FDA’s Final Custom Medical Device Guidance

New Reporting Requirements, Narrower Uses Allowed

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Custom Device Exemption

History

Statutory History

• Was an original provision of the 1976 Medical Device Amendments
  – Very Narrow, where a series of conditions were required to be met
  – “one off” new device, not a customized existing device (somewhat different.

• “This [custom device] exemption shall apply only for devices ordered by physicians and other health professionals designated by regulation, according to their specifications.”
Custom Device Historical Issues

• Historically, custom devices have always represented a narrow category for which, due to the rarity of a patient’s medical condition or physician’s special need, compliance with premarket review requirements and performance standards under sections 514 and 515 of the FD&C Act is impractical.

• Generally:
  – FDA has always interpreted the term "custom device" very strictly
  – Most devices claimed to be "custom" by the manufacturers have been determined not to be custom devices by FDA.
  – There exist numerous Warning Letters where FDA states their disagreement as to the "custom device" status of the devices in question.
Custom Device Historical Issues

• Previous guidance not necessarily clear in Warning Letters
  – 1991 WL - FDA disagreed with the company's claim that the liquid injectable silicone is a custom device, but gives no explanation as to the basis for its position.
  – 1992 WL - FDA states that "custom prosthetic implants" are not custom devices, apparently, because they are manufactured using device history records, which are considered to be device specifications.
  – 1992 WL - FDA states that orthotic walkers manufactured from component kits are not custom devices. No explanation for the decision is given by FDA.
  – 1993 WL - FDA states that the Omniscience heart valve is not a custom device because it was not handled in accordance with Sec. 812.3(b) and has been placed into commercial distribution.
  – 1994 WL - FDA states a dental implant device was not a custom device because the company planned to supply the device to other dentists and advertise its availability.
Custom Device Historical Issues

- 90s Warning Letters leads companies to not use the exemption
- Most recent Warning Letters
  - 2005 – 2 WLs – Still not clear: FDA concludes the devices did not meet the exemption - were not made to meet the need of an individual patient or to meet the needs of an individual physician.
  - 2011 – WL DePuy flatly violates the concept of the exemption. The devices did not deviate from generally available devices or from applicable performance standards, and they have common, standardized design characteristics, chemical and material compositions, or manufacturing processes. Design is the same and the fact that final specifications are tailored to match a patient’s anatomy does not preclude a clinical study or submission of a marketing application for the devices.
What Is a Custom Device - 520(b)(2)(B)

- A device that (A) is created or modified in order to comply with the order of an individual physician or dentist; (B) to comply with such order, it necessarily deviates from an otherwise applicable performance standard; (C) is not generally available in the US in finished form by the manufacturer, importer, or distributor for commercial distribution; (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 (ii) is intended for use by an individual patient named in such order of such physician or dentist; (F) is assembled from components or manufactured…
What Is a Custom Device

- FDCA 520b - Broken down, elements include:
  - Created to comply with order of physician
  - Deviates from an otherwise applicable performance standard;
  - Not generally available in the US;
  - Designed to treat a unique pathology that no other device can treat;
  - Meets special needs of such physician or is used by an individual patient named in such order;
  - Assembled from components or manufactured and finished on a case-by-case basis.
What Is a Custom Device

360j – FDASIA added requirements:

(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 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.
What Is a Custom Device

• 21 C.F.R. § 812.3 - Includes an additional requirement – that the device is not offered for commercial distribution through labeling or advertising.

• If you meet the definition - You are exempt from Performance Standards and Premarket Approval.
2014 Guidance


• Divided into two parts: I. Policy and, II. The Report.

• Policy section addresses “up to five,” and other common questions that FDA has encountered over the years.

• The Report Section addresses the content and logistics of the submission.
2014 Guidance, Policy Definitions

• Part I - Definitions – addresses key terms, which are largely based off of language in the statute or regulation.
  • Defines numerous parts of the statutory definition and provides clarity
  • “Necessarily deviates” 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.
2014 Guidance, Policy Definitions

Part I - Definitions

• Not generally available
• Order of a Physician
• Special Need
• Sufficiently Rare Condition
• Unique Pathology
• Unique Physiologic Condition
2014 Guidance, Policy Section

• Part I - “Definitions” – addresses key terms, which are largely based off of language in the statute or regulation.

