Is my Product a Medical Device?

Slide 1

Hello, my name is Commander Kimberly Piermatteo of the United States Public Health Service and I am a Consumer Safety Officer within the Division of Industry and Consumer Education at FDA's Center for Devices and Radiological Health. Welcome to CDRH Learn, CDRH's resource for multimedia industry education. Answering the question "is my product a medical device?" can often be challenging. During this CDRH Learn module I will provide you with various tools and resources to better equip and prepare you to answer this question.

Slide 2

FDA regulates a wide range of diverse products as medical devices. Medical devices may be as simple as a tongue depressor and as complex as an artificial heart. Because of the wide range of medical devices, it is important to gain a better understanding of how FDA defines medical devices, as well as to understand different approaches to determine if your product is a medical device or not.

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To help you gain a better understanding, I will be covering the following four learning objectives in this module. The first learning objective is to define what the FDA considers to be a medical device. Next, I will discuss various topics to consider when determining if your product meets the definition of a medical device. Thirdly, I will walk through a device determination example. And lastly, I will identify informal and formal ways for you to request further assistance, if you need.

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To begin, let's first review the FDA's definition of a medical device.

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According to Section 201(h) of the Federal Food, Drug and Cosmetic Act or what is also referred to as the FD&C Act, a medical 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:

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recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them, OR is 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;

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and which does not achieve 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 its primary intended purposes. The term "device" also does not include software functions excluded pursuant to section 520(o)." The first dash on this slide distinguishes a medical device from a drug. The second dash covers an amendment to section 520(o) of the FD&C Act, which I will discuss further on the next slide.

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The amendment to section 520(o) of the FD&C Act was made in December of 2016 as part of the 21st Century Cures Act. This amendment removed certain software functions from the definition of a device.

On this slide I have provided some examples of excluded software functions such as those software functions intended for the administrative support of a health care facility; Software functions for maintaining or encouraging a healthy lifestyle and is unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition; Software functions which serve as electronic patient records; and lastly, software functions for transferring, storing, converting formats, or displaying clinical laboratory test or other device data, results or findings but which are not intended to interpret or analyze them.

I encourage you to thoroughly review section 520(o) of the FD&C Act if you believe you may have a software function that might be excluded from the definition of a medical device based on this amendment.

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When determining if your product meets the definition of a medical device you should ask yourself the following questions: What is the intended use of your product? How does your product function? And what claims do you intend to make? By clearly addressing these questions, you will be better able to determine if your product meets the definition of a medical device.

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I'd like to emphasize that defining your intended use is key. You should clearly state and understand the general purpose or function of your device, as well as identify the disease or condition it is intended to diagnose, cure, mitigate, treat or prevent. You should also be able to identify the intended patient population, such as if the device is intended for use on adult and/or pediatric patients. All of these characteristics which make up the intended use of your device are important because if a product is labeled, promoted or used in a manner that meets the definition in section 201(h) of the FD&C Act, the product will be regulated by the FDA as a medical device and will be subject to premarket and postmarket regulatory controls.

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One approach to help you determine if a product meets the definition of a medical device is to check and see if there is an existing FDA medical device product classification. If you are able to identify an applicable product classification which appropriately describes your product's intended use or design, this would be a good indication that your product would be regulated as a medical device.

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To determine if an existing medical device product classification exists, you may search the FDA's public Product Classification database. On this slide I have provided you a screen shot of what this database looks like and a hyperlink to this database. The default search is the advanced search from which you can search various fields, such as by searching for the FDA product code, regulation number, or device class. I always recommend stakeholders search by key word using the quick search. The quick search allows you to capture a wider range of potential product classifications and then you can narrow them down to identify the most appropriate one for your proposed device. Later in this module, I will walk you through a search of the FDA's public Product Classification database as part of the device determination example.

Slide 13
Over the next several slides, I will be discussing a few special considerations for you. These topics should be considered when determining if your product meets the definition of a medical device or not.

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The first special consideration is regarding In Vitro Diagnostics or IVDs. The FDA regulates IVDs as medical devices. IVDs are tests done on samples such as blood or tissue that have been taken from the human body. These tests can detect diseases or other conditions and can be used to monitor a person's overall health to help cure, treat, or prevent diseases.

Some tests are used in laboratory or other health professional settings and other tests may be used at home by consumers. Examples of a few common IVDs include a home pregnancy test and a blood glucose test strip. If you intend to market an IVD it may meet the definition of a medical device and therefore would be regulated by the FDA.

At the end of this module, on the resources slides, I have provided links where you can access additional information related to IVDs.

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Another consideration is regarding radiation emitting products. Section 531 of the FD&C Act defines an electronic product as a product which, when in operation, one, contains or acts as part of an electronic circuit and, two, emits electronic product radiation.

