

## An Introduction to FDA's Regulation of Medical Devices

### Slide 1

Hello! I'm Elias Mallis, Director of the Division of Industry and Consumer Education at the Center for Devices and Radiological Health at the U.S. Food and Drug Administration. Welcome to CDRH Learn, FDA's preeminent catalog of multi-media educational modules about medical devices and radiological products! In this module, I'll present an Introduction to FDA's Regulation of Medical Devices.

### Slide 2

You may have the excitement of a bright idea, perhaps a breakthrough medical device, that you believe will help a lot of people. You may ask yourself: how can I get this to patients in need? And you may eventually realize that you'll need to go to the FDA in order for your bright idea to get into the hands of those people you're trying to help. So, if you're new to the FDA, you may not know where to start and where to go. The process may seem overwhelming. This module is a great place to start. I hope this will give you a basic foundation and roadmap to send you on your way.

### Slide 3

This presentation is an introduction. It's not intended to be a comprehensive overview of all aspects involved with the regulation of medical devices. We could devote an entire week just getting through the basics. Instead, the goal of this module is to provide you with a short introduction, so you can take your first step and decide how to best proceed from there.

With this in mind, let's review what we'll cover. First, we'll explain FDA's role in regulating medical devices. Next, we'll review the actual definition and some basics about device classification. We'll describe the steps to get a new product to market and the different types of premarket regulatory submissions you may send. And finally, we'll identify three actions you should take after watching this module.

### Slide 4

Let's start our discussion with the basics: FDA's role in regulating medical devices.

### Slide 5

FDA is the oldest comprehensive consumer protection agency in the U.S. Federal Government. Our mission is to promote and protect the public health. This scope is broad and covers foods, drugs, biologics, cosmetics, animal and veterinary medicines, tobacco, and, of course, medical devices and radiation-emitting products, the last two of which are regulated by the Center for Devices and Radiological Health, or CDRH.

### Slide 6

CDRH accomplishes this mission by evaluating the safety and effectiveness of medical devices before they get to market and ensuring that they stay safe once they reach the market. It's our public health goal for patients and providers to have timely and continued access to safe, effective, and high-quality medical devices.

### Slide 7

FDA's authority to regulate medical devices originates from the Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act, or FD&C Act, of 1976. The Agency has continued to evolve its laws to ensure that it regulates these products in the most efficient way as our scientific knowledge advances over time. Starting in 2002, CDRH began implementing a medical device user fee program in which the regulated device industry provides user fees to CDRH with the goal of advancing regulatory decision-making. For more information on the history of FDA's regulation of medical devices, please refer to the link at the bottom of this slide.

#### Slide 8

One of the most common questions that the Division of Industry and Consumer Education receives is this: "Is my product a medical device?" This is a great question and we look to the law to help us determine the answer.

#### Slide 9

The 1976 Amendments provide us with the definition of a medical device. The full definition is found in Section 201(h) of the FD&C Act. In summary, a device is an instrument, apparatus, machine, implant, or in vitro reagent that diagnoses, cures, treats or prevents a disease or condition. It does this by affecting the structure or function of the body but doesn't achieve its purpose through chemical metabolism or as a drug. This definition excludes certain software functions, mostly involved with the administrative data storage and support, and transmission of electronic patient records.

#### Slide 10

Innovative products may feature aspects of devices as defined in the prior slide, as well as components such as drugs or biologics. We refer to these as Combination Products, which, by definition, involve at least two regulatory component types of drugs, devices and biologics. An example of a drug-device combination product is a drug-eluting cardiovascular stent, whose two components work together to keep an artery open and prevent restenosis. Combination products involve the applicable regulatory responsibilities from all of the components involved. One FDA Center will usually take the lead and the Agency's Office of Combination Products helps facilitate product jurisdiction. More information about Combination Products is available at the link here.

#### Slide 11

Our Federal Laws are intentionally written to be broad. We elaborate on the details and specifics of Laws in regulations. The regulations that are specific to medical devices are found in 21 Code of Federal Regulations, Parts 800 - 1050. Parts 800 - 861 mostly address broad regulations that apply to most types of devices, and Parts 862 - 1050 largely address device-specific requirements. For example, 21 CFR 812 addresses Investigational Device Exemptions, a requirement that is applicable to all medical devices; whereas 21 CFR 876 provides classification information and requirements specific to gastroenterology or urology. In addition, 21 CFR Parts 1- 99 contain general regulations that apply to all medical products regulated by FDA, including medical devices. As a result, depending on your specific device, you may have regulatory responsibilities outlined in all of these sections.

#### Slide 12

Sometimes, the FDA Laws and Regulations are not sufficiently detailed to describe how FDA intends to regulate a device policy. In such cases, FDA will publish a guidance document that describes what FDA is thinking. A guidance document is not binding, but it does reflect FDA's current thinking, so it can often be an excellent source of detailed information and clarification on a particular policy.

