Device Registration and Listing: An Introduction – Part 1

Slide 1
Hello! I'm Elias Mallis, Director of the Division of Industry and Consumer Education, in 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, we're going to focus on one of the most foundational aspects of the medical device regulations: Device Registration and Listing. This is Part 1 of this introduction.

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The process of sorting and taking inventory is common to many fields, whether it be the various colors available in a paint store, the food that's currently in your refrigerator, or many other items at work and at home. It's a process that helps us to get organized and account for what we have. And as you'll learn, that's a little bit about what's involved with the registration and listing process that we have for medical devices.

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This introduction is divided into two modules. For this first module – Part 1, we're going to focus on the who, why and what is involved with registration and listing. In Part 2, we'll cover the "how" and the process.

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We're going to cover several learning objectives. First, we'll discuss some background and key terms. We'll next answer the question: "Am I required to register and list?" And finally, we'll identify when you must register and list.

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So, let's begin with some background, definitions, and a few key terms.

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I'm going to say the words "registration" and "listing" a lot in this module, and these terms might seem interchangeable. In fact, these are distinct from each other, so it's important to understand the difference. "Registration" refers to the business, which we call the establishment, and informs FDA where the establishment is located. "Listing" is about the activities that the establishment performs on a specific medical device. So, make sure to keep these themes in mind as we move along.

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Another key phrase is "commercial distribution". Commercial distribution refers to any distribution of a device intended for human use, which is held or offered for sale.

The full definition is found in 21 Code of Regulations, CFR, 807.3(b), and includes a few details on what's included as part of this scope.

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As defined in 21 CFR 807.3(c), "establishment" means a place of business, under one management at one general physical location, at which a device is manufactured, assembled, or otherwise processed.

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And finally, we have the term "general controls." These are regulatory requirements authorized by the Federal Food, Drug, and Cosmetic Act. These requirements generally apply to all medical devices, and you can learn more about general controls at the link shown on this slide.

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So, let's get into some more background. Medical device establishments are required to (1) register their establishment, and (2) list the devices that are manufactured, prepared, propagated, compounded, assembled, or processed at their establishment. The regulations mandate the use of an electronic registration and listing system, and also require the payment of a user fee.

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The regulatory authorities for device registration and listing are found both in laws and regulations. FDA's regulatory authority for medical devices originated with the Federal Food, Drug, and Cosmetic Act. Subsequent laws have been passed over time which, in turn, have continued to evolve FDA's authority over this program.

The regulatory requirements are largely described in 21 CFR 807 and provide important details involving definitions, provisions, and procedures. I've included a link to the regulation on this slide, and I encourage you to read this section carefully and become familiar with it.

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This is a good time in this introduction to note a few disclaimers that often cause confusion to our stakeholders. First, "registration", or more specifically, the process for completing your registration, does not, in any way, indicate FDA approval or clearance of establishments or products.

Any representation that creates an impression of official FDA approval because of registration is misleading and constitutes misbranding. So, for example, if you intend to market a Class II medical device that requires clearance of a 510(k) prior to commercial distribution, you must obtain a substantial equivalence determination on your 510(k) prior to doing so. It is not sufficient to merely register your establishment. And second, FDA does not provide certificates to establishments for device registration and listing.

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Okay now, let's get to probably the biggest question to answer in this module: "Am I required to register and list?"

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This answer is a little complicated, and in part depends on where you're located and what activities you perform, so we're going to address these one at a time. Let's first determine whether you're a domestic or foreign establishment. A domestic establishment is physically located in the United States, whereas a foreign establishment's physical location is outside the U.S.

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Let's now review the types of domestic establishments that are required to register. Keep in mind, for our context here, this is specific to establishments whose device is marketed in the United States.

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Here we list each of the establishment types that we'll review over the next few slides. Each of these types is required to register.