Most radiation emitting products are not considered to be medical devices. However, certain radiation emitting products with medical applications and claims meet the definition of a medical device and therefore must comply with both the medical device regulations as well as the electronic product regulations. Examples of radiation emitting products which also meet the definition of a medical device are diagnostic ultrasounds, x-ray machines and medical lasers. Links to where you can find more information on radiation emitting products and the electronic product regulations are found on the resources slides at the end of this module.

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Next, if you have a mobile application or mobile app it may be considered a medical device. If a mobile app is intended for use in performing a medical device function, it would be considered a medical device, regardless of the platform on which it is run.

Slide 17
The FDA intends to focus its regulatory oversight on a subset of mobile apps that present a greater risk to patients if they do not work as intended. This subset is represented by the small red circle on the image on this slide which I have drawn attention to using the yellow arrow. The FDA refers to this small subset of mobile apps as mobile medical applications or MMAs. MMAs are software programs that run on mobile platforms and perform the same functions as traditional medical devices. The FDA's guidance document on Mobile Medical Applications outlines the FDA's tailored approach to mobile apps in more detail. You may access this guidance via the link provided at the bottom of this slide.

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Another special consideration is that software, which on its own is a medical device, is referred to as Software as a Medical Device or SaMD. The FDA considers software intended to be used for one or more

medical purposes that perform these purposes without being part of a hardware medical device to be SaMD. An example of a SaMD is, software that allows a smartphone to view images obtained from a magnetic resonance imaging or MRI for diagnostic purposes. More information is available on the Software as a Medical Device webpage and a link to this webpage is provided at the end of this module on the Resources slides.

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The next special consideration I would like to discuss is about general wellness products. If your product is intended for general wellness use only, and is low risk, it may not be actively regulated by the FDA as a medical device. According to the FDA guidance document titled, General Wellness: Policy for Low Risk Devices, which can be accessed via the link provided at the bottom of this slide, CDRH defines general wellness products as products that meet the following two factors, those that are intended for only general wellness use, as defined in the guidance, and those which present a very low risk to users' safety.

The guidance document also states CDRH does not intend to examine low risk general wellness products to determine whether they are devices within the meaning of the FD&C Act or, if they are devices, whether they comply with the premarket and post market regulatory requirements for devices under the FD&C Act. You should review the General Wellness guidance document thoroughly if you believe your product may meet these factors and therefore would not be actively regulated by the FDA as a medical device.

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Another consideration is combination products. Combination products are defined in the code of federal regulations or CFR, under 21 CFR 3.2(e), as therapeutic and diagnostic products that combine drugs, devices, and/or biological products. A combination product is assigned to an FDA Center or alternative organizational component that will have primary jurisdiction for that product's premarket review and regulation. Under section 503(g)(1) of the FD&C Act, assignment to the center with primary jurisdiction, or what is also referred to as the lead center, is based on a determination of the "primary mode of action" of the combination product.

A few examples of different types of combination products include a drug eluting stent, a heparin coated dialysis catheter, and a first-aid kit with a drug. A link to the FDA's combination products homepage is provided on the resources slides at the end of this module.

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The last special consideration I would like to mention is if you determine your product does not meet the definition of a medical device, it may still be regulated by another Center within the FDA. 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 the FDA's Center for Drug Evaluation and Research.

Biological products which include blood and blood products, as well as blood banking equipment are regulated by the FDA's Center for Biologics Evaluation and Research. The FDA's Center for Veterinary Medicine regulates products used with animals. And the FDA's Center for Tobacco Products regulates tobacco products including vaporizers and electronic cigarettes. If you believe your product is regulated by another FDA Center, you may contact that Center to discuss potential regulatory requirements. I

have provided links to the other Centers on this slide and from those webpages, you will be able to find their respective contact information.

Slide 22
Next, I will walk through an example of how to determine if a product meets the definition of a medical device.

Slide 23
For this device determination example, the two products I'm going to assess and determine if they meet the definition of a medical device are an adult diaper and an infant diaper.

Slide 24
Defining the intended use of your product is key. In this example, the broad intended use for both diapers is to protect garments from urine or stool. This broad use doesn't exactly tell me if one or the other is intended to treat a medical condition. Therefore, I will expand upon and describe the disease or condition each diaper is intended to treat.

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The inability to control leaking urine or stool is often referred to as incontinence. For an adult, incontinence is considered to be a medical condition. For an infant, incontinence is not considered a medical condition since it is normal for an infant to not be able to control their elimination until they are of an appropriate age. Therefore, I can further define each product's intended use with the adult diaper being intended to treat incontinence and the infant diaper is not.

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To help me evaluate whether these products meet the definition of a medical device, I'm going to break down the medical device definition into three questions. These questions are outlined on the table provided on this slide. By answering these three questions, I will be able to determine whether the adult diaper, the infant diaper, or both meet the definition of a medical device.

