Custom Device Exemption

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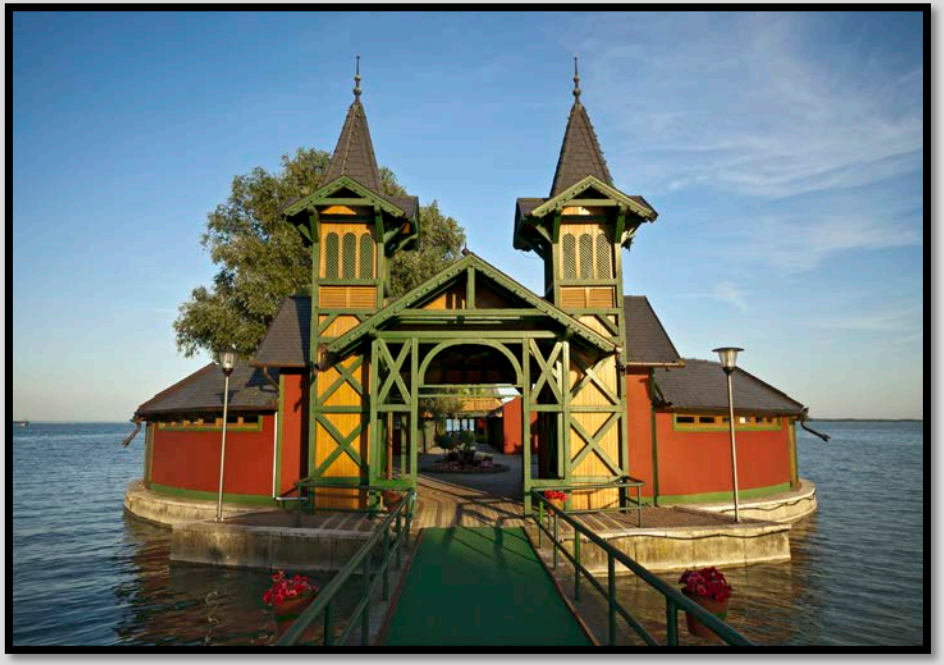


Learning Objectives

1. Describe Custom Device Exemption and its key concepts
2. Discuss the 5 per year allotment limit
3. Explain the annual reporting requirements

What is a Custom Device Exemption?

Regulatory Authority

Section 520(b) of the Food, Drug, and Cosmetic Act (FD&C Act) provides the basis for the Custom Device Exemption Program

Section 520(b) Food, Drug and Cosmetic Act

What is 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

What is Necessarily Deviates?

“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

Requirements of a Custom Device Exemption

PMA and Performance Standards

Sections 514 and 515 of the FD&C Act **do not apply** to devices that meet the requirements for a custom device

Custom Device

- Written request of a physician or dentist to meet a need
- Not generally available in the US in finished form
- Firms should not solicit orders for custom devices

Section 520(b)(1)(A) and (B) Food, Drug and Cosmetic Act

Patient-Centric

- Patient with unique physiology or pathology
- Example: physiology
  - A custom device that is outside of the legally marketed envelope of available devices
  - A patient who requires an oversize hip replacement that is beyond the legally marketed size limit

Section 520(b)(1)(D) Food, Drug and Cosmetic Act

Physician (or Dentist)-Centric

- For a physician or dentist with a unique pathology or a unique physiologic condition, a special need device could be made for them in their practice
- Example: condition
  - A custom device to meet a physician's need for an adaptive device to perform surgery because of a permanent hand injury may qualify *(specialized handle on their surgical instrument)*

Section 520(b)(1)(E) Food, Drug and Cosmetic Act

Case-by-Case Basis

- A custom device is produced on a case-by-case basis

- A custom device may have similar design characteristics, materials and manufacturing processes in common with commercially distributed devices

