On February 2, 2024, FDA published the final rule to amend the Quality System (QS) regulation in 21 CFR part 820 (89 FR 7496, effective February 2, 2026). The revised 21 CFR part 820 is now titled the Quality Management System Regulation (QMSR). The QMSR harmonizes quality management system requirements by incorporating by reference the international standard specific for medical device quality management systems set by the International Organization for Standardization (ISO), ISO 13485:2016. The FDA has determined that the requirements in ISO 13485 are, when taken in totality, substantially similar to the requirements of the QS regulation, providing a similar level of assurance in a firm's quality management system and ability to consistently manufacture devices that are safe and effective and otherwise in compliance with the Federal Food, Drug, and Cosmetic Act (FD&C Act).

This guidance document was issued prior to the effective date of the final rule. FDA encourages manufacturers to review the current QMSR to ensure compliance with the relevant regulatory requirements.

Contains Nonbinding Recommendations

Custom Device Exemption

Guidance for Industry and Food and Drug Administration Staff

Document issued on September 24, 2014.

The draft of this document was issued on January 14, 2014.

For questions about this document, contact Office of Regulatory Programs, Division of Regulatory Programs 1 (Submission Support) at 301-796-5640 or customdevices@fda.hhs.gov.



U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

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See additional PRA statement in Section VIII of this guidance.

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Preface

Public Comment

You may submit electronic comments and suggestions at any time for Agency consideration to http://www.regulations.gov. Submit written comments to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Rm 1061, (HFA-305), Rockville, MD 20852. Identify all comments with the docket number FDA-2013-D-1601. Comments may not be acted upon by the Agency until the document is next revised or updated.

Additional Copies

Additional copies are available from the Internet. You may also send an e-mail request to CDRH-Guidance@fda.hhs.gov to receive a copy of the guidance. Please use the document number 1820 to identify the guidance you are requesting.

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Contains Nonbinding Recommendations

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Custom Device Exemption

Guidance for Industry and Food and Drug Administration Staff

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. Introduction

The Food and Drug Administration (FDA) has developed this document to provide guidance to industry and FDA staff about implementation of the custom device exemption contained in Section 520(b) of the Food, Drug and Cosmetic Act (FD&C Act). The guidance provides definitions of terms used in the custom device exemption, explains how FDA interprets the "5 units per year of a particular device type" language contained in section 520(b)(2)(B) of the FD&C Act, describes what information should be submitted in a Custom Device Annual Report ("annual report"), and provides recommendations on how to submit an annual report for devices distributed under the custom device exemption.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. Background

Effective July 9, 2012, section 617 of the Food and Drug Administration Safety and Innovation Act (FDASIA) (Pub. L. 112-144) required the implementation of changes to the custom device exemption contained in section 520(b) of the FD&C Act. The new provision amended an existing custom device exemption and introduced new concepts and procedures applicable to custom devices addressing, among other things:

- devices created or modified in order to comply with the order of an individual physician or dentist;[1]
- the potential for multiple units of a device type (not to exceed 5 units per year) qualifying for the custom device exemption; and
- annual reporting requirements by the manufacturer to FDA about devices manufactured and distributed under section 520(b) of the FD&C Act.

Although the revisions to the custom device exemption clarify the availability of the exemption in certain circumstances—for example, when more than one (but not greater than five) devices are manufactured per year and when modifications are made to a marketed device—the new statutory language does not create a broad, new exemption from sections 514 and 515 of the FD&C Act. Under the revised provision, as under the original custom device exemption, custom devices should represent 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.

Historically, practitioners and manufacturers have sought custom device exemptions for devices more properly considered under a compassionate use protocol. FDA notes that some devices deemed ineligible for custom devices status prior to FDASIA would remain ineligible under the new provision, but may qualify for compassionate use. Although a full discussion of compassionate use is outside the scope of this guidance, a short discussion of compassionate use is included in the Question and Answer section of this guidance.

III. Definitions

Device Type
A generic device type is defined as 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.[2]

Importer
"Importer" means any person who imports a device into the United States.[3]

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.[4]

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[1] For the readability of this document, the word "physician" is defined to represent "physician or dentist (or any other specially qualified person designated under regulations promulgated by the Secretary)." Section 520(b)(2)(A) of the FD&C Act.
[2] See 21 CFR 860.3(i).
[3] See, e.g., 21 CFR 806.2(f).
[4] 48 FR 248 Pages 56778, 56796, December 23, 1983.

Not Generally Available
A device that is "not generally available" is a device not generally available in finished form through labeling or advertising by the manufacturer, importer, or distributor for manufacture and/or commercial distribution in the United States and is of a type available for introduction into commercial distribution in quantities of no more than five units per year. This includes, but is not limited to, devices not addressed in electronic or hard copy literature, promotional material, or available testimonials. For example, a manufacturer could make a custom device in response to an unsolicited request by a physician who specifies unique design inputs when no similar product is commercially available in the United States and clinical investigations on such device would be impractical.

Order of a Physician
"Order of a physician" refers to the written request for a custom device made by a physician. In the case of a prescription device, this would include the written or electronic prescription.

Special Need
A "special need" is a need related to an individual physician's unique pathology or unique physiological condition.

Sufficiently Rare Condition
A "sufficiently rare condition" is a condition in a patient population in which the incidence or prevalence is so small that conducting clinical investigations on a device to treat it would be impractical.

Unique Pathology
"Unique pathology" is pathological anatomy that no other device is domestically available to treat.

Unique Physiologic Condition
A "unique physiologic condition" is a physiologic condition that no other device is domestically available to treat.

