



Custom Device Exemption

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*Thank you for your patience while we register all
of today's participants.*

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History of the Custom Device Exemption

- **Original Provision of 1976 Medical Device Amendments**
 - Very narrow exemption from premarket requirements - series of conditions must be met
 - “One Off” new device, not a customized existing device
- **Amended in FDASIA July 2012**
 - Expanded the exemption, still narrow with a series of conditions that must be met
 - Added new requirement for Industry



FDASIA Section 520(b)

(b) CUSTOM DEVICES.—

(1) IN GENERAL.—The requirements of sections 514 and 515 shall not apply to a device that—

(A) is created or modified in order to comply with the order of an individual physician or dentist (or any other specially qualified person designated under regulations promulgated by the Secretary after an opportunity for an oral hearing);

(B) in order to comply with an order described in subparagraph (A), necessarily deviates from an otherwise applicable performance standard under section 514 or requirement under section 515;

(C) is not generally available in the United States in finished form through labeling or advertising by the manufacturer, importer, or distributor for commercial distribution;



FDASIA Section 520(b)

(D) is designed to treat a unique pathology or physiological condition that no other device is domestically available to treat;

(E)(i) is intended to meet the special needs of such physician or dentist (or other specially qualified person so designated) in the course of the professional practice of such physician or dentist (or other specially qualified person so designated); or (ii) is intended for use by an individual patient named in such order of such physician or dentist (or other specially qualified person so designated);

(F) is assembled from components or manufactured and finished on a case-by-case basis to accommodate the unique needs of individuals described in clause (i) or (ii)

of subparagraph (E); and



FDASIA Section 520(b)

(G) may have common, standardized design characteristics, chemical and material compositions, and manufacturing processes as commercially distributed devices.

(2) **LIMITATIONS.**—Paragraph (1) shall apply to a device only if—

(A) such device is for the purpose of treating a sufficiently rare condition, such that conducting clinical investigations on such device would be impractical;

(B) production of such device under paragraph (1) is limited to no more than 5 units per year of a particular device type, provided that such replication otherwise complies with this section; and

(C) the manufacturer of such device notifies the Secretary on an annual basis, in a manner prescribed by the Secretary, of the manufacture of such device.



FDASIA Changes

- Both new and modified existing devices can potentially qualify for the custom device exemption
- Potential for multiple units of a device type (no more than five per year)
- Annual reporting requirement for the Manufacturer
- Issue a guidance document addressing how to count to five



Guidance Document

- **Policy Section**
 - Definitions
 - Counting to five
 - Common custom device exemption questions
- **Annual Report**
 - General content and logistics of submission
 - Specific information for a patient centric custom device
 - Specific information for a physician centric custom device



Final FDA Custom Device Guidance Document:

POLICY SECTION



Key Definitions

- Device Type
- Necessarily Deviates
- Not Generally Available
- Special Need
- Sufficiently Rare Condition
- Unique Pathology
- Unique Physiologic Condition



Counting to Five

- Law limits device units per year
 - No more than five units per year of a device type
- Law directs FDA to issue final guidance on replication or multiple device (i.e., counting to five)



Counting to Five

- FDA interprets “five units”
 - Five valid new custom device cases per year
 - Includes all devices of type provided by a manufacturer to, and remaining in the possession of the ordering physician and/or the patient
 - Allows for sizing by not counting devices either returned to the manufacturer or destroyed by the physician
 - Patients needing multiple devices of a given type (i.e. bilateral joint replacement) in a given year are one unit

Common Custom Device Exemption Questions

- What premarket and post market requirements are custom device exempt from fulfilling
- Can a device subject to an IDE be a custom device
- Can a custom device be both a physician centric [520(b)(1)(E)(i)] and patient centric device [520(b)(1)(E)(ii)]



Common Custom Device Exemption Questions

- Can modifications to 510(k) device qualify as a custom device
- How are revisions and servicing of existing custom devices including in the limit of no more than five
- How to label a custom device
- Examples of what is and is not a valid custom device



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Final FDA Custom Device Guidance Document:

ANNUAL REPORT SECTION



Annual Reports

- The statutory amendments in FDASIA to the custom device exemption added a new reporting requirement
- The manufacturer of a custom device must report to FDA annually on the custom devices it supplied
- Annual reports should cover an entire calendar year and be submitted to FDA within the first quarter of the following calendar year - no later than March 31
- The first year's reports due March 31, 2015 should cover July 9, 2012 through December 31, 2014



Annual Reports

Information to include in the annual report:

- The number of all custom devices distributed
- An account of custom devices that were returned or destroyed
- The number of patients who received a device or revisions of a previous custom device
- If multiple custom devices were used in one patient, each custom device used must be accounted for in the annual report



Annual Reports

- Cover Letter
 - Reference line - “Custom Device Annual Report”
 - Contact Information
 - Custom Devices Manufactured and Distributed
 - Reporting Period

- Truthful and Accurate Statement

I certify that, in my capacity as (the position held in company) of (company name), I believe to the best of my knowledge, that all data and information submitted in the custom device annual report are truthful and accurate and that no material fact has been omitted.



Annual Reports

The annual report for patient-centric custom devices should include a justification for how or why the device manufactured to treat an individual patient meets the following conditions contained in the FD&C Act:

- 520(b)(1)(B) & 520(b)(2)(A) - why the device necessarily deviates from the premarket requirements including treating a sufficiently rare condition such that conducting clinical investigations are impractical



Annual Reports

- 520(b)(1)(A) - indicate whether the device is a newly created device or modified from an existing legally marketed device in order to comply with the order of an individual physician
- 520(b)(1)(C) - attest that the device is not generally available in the United States in finished form through labeling or advertising by the manufacturer, importer or distributor for commercial distribution



Annual Reports

- 520(b)(1)(D) & 520(b)(2)(B) - provide a complete description of the device including device type and the patient's unique pathology or physiological condition
- 520(b)(1)(D) - provide a statement that no other device is domestically available to treat the patient's unique pathology or physiological condition
- 520(b)(1)(E)ii - provide a unique patient identifier for the individual patient in the physician's order



Annual Reports

- 520(b)(1)(F) - state whether the device is assembled from components or manufactured and finished on a case-by-case basis to accommodate the unique needs of individuals
- 520(b)(1)(G) - explain whether the device or device components have common, standardized design characteristics, chemical and material compositions and the same manufacturing processes as commercially distributed devices



Annual Reports

Submitting annual reports to FDA:

- Custom device manufacturers should submit two copies of their annual report, including at least one hard copy
- Although it is not required for annual reports, it is strongly encouraged that one of the two copies be submitted as an eCopy, i.e., a PDF file on a CD, DVD or flash drive
- For more information about submitting an eCopy, see [“eCopy Program for Medical Device Submissions: Guidance for Industry and Food and Drug Administration Staff”](#)



Annual Reports

How will FDA use the information from annual reports?

- Information will help FDA understand how industry is interpreting and applying the custom device exemption
- Annual reports will allow FDA to ensure compliance with the custom device exemption
- FDA will use the information to track the number and type of custom devices to respond to inquiries from stakeholders, such as Congress



Annual Reports

What if FDA determines that a device distributed did not meet the requirements of the exemption?

- The FDA's primary focus is helping manufacturers implement the Custom Device Exemption correctly and efficiently. The FDA intends to notify a manufacturer in writing about the reasons the devices are not eligible for the exemption.
- The FDA will consider taking enforcement actions (e.g., Warning Letters) when the situation calls for it.



Questions?

Division of Industry and Consumer Education:
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Slide Presentation, Transcript and Webinar
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