Section 520(b)(1)(F) and (G) Food, Drug and Cosmetic Act

Modified Devices

- A legally marketed device that has been **modified** may not be a custom device
- If an existing 510(k) cleared device is modified to treat a **unique pathology** or **unique physiological condition**, which renders clinical study impractical, the device could potentially qualify as a custom device

Personalized or Patient Fitted

- A personalized or patient fitted device is a device that **is legally marketed** in a **form that is modified** prior to being used in each patient. These are not custom devices
- Examples:
  - A dental abutment where each patient has a differently shaped oral space and the device blank is milled for individual patients, is not a custom device
  - An orthopedic 3D printed device where a conventional device has been cleared for patients, is not a custom device

Regulatory Requirements

Quality Systems Regulation 21 CFR 820

- Custom Devices are **NOT** exempt from the QS regulation
- Additional regulatory requirements for custom devices:
  - Medical Device Reporting (21 CFR Part 803) (adverse event reporting)
  - Labeling (21 CFR Part 801)
  - Corrections and Removals (21 CFR Part 806)
  - Registration and Listing (21 CFR Part 807)

Medical Device Labeling

- Adequate directions for use
- May not be false or misleading

21 CFR 801

www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=801

Custom Device Labeling

- Statement that the device is a custom device
- Name of the ordering physician
- Identifying information for the patient (if applicable)

Custom Device Labeling

- Indications for use
- Sterilization status
- Relevant composition information
  - materials, components
- Storage conditions

Custom Device Exemption Allotment

No More Than 5 Per Year

- Limited to no more than **5 allotments** per year of a generic device type
  - Five **new patients, allotments,** for the patient-centric
  - Five **new physicians, allotments** for the physician-centric

One Allotment or Two?

- 1 patient with a unilateral hip replacement in one calendar year is one allotment in the annual report
- 1 patient, bilateral hip replacement in one calendar year is one allotment in the annual report
- 1 patient, bilateral hip replacement across two calendar years is two allotments in the annual reports
- 1 patient, four devices made in four sizes. One implanted and three destroyed or returned in one calendar year is one allotment in the annual report

Custom Device Annual Report

Custom Device Annual Report

- The report provides an **accounting and justification** that each device supplied by a manufacturer to a patient or physician as a custom device **meets the statutory requirements**
- Submit the report annually by March 31st for devices issued the prior calendar year (January 1 through December 31)
- Provide a hard copy of the report in English

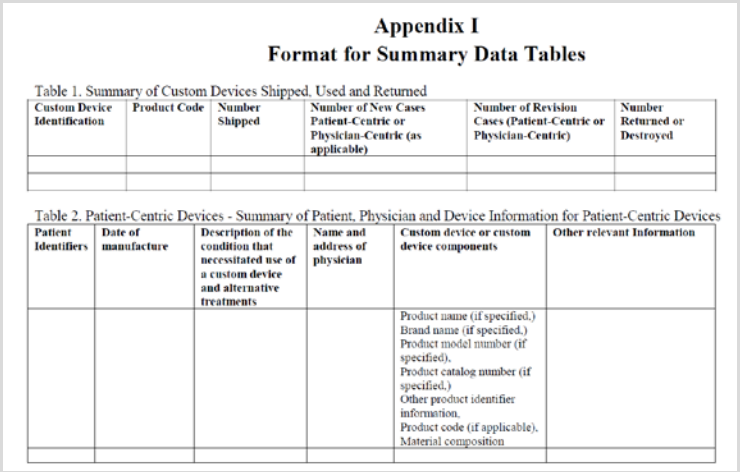
Where to Submit Report

Email the Custom Device Exemption program for the current address to submit your annual report:

CustomDevices@fda.hhs.gov

Report Contents

Template format provided in Appendix 1 of the guidance



Appendix I

Format for Summary Data Tables

Table 1. Summary of Custom Devices Shipped, Used and Returned

Custom Device Identification	Product Code	Number Shipped	Number of New Cases Patient-Centric or Physician-Centric (as applicable)	Number of Revision Cases (Patient-Centric or Physician-Centric)	Number Returned or Destroyed

