

## **CDRH Industry Basics: Custom Device Exemption**

### **Slide 1**

Hello. My name is Nathan Ivey and I'm a Regulatory Health Project Manager for the Office of Product Evaluation and Quality at FDA's Center for Devices and Radiological Health. I am also currently the Lead for Custom Device Exemption. Welcome to this introduction to the Custom Device Exemption Program and its reporting requirements.

### **Slide 2**

Custom device exemption can be thought of like a custom home. Unlike a traditional home that's built with many features in common with other homes, a fully custom home is unique and built for the individual. In other words, a device with multiple models, sizes and features is not necessarily a custom device. However, a device that is not available in the United States and is made specifically for a patient or healthcare provider, could be a custom device. You can think of it like the picture of the home on the right.

### **Slide 3**

After watching this module, I hope that you'll have a better understanding of Custom Device Exemption. The learning objectives are: First, to describe Custom Device Exemption and key concepts. Second, to discuss the 5 per year allotment limit, and third, to describe the annual reporting requirements, both for patient and physician-centric custom devices.

### **Slide 4**

First things first. What do we mean when we call a device a custom device? Let's begin with where FDA receives its regulatory authority for custom device exemption. Then I will describe two key concepts. Understanding them will provide insight on how to navigate the regulatory requirements for custom devices. Then we'll look at these requirements and what is and what isn't a custom device.

### **Slide 5**

The regulatory authority for Custom Device Exemption is in section 520(b) of the Food Drug and Cosmetic Act, referred to as the FD&C Act. 520(b) provides FDA the regulatory basis for our oversight of the custom device exemption program.

### **Slide 6**

A key concept in understanding custom device exemption is understanding what is meant by generic device type. FDA considers a generic device type a grouping of devices that do not differ significantly in purpose, design, materials, energy source, function, or any other feature related to safety and effectiveness, and for which similar regulatory controls are sufficient to provide reasonable assurance of safety and effectiveness.

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Another key concept of Custom Device Exemption is understanding the meaning of “Necessarily deviates”. This means that a device should be sufficiently unique so that clinical investigations would be impractical and could not be performed to demonstrate conformance to applicable performance standards and/or support premarket review.

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Now let’s discuss the regulatory requirements of a Custom Device Exemption. It’s very important for physicians and manufacturers to understand what kinds of devices and situations qualify for custom devices and when to use them.

### Slide 9

The requirements of premarket approval, referred to as PMA, and performance standards do not apply to custom devices. In other words, premarket authorization is not required if the conditions are met. The statute for custom devices provides a balance between the flexibility to meet the unique needs of patients and physicians while also ensuring the safety of the devices.

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A custom device is only made at the written request of a physician or dentist. Every custom device is one where there is no alternative available in the United States market to treat a unique condition. When we say that a custom device is “not generally available” in the United States, we mean that it cannot be legally obtained in finished form. As a reminder, firms are not to solicit orders for custom devices.

### Slide 11

In select circumstances, a patient may need a custom device for their unique physiology or pathology. Let’s discuss an example of a custom device that is outside of the legally marketed envelope of available devices. Such a case could be one where a patient requires an oversize hip replacement beyond the legally marketed size range. For this patient, a firm may manufacture a unique size hip system for their specific anatomical needs. This would be considered a patient-centric custom device.

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Custom devices can also be made for a physician or dentist in the course of their work. These are referred to as physician-centric custom devices. If a physician or dentist has a unique pathology or a unique physiologic condition, a special need device could be made for them in their practice. For example, if a physician has a permanent hand injury, they may need an adaptive surgical device like a specialized surgical instrument handle to perform surgery. Adaptive technology like this would qualify for a custom device exemption.

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While a custom device may be unique in the sense that every custom device is made on a case by case basis, these devices will still likely have similar design characteristics, materials, and manufacturing processes in common with other commercially distributed devices. Earlier I noted an oversize hip device example. In a device like that, just because it's a custom device doesn't mean it couldn't be manufactured with the same conventional materials used in a standard hip replacement system.

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A legally marketed device that has been modified may not be a custom device. However, if an existing premarket notification, 510(k)-cleared device is modified to treat a unique pathology or unique physiological condition, which renders clinical study impractical, and the device necessarily deviates, this could potentially qualify as a custom device.

