Custom Device Exemption

Nathan S. Ivey, PhD
Regulatory Health Project Manager
Office Product Evaluation and Quality (OPEC)
Center for Devices and Radiological Health
U.S. Food and Drug Administration
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](mailto:CustomDevices@fda.hhs.gov)
Report Contents

Template format provided in Appendix 1 of the guidance

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 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
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