FDA may initially issue a draft guidance document that describes the Agency's proposed thinking on a topic. During this period, the public is invited to provide comment on the proposal. At the completion of

the comment period, FDA will evaluate the public feedback and issue a final guidance document, which reflects the Agency's current thinking. This link will take you to the FDA Guidance Database. This is another important resource you should use.

#### Slide 13

FDA classifies devices, or more accurately, device types, in order to identify the degree of regulation for that product area. Classification is largely based on two factors: the device description, that is, its physical characteristics, and the intended use. As a result, in order to fully understand your device's classification, you need to identify both the device description and intended use. FDA classifies devices into Class I, II, or III. The class of a device generally increases with its degree of risk. In addition, each device type is assigned a product code, which refers to a three-letter coding. This allows FDA to group similar devices and intended uses. Note that the same device with a different intended use may have a different classification, product code, and Class.

#### Slide 14

This table describes the key characteristics of each class of medical devices. Moving from left to right, we describe each Class according to the general risk of devices, controls necessary, and submissions required. As the risk of the device increases, so does the regulatory control to ensure its safety and effectiveness. Controls may be general, special, and PMA. Devices may be exempt from submission to FDA, or require 510(k) or PMA, with some alternatives. For example, Class I devices generally present the lowest level of risk. They are subject to general controls only and most are exempt from premarket submission, but some may require a 510(k).

#### Slide 15

So, what are regulatory controls? These are requirements that apply to a product area, or product code. They provide consistent requirements to predictably foster safe and effective medical devices with the appropriate level of regulatory burden or oversight. Regulatory controls are usually broad, but some may be specific to a product area.

#### Slide 16

General controls are the one type of regulatory controls that apply to all classes of medical devices, that is, Class I, II, and III. This table lists some examples of general controls, along with where they appear in the regulation or law, and a brief description.

For example, one fundamental general control is labeling. 21 CFR Part 801 provides details involving labeling, which, broadly speaking, requires providing information about the device to ensure its safe and effective use.

Another example is establishment registration. As described in 21 CFR 807, businesses are required to register with FDA on an annual basis.

I'll note that the last two items listed in this table, Adulteration and Misbranding, are described in the FD&C Act, whereas the other controls are described directly in the regulation.

#### Slide 17

Special controls are another type of regulatory control. These are specific to Class II devices only, so a Class II device would need to comply with both general and special controls.

Special controls are not common. They are generally developed for well-established device types. Because we have a sufficient understanding about them, we are able to identify some consistent requirements to ensure their safety and effectiveness. All devices regulated under that section must comply with any identified special controls.

Special controls will be identified in the Code of Federal Regulations for that device type, under the Classification sub-section. Recall I previously mentioned that device-specific requirements will be found in Parts 862 through 1050. If a special control is identified for a device type, it will be found in the sub-section B of the device-specific regulation. For example, 21 CFR 876.5860 addresses the regulation of high permeability hemodialysis systems. If we read sub-section B of this section, we note that the device type is Class II and subject to 5 special controls listed in that section.

#### Slide 18

Special controls can be anything involved with a device type. Some common examples of special controls include: device design, characteristics or specifications, device testing, special labeling, or an applicable guidance document.

#### Slide 19

Now that we have some background, let's see if we can put some of this together so we can figure out how to get your new medical device to market. Over the next few slides, I've outlined 5 steps that you can generally follow.

#### Slide 20

The first step is for you to establish your product. This means to establish your product design as well as its purpose. The purpose can be described in terms of the intended use, which is usually broad, as well as the indications for use, which are usually more specific. You may also need to describe the duration of use for your product, as well as the target patient population, such as an age range of use or disease condition.

#### Slide 21

Once you've established these details, the next step is to confirm that the product is a medical device. This step may appear to be unnecessary, and in many instances, it may be obvious that a product is a medical device. This goes back to our legal definition of a medical device, including combination products.

#### Slide 22

Once you've established that your product is, in fact, a medical device, step 3 is to identify its anticipated classification and regulatory pathway. The classification will identify the Class of the device as I, II, or III, and will generally tell you what regulatory submission will be needed in order for the device to get to market.

#### Slide 23

After establishing the anticipated classification of your device, you're now prepared to generate the information needed to support its safety and effectiveness.

We refer to this information as valid scientific evidence, which is required and defined in the regulation under 21 CFR 860.7(c)(1) and (2), respectively. Evidence to support your device may include preclinical, animal, and clinical testing.

#### Slide 24

And finally, once you've gathered all of your information and evidence, the last step is to prepare and send in the premarket submission in order to get your product to market. Each submission type has its own set of processes, applicable requirements, review times, and evidence burden. So, if you follow these 5 steps, you should have a clear path to get your product to market.

#### Slide 25

Let's take a closer look at the different types of premarket submissions that you may submit.

#### Slide 26

Five of the most common types of submissions are: investigational device exemption, premarket notification, premarket approval application, De Novo, or humanitarian device exemption.