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A common question we receive is related to whether a Personalized or Patient Fitted device is a custom device. The simple answer is No. For example, dental abutments where each patient has a differently shaped oral space, and the patient-matched device blank is milled for the individual patient, would not qualify as a custom device. This type of modification falls within the expected use and cleared maximum/minimum dimensions. In other words, the device range design envelope. As another example, a 3D printed version of an orthopedic device is not considered a custom device if a conventional device has been cleared that could fulfill the patient's need. For example, devices like patient cutting guides for bones, knees and other joints, and spinal fusion cages are devices that are not likely to be custom devices because the range of cleared products allows for the use in most patients.

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Now that we've defined the custom device exemption, I'm going to discuss the regulatory requirements for these devices.

### Slide 17

A common question we receive is: Are custom devices exempt from the Quality System Regulation? The answer is No. Custom Devices are not exempt from the Quality System Regulation identified in 21 Code of Federal Regulations Part 820. They also follow other regulatory requirements including: Medical Device Reporting, Labeling, Corrections and Removals, and Registration & Listing.

### Slide 18

There are additional labeling requirements for Custom Devices. Over the next couple of slides, I'll highlight some items to include in the labeling. For detailed labeling requirements, please review 21 CFR 801, which includes adequate directions for use and states that the labeling may not be false or misleading.

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Some of the additional labeling items to include for a custom device are: a statement that the device is a custom device, the name of the ordering physician, and patient identification information, if applicable.

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Also, in the labeling, include the Indications for use, sterilization status, relevant composition information, including materials, components and storage conditions for the device. As with all medical device labeling, please ensure that the labeling is understandable, truthful, and accurate.

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How many custom devices can a firm make per calendar year?

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Custom devices are limited to 5 or fewer per year of a generic device type. However, for the purposes of reporting, a single patient with multiple devices can be counted as one if they had, for example, a device placement in two locations of their body, such as with a bilateral condition. This is true as long as the devices are implanted within one calendar year.

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So, one patient with a unilateral hip replacement in one calendar year is one allotment in the annual report. A patient who needed to have two hips replaced in a single year as a bilateral hip replacement could be counted in the annual report of the manufacturer as one allotment. However, if the requests span multiple years, each hip replacement will count separately in the allotment. Any custom devices, such as four devices that are manufactured where only one is used and the other three aren't used, do not count in the annual report as long as the manufacturer provides a statement that the three devices were destroyed or returned.

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Our final topic is the annual reporting requirements for manufacturers of custom devices.

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The purpose of the annual report is for manufacturers to provide FDA with an accounting, and to justify that each device supplied by a manufacturer to a patient or physician as a custom device, meets the statutory requirements. The annual report should summarize the number of custom devices manufactured and distributed in the United States during a one-year reporting period. Each annual report should cover an entire calendar year. That is, January 1st through December 31st of a given year. For example, reports submitted by March 31st of 2020 should cover device usage for the calendar year 2019. Please provide at least one hard copy of the report in English.

### Slide 26

To ensure that you have the most current physical address to send your annual report, please send an email to the Program listed on this slide, and we will respond promptly.

### Slide 27

To assist you in including all the needed information in your report, you can use the template format in Appendix 1 of the guidance, Custom Device Exemption: Guidance for Industry and Food and Drug Administration Staff. The link to the guidance is provided on this slide.

### Slide 28

General information to provide in annual reports, for both patient and physician-centric custom device exemptions includes a cover letter containing your contact information, for example, the company name, address, and website. You should also include a contact person, their title, contact numbers, and their email address. In the report, remember to specify the reporting period - the dates the reporting period begins and ends. Also include the annual number of patients who received a new device or revisions of a previous custom device. In the cover letter, clearly identify the custom devices manufactured and distributed during the reporting period. On the cover letter, include the signature of the responsible party.

Additionally, multiple custom devices or components used in one patient should be accounted for in the annual report. As noted in Section IV of the guidance, typically only new custom devices will be counted toward the maximum allotment of five units per year of a particular device type. However, revisions to an existing custom device should be accounted for in the annual report. The annual report should account for the number of custom devices physicians are provided, have returned to the manufacturer, or have destroyed.