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Let's start with "manufacturer". A manufacturer is defined as an establishment that makes any article that meets the legal definition of a device, and makes their device by chemical, physical, biological, or other procedures. This includes a kit assembler.

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A kit assembler places another establishment's finished device into a kit. The assembler is not permitted to modify the device or change its intended use. In this case, the kit assembler may register as either a "manufacturer" or "contract manufacturer", based on the activity being performed.

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A manufacturer of accessories or components is a type of establishment that packages or labels the accessory or component that is ready to be used for any "health related purposes" to an end user. In other words, this is for a product that can be used as is.

A manufacturer of export-only devices is an establishment that manufactures devices not sold in the U.S, and are solely intended for export to foreign countries, that is, outside the U.S. Now for a manufacturer of a custom device, it is helpful to go to the Federal Food, Drug, and Cosmetic Act for how FDA generally interprets the limits of what is considered a custom device. The FDA guidance document listed here, and specifically Section V(A) provides more information about custom devices and the requirements for registration and listing.

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A "remanufacturer" is defined in 21 CFR 820.3(w). This is an establishment that processes, conditions, renovates, repackages, restores, or does any other act to a finished device that significantly changes its performance, safety specifications, or intended use.

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A "specification developer" is defined as an establishment that develops specifications for a device distributed under the establishment's own name. In this situation, the establishment performs no manufacturing and uses a contract manufacturer to make the finished device.

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A "contract manufacturer" or a "contract sterilizer" is an establishment type that sterilizes or otherwise makes a device for, or on behalf of, a specification developer, or any other person; or, they may arrange manufacturing for another establishment.

Slide 23
A "repackager" is a type of establishment that packages finished devices from bulk, or repackages devices made by a manufacturer into different containers, excluding shipping containers. The repackager is not permitted to modify the device or change its intended use.

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A “relabeler” is a type of establishment that changes the content of the labeling from the original manufacturer and distributes the device under its own name. Note that this doesn’t include establishments that only add their own name to the labeling.

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A “reprocessor” of a single-use device is defined as an establishment that modifies a single-use device that was previously used on a patient and is prepared to be used for more than one use. The reprocessor has responsibility for the device. A “complaint file establishment” maintains complaint files in accordance with 21 CFR 820.198.

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And finally, we have the “initial importer”. As defined in 21 CFR 807.3(g), this type of establishment is any importer who furthers the marketing of a device from a foreign manufacturer to the person who makes the final delivery or sale of that device to the consumer or user.

The initial importer does not repackage or otherwise change the container, wrapper, or labeling of the device or device package. So, as you can see, we reviewed a number of different types of establishments and activities involved with medical devices. Please review this carefully to confirm the type of establishment that you are, and to confirm whether you’re required to register.

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So now that we’ve covered domestic establishments, let’s review the foreign establishments that are required to register.

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Let’s start out with what’s the same for both domestic and foreign establishments. We reviewed the establishment types listed here in our discussion of domestic establishments that are required to register, and this is the same for foreign establishments.

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In addition, two types that are specific to foreign establishments are required to register.

A “foreign exporter” is an establishment that exports, or offers for export, a device to the United States. This is for a device that is manufactured, prepared, propagated, compounded, or processed in a foreign country, and includes devices that may have been originally manufactured in the U.S. A foreign exporter must have an establishment address that is located outside of the United States. And a “private label distributor” is an establishment that exports a device manufactured and owned by another party, under its own name, and under a private label agreement.

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So, now that we’ve reviewed who’s required to register, let’s review the establishment types that are exempted from device registration and listing. Please note that this exemption applies if the establishment activities are within the scope of the exemption.

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You're exempt if you're a component manufacturer that provides raw materials or components used in the manufacture or assembly of a device, and only to the finished device manufacturer. Recall from earlier, if you make a component that is ready for use, then you must register. You are exempt if you're a manufacturer of devices used solely for veterinary purposes. Veterinary-use only devices are regulated by FDA's Center for Veterinary Medicine and are not within the scope of regulation by FDA's Center for Devices and Radiological Health. A licensed practitioner is exempt. This is an establishment that manufacturers or otherwise alters a device solely for use in their own practice. In this case, the practitioner may not distribute the device to other practitioners.