Table 2. Patient-Centric Devices - Summary of Patient, Physician and Device Information for Patient-Centric Devices

Patient Identifiers	Date of manufacture	Description of the condition that necessitated use of a custom device and alternative treatments	Name and address of physician	Custom device or custom device components	Other relevant Information
				Product name (if specified,) Brand name (if specified,) Product model number (if specified), Product catalog number (if specified,) Other product identifier information, Product code (if applicable), Material composition	

Custom Device Exemption: Guidance for Industry and Food and Drug Administration Staff

www.fda.gov/regulatory-information/search-fda-guidance-documents/custom-device-exemption

Annual Report-General Contents

- Cover letter
  - Contact information
  - Reporting timeframe
  - Number of devices manufactured and distributed
  - Signature
- Truthful and Accurate Statement
- Other Logistical Information

Patient-Centric Report

- **Justification** for how or why the device manufactured to treat an individual patient meets the following:
  - Deviates from the premarket requirement
  - Whether newly created device or modified device from a legally marketed device
  - Statement that it is not generally available

Patient-Centric Report (continued)

- Description of device
- Statement to treat patient's unique pathology or physiological condition
- How device is assembled from components or manufactured, and finished

Patient-Centric Report (continued)

- Patient and Physician Information
  - Patient information, including unique patient identifiers
  - Physician information
  - Custom device or custom device components

Physician-Centric Report

- Justification how or why device is unique, special need condition:
  - Deviates from the premarket requirement
  - Whether newly created device or modified from a legally marketed device

Physician-Centric Report (continued)

- Statement that it is not generally available
- Statement special need in course of conducting their practice
- Description of device
- How device is assembled from components or manufactured, and finished

Physician-Centric Report (continued)

- Custom devices distributed
- Physician information
  - name, address, and other contact information
- Device or components

FDA Annual Report Review

- Provides an acknowledgement receipt of report
- Notice that the report has been approved
- If we have questions or concerns, we will reach out to you for more information

Providing Industry Education

1. **CDRH Learn – Multi-Media Industry Education**
   - Videos, audio recordings, power point presentations, software-based "how to" modules describing aspects of medical device and radiation emitting product regulations:
     www.fda.gov/CDRHLearn

2. **Device Advice – Text-Based Education**
   - Text-based resource that explains many aspects of medical device laws, regulations, guidances, and policies:
     www.fda.gov/MedicalDevices/DeviceRegulationandGuidance

3. **Division of Industry and Consumer Education (DICE)**
   - If you have a question - Email: **DICE@fda.hhs.gov**
   - Phone: 1(800) 638-2041 or (301) 796-7100 (Live Agents 9am – 12:30 pm; 1-4:30 pm EST)

Contact

- Email

CustomDevices@fda.hhs.gov

References

- Custom Device Exemption Guidance for Industry and Food and Drug Administration Staff
  www.fda.gov/regulatory-information/search-fda-guidance-documents/custom-device-exemption

- Technical Considerations for Additive Manufactured Medical Devices
  www.fda.gov/files/medical%20devices/published/Technical-Considerations-for-Additive-Manufactured-Medical-Devices---Guidance-for-Industry-and-Food-and-Drug-Administration-Staff.pdf

Summary

- A Patient-Centric Custom Device is a unique device to treat unique Pathology or Physiology of a patient
- A Physician-Centric Custom Device is a unique device to meet the special need or condition of a physician or dentist
- A custom device is limited to 5 device allotments per year
- Annual reporting is required for Custom Device Exemption

Your Call to Action

- Ensure custom devices used in patients or by physicians qualify for a custom device exemption
- Follow all custom device requirements
- Submit Annual Reports on time and include all the necessary information
- Submit a Q-Submission request for device-specific questions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