The Truthful and accurate statement indicates that the submitter is an authorized representative for the manufacturer, and that all information provided in the paper and electronic copies of the Custom Device Annual Report is truthful and accurate to the best of their knowledge, and that no material fact has been omitted.

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Now let's discuss patient-centric custom device annual report requirements. In addition to the general information, there is specific information for this type of custom device. Include an explanation of how or why the device that was manufactured to treat an individual patient deviates from the premarket requirements, regardless of whether it's a newly created device or modified from a legally marketed device. Also, include a statement that the device is not generally available.

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Include a description of the device, and a statement that the device was manufactured to treat a unique, and rare, pathological or physiological condition, and how the device is assembled from components, or manufactured and finished.

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For patient-centric devices, also provide the following detailed information on custom devices manufactured during the reporting period: Patient Information includes the total number of patients receiving custom devices. This should be broken down into patients receiving a new device and those undergoing revisions of previously existing custom devices. Additional information on the patients should also be provided, including unique patient identifiers in the physician's order, and a description of the condition that necessitated use of a custom device.

Treating physician information includes the name, address, and other contact information for the treating physician for each patient procedure. Also include a detailed description of each custom device or device component remaining with the patient. These details should include the date of manufacture; the product name; brand name; product model number; product catalog number or other product identifier information; and closest fit product code, if applicable.

### Slide 32

For physician-centric devices, in your annual report please justify the unique special need, and the reason why conducting clinical investigations is impractical, such as the low incidence or prevalence of the condition or disease. Indicate whether the device was newly created or modified from an existing legally marketed device, as well as the name of the individual doctor in the order.

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Provide a statement that no other device is generally available to address the physician's special need in the course of conducting their practice. You should maintain records of the evaluation that you used to determine that no other device is domestically available to meet the doctor's or dentist's special needs. Provide a description of the device. Explain whether the device was assembled from components or manufactured and finished on a case-by-case basis to accommodate the special needs of individuals described above. Additionally, explain whether the device or device components have common, standardized design characteristics, chemical and material compositions, and manufacturing processes as commercially distributed devices.

### Slide 34

The report should include information on custom devices distributed during the reporting period, such as the name, address, and other contact information for the physician ordering the custom device; the number of custom devices or custom device components that were shipped, sold, and returned or destroyed by the ordering physician during the reporting period; and the date of manufacture, the product name, brand name, product model number, product catalog number, or other identifier.

### Slide 35

When we receive the report, we'll send you an email to acknowledge that the report has been received. Then we'll send a follow up notice if the report has been approved. If we have questions or concerns, such as "does the device meet the custom device exemption criteria?", we'll reach out to you for more information and clarification.

### Slide 36

CDRH provides multiple opportunities for industry education. On this slide, I've provided 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, the phone number and email address for the Division of Industry and Consumer Education, or DICE, so you may contact us with any questions.

### Slide 37

Custom Device Exemption Staff and FDA reviewers are available for any future questions or concerns at the custom device exemption email address provided on this slide.

### Slide 38

I want to point out that there are some very important guidance documents that you may want to reference to get more detailed information about custom device exemptions. Most importantly, the custom device exemption guidance is there to help you along. Also, for manufacturers that may be engaged in additive Manufacturing, you may want to take a careful look at the technical considerations for additive manufacturing guidance.

### Slide 39

In closing, let's talk about some of the key points we touched on today. Remember, a custom device exemption can be used for devices that are unique to an individual patient or a physician who has a special need. A custom device can only be manufactured in an amount up to five allotments per year. An annual report is due to the FDA by March 31st of every year that custom devices are used. There's a great template in the guidance document of exactly what to report.

### Slide 40

The Custom Device Exemption Program is an avenue for patients, physicians and dentists to obtain devices for unique circumstances. Your call to action is to first, make certain that devices being used in patients or by physicians appropriately qualify for a custom device exemption. If you're a manufacturer, be sure that the custom devices that you're using meet the requirements of the custom device exemption program. Next, submit annual reports on time, and include all the necessary information. Last, if you do not know, you may submit a Q-Submission request for device-specific questions. We appreciate your time and attention and we look forward to your questions. Thanks for watching!

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