• Part II - “No more than 5 units Per Year”
  • Statute: “limited to no more than 5 units per year of a particular *device type*” that otherwise meet all the requirements necessary to qualify for the custom device exemption.
2014 Guidance, Policy Section

“No more than 5 units Per Year”

- FDA says

  - 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.

  - FDA takes into account multiple considerations such as anatomical location, disease state, material, technology, and indications.

  - 5 units per year = five new custom devices per year (or five new devices for five patients (or five physicians)).
2014 Guidance, Policy Section

“No more than 5 units Per Year”

- FDA says
  - Device Type = take into account multiple considerations such as anatomical location, disease state, material, technology, and indications. For example, knee replacement device systems comprise multiple device types; although used in the same anatomical location, knee systems with different technological characteristics (including materials) or used in different disease states can constitute different types of knee systems.
2014 Guidance, Policy Section

• Part III – “Questions and Answers and Examples”
  • Many basic questions, others not:
  • Which premarket and postmarket requirements are exempt?
  • “Specific to the special needs of the physician’s practice” versus “specific to the patient’s unique physiological/pathology needs”? Can a device be unique to both?
  • Can a device be subject to an IDE be a custom device
2014 Guidance, Policy Section

Part III – Q and A

• What is the relationship between compassionate use and a custom device?
  – Manufacturers have sought custom device exemptions for devices more properly considered under a compassionate use protocol. (FDA notes this in the September 2014 guidance).
  – Devices that do not qualify for the custom device exemption, may qualify for compassionate use.

• Can modifications to an existing 510(k)-cleared device be made under the custom device exemption?
2014 Guidance, Policy Section

Part III – Q and A

• How are revisions and servicing of existing valid custom devices included in the total of five units of a device type per year?

• If a patient needs to undergo revision surgery to replace a component of her implant that is no longer being manufactured, is the component a custom device?

• Are Pediatric devices automatically custom devices, simply because they are for a pediatric population?

• How should I label my custom device?
2014 Guidance, Policy Section
Part III – Q and A
• Can I market my custom device to the general public?
• What are examples of custom devices?
• What are examples of a device that is not a custom device?
2014 Guidance, Annual Reporting Section

• First real pronouncement on the Annual Report.

• Requirements include:
  • Number of patients who received a new device or revisions of previous custom device.
  • Multiple devices in one patient should be accounted for (maximum of 5; as well as revisions to existing custom devices). Include the number physicians are provided, the number returned, or destroyed.
  • January 1 – December 31.
  • Submit no later than March 31 the following year.
2014 Guidance, Annual Reporting Section

• Content:
  • Cover Letter
  • Truthful and Accurate Statement
  • Other Logistical Information
  • If Patient Centric –
    – Explain how the device satisfies Section 520(b); Summary of custom devices shipped, used, returned and destroyed; Details on custom device use
  • If Physician Centric –
    – Explain how the device satisfies Section 520(b); Summary how accommodating physician’s special needs; Details on custom device use
2014 Guidance, Annual Reporting Section

• Use of Annual reports
  • Will allow FDA to ensure compliance with the exemption
  • FDA will use the information to track the number and type of custom devices to respond to inquiries from stakeholders and congress.
  • Information will assist FDA understand how industry is interpreting and applying the exemption
2014 Guidance, Annual Reporting Section

• If FDA determines that a device does not meet requirements of exemption
  – Will notify the manufacturer of violation in writing
  – May use enforcement discretion and will not issue a Warning Letter unless the situation is egregious or repeated.
Differences between Draft and Final Guidances

• Includes a question on replacement of a component of a device that are no longer manufactured.

• Examples on physician-centric custom devices
  – “instrument requiring premarket review that needs to be modified to accommodate a deformity of a surgeon’s hand.”

• Modifies advice regarding submission of electronic copies of the annual report.
QUESTIONS?

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