#### Slide 27

Let's start with the Investigational Device Exemption, or IDE. Of the five we'll review, this is the one submission where you are not asking to get your product to market. Instead, this is the submission where you are asking for FDA approval to conduct clinical research on your investigational device. In an IDE, you're collecting clinical safety and effectiveness evidence, as part of your overall valid scientific evidence, that you plan to include in a future marketing application. Clinical studies will typically require FDA approval as well as approval by an Institutional Review Board, with the goal of protecting the safety of patients as much as possible during the research being proposed.

#### Slide 28

Next, we'll highlight the premarket notification, or 510(k), as it's more commonly known. 510(k) is the most prolific premarket submission type with several thousands of 510(k)s submitted to FDA each year. This is a marketing application mostly for low and moderate risk devices - these are the ones that are Class I or II. The 510(k) is a comparison-type of submission, in which FDA determines whether a new device is substantially equivalent to a predicate device, which is a legally marketed Class I or II device. In this comparison, FDA examines three main aspects: the intended use, device characteristics or features, and, if necessary, the results of performance testing.

#### Slide 29

Another type of submission is the premarket approval application, or PMA. PMA is a marketing application for high risk devices - these are ones that are Class III, as well as devices without an existing classification. In a PMA, a device must demonstrate a reasonable assurance of safety and effectiveness. In contrast to the 510(k), PMA evidence must stand on its own. It is not an equivalence evaluation to another legally marketed device. The next two submission types are alternatives to the 510(k) and PMA to get a new product to market. They have specific conditions where they apply, so let's review them.

#### Slide 30

Let's start with the De Novo. This submission type is intended for devices for which there is no existing classification regulation. As a result, a De Novo is usually for devices that the Agency hasn't previously evaluated. These are usually new, novel device types. The De Novo submission process will allow a new product to get to market by creating a new classification regulation for that device type in Class I or II. A De Novo may be considered an alternative to the PMA. The benefit of the De Novo is to regulate the new device type with a reduced regulatory burden than that of a PMA.

#### Slide 31

And second, we have the humanitarian device exemption, or HDE. This is the premarket submission type for humanitarian use devices, that is, devices that are intended to treat or diagnose patients of a disease or condition that affects or is manifested in not more than 8,000 individuals per year in the United States. Unlike PMAs, HDE devices are exempt from demonstrating effectiveness. Instead, an HDE must show reasonable assurance of safety and probable benefit. As you can see, each of the premarket submission types has specific requirements and characteristics. Understanding which submission type is most applicable to your new device will help guide you to develop the appropriate information and valid scientific evidence necessary to get your product to market.

#### Slide 32

This is a good place in the presentation for a brief note about Quality Systems.

#### Slide 33

The Medical Device Quality System Regulation is a general control and at the core of all aspects of all medical devices. I encourage you to view our CDRH Learn module on this important overview, which you may find under the Postmarket Activities section of CDRH Learn and at the link shown on this slide.

#### Slide 33

We've touched on a lot of topics in this introduction, and you may have more questions after watching this module. What should you do next? The answer is as easy as 1-2-3.

#### Slide 34

First, become familiar with Device Advice. Device Advice is a comprehensive, regulatory educational resource about medical devices. Device Advice consists of hundreds of pages of web content spanning the total product life cycle about medical devices, on over 30 regulatory categories. It includes detailed, written instructions, including various guides on how to complete various tasks. The website for Device Advice is simply: [www.fda.gov/DeviceAdvice](http://www.fda.gov/DeviceAdvice).

This is a great place to start.

#### Slide 35

Second, after checking out Device Advice, I encourage you to go to CDRH Learn. CDRH Learn features multi-media, video training modules, such as presentations, computer-based training guides, and webinars. We have well over 100 CDRH Learn modules that you can access on many of the topics you're interested in. Most are less than 20 minutes long and the modules are mobile-friendly, so CDRH Learn can serve as an efficient resource wherever you are. The link to CDRH Learn is listed on this slide.

#### Slide 36

And finally, if you can't find the information you need from Device Advice or CDRH Learn, you may always contact us at the Division of Industry and Consumer Education. You can call us at the phone number listed on this slide for a live discussion, or if you prefer, you may email us at: [DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov). We'll get to your email and respond within two business days. More information about the Division and educational programs we offer may be found at: [www.fda.gov/DICE](http://www.fda.gov/DICE).

#### Slide 37

Let's recap what we covered in this module. First, we learned that FDA regulates medical devices by evaluating their safety and effectiveness. FDA classifies device types and assigns them to classes, with regulatory controls and submission requirements. There is a general process for getting a new product to market and different types of regulatory submissions. And finally, we identified the 3 resources to help you after watching this module.

Slide 38

Let's conclude this module with your call to action. Understand your regulatory responsibilities. Stay informed of current FDA policies. And use the available FDA resources to help you in your journey. We thank you for your investment in the public health in bringing safe and effective medical devices to patients. We want you to be successful in your journey, so your bright idea becomes reality. Thank you for watching this program.

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