not appropriate. Sometimes we see questions pertaining to performance data where the submitter is asking whether performance data is needed or appropriate. These types of questions are not appropriate for a 513(g). They are more appropriate for a Q-submission. Questions pertaining to requests for reclassification are not appropriate. For example, if you have a Class II device and you believe your device is also Class I, the 513(g) process is not the appropriate mechanism for addressing this issue. FDA has a separate reclassification process. FDA’s 513(g) response only addresses inquiries appropriate for a 513(g).

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This slide provides a very high-level overview of the 513(g) review process. All 513(g)s are received via CDRH’s document control center. 513(g)s are associated with a user fee and have ecopy requirements. These requirements are checked before a submission is assigned to a lead reviewer in a Division. The lead reviewer provides a review and recommendation. Final concurrence is then provided by senior management before the letter is issued to the submitter. For additional information on the FDA user fee program and eCopy requirements, please refer to the links provided on this slide.

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The lead reviewer makes a device determination and classification recommendation based on the technology, intended use, and medical claims associated with a device. As part of the review process, we refer to the regulations and consider precedent set by existing medical devices. During the review, the lead reviewer may ask for additional information if it’s needed to help make a recommendation. Additionally, the lead reviewer may work with internal subject matter experts during the course of a review. A recommendation is provided within 60 calendar days.

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FDA provides a response via a formal letter. The letter specifies whether or not the product is a medical device. If it is a medical device, we provide a recommended classification based on the information provided.

There are situations where we might not indicate a classification, especially in situations where the product falls under enforcement discretion. We also recommend the appropriate regulatory pathway. In other words, we indicate which pre-market requirements are appropriate for the device. If there are available resources associated with the device, such as a guidance document, we may include a link to the resource as well.

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This slide shows an example 513(g) Letter. 513(g) letters typically do not exceed two pages. The letter covers, among other things, the device determination, classification, and the type of premarket submission required, if applicable.

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It's important to note that information received via the mailbox or a 513(g) is not binding and does not constitute FDA clearance or approval for commercial distribution. Additionally, information that we receive either via the mailbox or 513(g) is confidential. We do not post 513(g) letters or recommendations on a database like we do for most of our program areas.

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If you have questions on how to submit a 513(g) or how much it would cost, FDA has a number of resources, including guidance documents, available to help you. We also have a website that explains the steps to take to determine whether a product is a medical device.

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We get a lot of questions about general wellness products, mobile medical apps, and software as a medical device. We also have guidance documents to help you better understand these product areas. These guidance documents are all available on FDA's website.

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FDA also provides video training modules for your viewing pleasure on CDRH Learn and a text-based resource at Device Advice. Additionally, if you have a general question and want to talk to someone, do not hesitate to contact the Division of Industry and Consumer Education, also known as DICE for short.

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In summary, a product is considered a medical device if it meets the definition of a medical device as defined in Section 201(h) of the FD&C Act. There are two mechanisms to receive feedback from FDA - email CDRH for an informal device determination or submit a formal 513(g) request.

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Your call to action. What should you do if you have a product and you're not sure whether it's a medical device, or how the medical device is classified?

First, search for similar devices in FDA's databases. If you're still unsure, then, for a simple inquiry, email the device determination mailbox with all the necessary information so we can make an appropriate determination.

For a complex inquiry, or if you're seeking a formal classification determination, submit a 513(g) request for information. If you plan to submit a 513(g) request, please include all the necessary information in your submission as specified in the 513(g) guidance document. This information will help FDA provide you with a recommendation.

Thank you for joining us. Have a wonderful day.

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