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An installer by the manufacturer's agent or by the user is exempt. A domestic distributor is exempt. This is an establishment type that distribute devices only from a manufacturer located in the United States.

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A retail establishment that provides the device directly to the end user is exempt. This may include entities such as pharmacies and surgical supply outlets. Note that if the device comes from a foreign establishment, please ensure that the shipment is labeled as required.

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And the final exemption we'll review is a manufacturer of devices intended for research use, or investigational use only. This is specific to devices that are labeled as required and used solely for research, teaching, or analysis, and not introduced into commercial distribution. This exemption only applies to a domestic establishment.

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Well, we've just gone over a lot of information and terminology, and it may be a lot to keep organized. Here's a link on Device Advice that summarizes all of this information for you.

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So, now that you've figured out whether or not you're required to register, the next question you may have is: when do I do this, and what's the deadline? Let's get to that next.

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As with many things in the government, the answer is, it depends! Is this the first time ever that you are registering? We refer to this as "initial registration". Or is this not your first time, but is your annual registration?

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Let's review what's required if this is your initial registration and listing. If you're a domestic establishment, you're required to register and list within 30 days of placing your device into commercial distribution. If you're a foreign establishment, you must register and list prior to importing your device into the United States for the first time.

Just like the foreign establishment, if you're an initial importer, you're required to register your establishment prior to importing your device into the U.S. for the first time. Unlike them, you don't need to list your device, but you must identify the manufacturer of each imported device. A word of caution

for foreign establishments and initial importers. All devices imported into the United States must meet the regulatory requirements of both the U.S. Bureau of Customs and Border Protection, or CBP, as well as the FDA. Products that don't meet the FDA regulatory requirements may be detained at the port of entry.

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After you've completed your initial registration – that is, the first time you ever register, the next times you register are considered your annual registration and listing. Let's review what you need to do here.

You must submit your annual registration between October 1 and December 31 of each year. Make sure to submit any necessary changes. While you're preparing your registration, you'll also review your listing information to verify that it's accurate. This is also done annually, between October 1 and December 31 of each year. And finally, you're able to update your information at any time during the fiscal year if something changes with your establishment or device listing.

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If you've previously registered your establishment and now discontinue marketing and distributing your device, we recommend that you deactivate your registration.

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On the next two slides, I included a table that organizes some of the resources, links, and regulatory citations that we reviewed in this module.

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I encourage you to refer to these for more details and some of the specific language that clarifies terms we reviewed.

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Let's now summarize what we covered in this module. Registration and listing is a regulatory requirement and general control that applies to all medical devices. There are different establishment types that are required to register and list. And finally, registration and listing is required at the time of initial distribution, and then, on an annual basis.

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We in the Division of Industry and Consumer Education provide you with regulatory education in several key formats, so you can choose the most effective way you wish to learn. CDRH Learn consists of over 200 multi-media industry education modules, such as the one that you're watching here. These include videos, webinars, presentations, and various "how to guides." Use your computer, phone, or portable device to click on the link shown here. Now, if you prefer to learn by reading, check out Device Advice! Device Advice consists of several hundred pages of comprehensive regulatory information across the device total product life cycle. And finally, if you have a specific question and wish to ask us directly, I encourage you to call or email us. Our contact information is listed here, and we look forward to speaking with you.

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Let's conclude this module with your call to action. First, identify your type of establishment and determine whether you need to register and list. And if the answer is yes, your second call to action: please watch Part 2 of this Introduction on CDRH Learn!

Thanks for your attention to the module “Device Registration and Listing, An Introduction, Part 1.” Take care and we’ll see you next time!

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