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The first question I going to ask myself is whether the product is intended to diagnose, cure, mitigate, treat, or prevent disease in a human? My answer for the adult diaper is yes, it is intended to treat incontinence in adult patients. As for the infant diaper, the answer to this question is no, it is not intended to treat a medical condition in babies or infants. The second question I'm going to ask is whether the product is intended to affect the structure or any function of the body. For both, I can answer no, because neither product physically impacts the structure or function of the body. The third question I'd ask is whether the product achieves its primary intended purpose by chemical action or by being metabolized. Again, for both, I can answer no.

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Therefore, based on addressing these three questions which break down the medical device definition, I can now answer the question whether the product meets the definition of a medical device.

The adult diaper does meet the definition of a medical device, but the infant diaper does not.

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Let's say I'm not sure if either diaper would be considered a medical device after reviewing the medical device definition. I can search the FDA's public Product Classification database to determine if there is an existing product classification appropriate for either diaper. If I'm able to find one, and it appropriately describes either diaper then yes, I can conclude that either or both would be regulated as a medical device.

Slide 30
On this slide, I have again provided a screen shot and link to the public product classification database. To determine if there is an existing product classification for either diaper, I'm going to utilize the Quick Search which is circled in red on this slide.

Slide 31
This slide shows what the Quick Search looks like in the Product Classification database. By using the quick search, I can conduct numerous searches using a variety of related terms including the term diaper or urine. However, I often find it more beneficial to search using a key word which describes the disease or condition the product is intended to treat.

Slide 32
Thinking back when I further defined the intended use of both diapers, I determined that the adult diaper was intended to treat incontinence; therefore, I am going to search using incontinence as my key term, which I have circled in green on this slide.

Slide 33
On this slide, I have provided a screen shot of my search results when I used the key word incontinence. As circled in red on this slide, I was able to identify 23 potentially related product classifications. After reviewing these results, I do see one device specifically titled garment, protective, for incontinence. From the product classification database, I could select the hyperlink for the product code EYQ for this device or select the hyperlink for the device description title. Either selection will take me to additional information about this device, which I can then review and determine if the description appropriately describes either the adult or infant diaper.

Slide 34
For this example, I'm going to select the hyperlink to the device name to further review the information.

Slide 35
This slide includes a screen shot of the product classification results for a protective garment for incontinence. A lot of regulatory information is provided; however, for this example, I'm specifically looking at whether there is an existing product classification which appropriately describes my product.

Slide 36
Therefore, to review a detailed device description, I can review the regulation description. To do this, I'm going to select the hyperlink for the regulation number 876.5920 which I have circled in red on this slide.

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According to the regulation 21 CFR 876.5920, this type of device is described as…

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A protective garment for incontinence that consists of absorbent padding and a fluid barrier and that is intended to protect an incontinent patient's garment from patient's excreta. This description sounds very much like the adult diaper in my example. Even more specifically, this regulation states that this device type does not include diapers for infants.

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To summarize this device determination example, after reviewing the regulation description and comparing it to the intended use of the adult diaper and the infant diaper, I can now answer the question – "Is there an existing product classification?" For an adult diaper the answer is yes, there is an existing classification; however, for the infant diaper there is not, so the answer is no. Tying this back to my original intent for this example, which was to determine whether either diaper would be regulated as a medical device, I can conclude that because there is an existing classification for the adult diaper, yes, it would be regulated as a medical device. And the infant diaper would not be considered a medical device because the existing classification I did find, specifically excluded infant diapers.

Slide 40

If after reviewing the definition of a medical device and searching for an existing product classification you are unable to determine if your proposed product would be regulated as a medical device, you may consider requesting further assistance.

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If you would like informal assistance, you may contact the Division of Industry and Consumer Education or the Device Determination experts. DICE may help you better understand the resources available to you and assist you in searching the product classification database to identify potentially relevant existing product classifications. If after you have utilized the resources available to you, or if you cannot make a determination, you may contact the Device Determination experts. Please note, responses to either informal assistance mentioned on this slide are not classification decisions and do not constitute FDA clearance or approval for commercial distribution of your product.

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If you would like a formal device determination from the FDA, you should consider submitting a 513(g) Request. 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. Lastly, please note, FDA's response to a 513(g) Request does not constitute FDA clearance or approval for commercial distribution.

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In summary, medical devices are defined under Section 201(h) of the FD&C Act. As a reminder, a clearly defined intended use is key when you are trying to determine if your product meets this definition. You may also search for an existing medical device product classification and if you find an applicable one, then you can presume that product is likely regulated as a medical device. And lastly, further assistance regarding device determinations, both informal or formal, is available to you if needed.

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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 listed for your reference as needed.

Slide 47
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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I leave you with this call to action: familiarize yourself with the definition of a medical device as well as how to search the FDA's public product classification database. By familiarizing yourself with both of these, I hope if you are presented with the question, is my product a medical device in the future, you will feel more equipped and confident to answer it. Thank you for watching and I hope you have found this module helpful.

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