IV. No More Than Five Units Per Year of a Device Type

Under FDASIA, devices that qualify for the custom device exemption contained in section 520(b) of the FD&C Act are "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.

FDA has applied the definition of device type to 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.

FDA interprets the five units in terms of five new custom device cases per year (i.e., five new ***patients*** for the patient-focused custom device or five new physicians for the physician-focused custom device, assuming all other required elements for the custom device exemption are satisfied). The five-unit limitation includes all devices of a type provided by a manufacturer to, and remaining in the possession of, the ordering physician and/or the patient.

FDA does not intend to include in the tally of five units per year any extra units produced for a unique case because of sizing concerns, so long as the ordering physician has either destroyed those devices not used for that case or they have been returned to the manufacturer and not redistributed without valid U.S. marketing authorization or for a subsequent valid custom device case. FDA expects the manufacturer to use appropriate quality system procedures to control returned product and ensure they are only redistributed under appropriate circumstance (i.e., another valid custom device case or U.S. marketing authorization). For example, if four sizes of a valid custom orthopedic implant are manufactured for a specific patient and one device is ultimately implanted into the patient, then the remaining three sizes should either be returned to the manufacturer or destroyed by the ordering physician. If these units are not returned to either the manufacturer or the ordering physician does not provide the manufacturer a statement of destruction, then FDA considers four of the five total units per year of that device type to have been used. On the other hand, if the three other units are returned to the manufacturer or the ordering physician provides the manufacturer a statement of destruction, only one of the five units per year will have been used to treat this patient, provided the returned devices are not redistributed without valid U.S. marketing authorization or for use in a subsequent valid custom device case.

The devices used in the case where a patient requires multiple devices of the same type (such as bilateral conditions) to treat multiple anatomical locations within a given reporting year will be considered one unit for purposes of tallying the five units of a device type per year, so long as those devices are ordered together and the ordering physician either destroys any unused devices or those devices are returned to the manufacturer and not redistributed without valid U.S. marketing authorization or used in a subsequent valid custom device case. For example, in the event that a patient requires valid custom bilateral joint replacement devices (such as might occur in bilateral knee replacement procedures), so long as those devices are ordered together in the same reporting year, and the ordering physician provides the manufacturer with either a statement of destruction or returns all unused product to the manufacturer, FDA will consider the multiple joint replacement devices needed to treat the bilateral patient as only one of the five allotted units per year of a device type. If the patient's multiple replacement devices are ordered during different reporting years, each treatment will contribute one unit to the tally for the reporting year in which the ordering occurs (so long as the ordering physician provides the manufacture a statement of destruction for the unused devices or returns them to the manufacturer, and the manufacturer does not redistribute without either a valid U.S. marketing authorization or for use in a subsequent valid custom device case).

V. Questions and Answers/Examples of Custom Devices

A. From which premarket and postmarket requirements is my custom device exempt ?

Under Section 520(b) of the FD&C Act, custom devices are exempt from Premarket Approval (PMA) requirements and conformance to mandatory performance standards. [5] Custom Devices are *not* exempt from any other requirements, including, but not limited to, the Quality System Regulation, including Design Controls (21 CFR Part 820); Medical Device Reporting (21 CFR Part 803); Labeling (21 CFR Part 801); Corrections and Removals (21 CFR Part 806); and Registration and Listing (21 CFR Part 807).

B. The custom device exemption describes two types of custom devices: one specific to the special needs of the physician's practice, and the other specific to the patient's unique physiological/pathology needs. Can a single custom device be unique both to a physician's practice and the patient's unique needs?

No, the custom device provision allows for development of two different categories of custom devices. One is patient-centric, and the other physician-centric; a custom device cannot be both patient- and physician-centric. A custom device made to treat a patient's sufficiently rare condition leaves a medical practice with the patient, while a custom device made to satisfy a physician's unique special need remains with that physician for use in his/her practice.

C. Can a device subject to an IDE be a custom device?

No, a device that is currently being studied or capable of study under an IDE does not meet the definition of a custom device. Additionally, the IDE is a broad exemption under which devices used in clinical investigations that meet IDE requirements are exempt from FD&C Act sections 514, 515, 502, 510, 516, 519, 510(e), 520(f) and 721. There is no reason to seek a custom device exemption for a device capable of study under an IDE, because custom devices represent a narrow category of devices used to treat sufficiently rare conditions or rare physician needs for which clinical investigations cannot be practicably conducted.

D. What is the relationship between compassionate use and a custom device?

Devices that do not meet all elements of the custom device definition described in section 520(b) of the FD&C Act may qualify, under appropriate circumstances, for compassionate use. An unapproved and uncleared medical device may be used on human subjects when its use is under clinical investigation and complies with all

[5] A device not covered by an existing marketing approval would require either a PMA or a valid exemption from the requirements to obtain PMA approval in order to be introduced into interstate commerce. Examples of potential valid exemptions or alternatives from the PMA requirement include: (1) establishing the substantial equivalence of the new device to a valid predicate device, (2) approval of an Investigational Device Exemption (IDE) or (3) meeting all custom device exemption requirements.

applicable requirements.[6] FDA recognizes there may be limited circumstances under which a health care provider may seek to use an unapproved and uncleared device to treat a patient suffering from a serious disease or condition for which no alternative therapy exists. FDA provides more information on how to request compassionate use of an unapproved device in the guidance document "Guidance on IDE Policies and Procedures" (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080202.htm).

Compassionate use of an unapproved and uncleared device may occur when a device is the only option available to a patient with a serious condition. All compassionate uses require, among other things, prior FDA approval. See Section 561(b) of the FD&C Act and 21 CFR 812.35(a). Please refer to the guidance listed above for more information on compassionate use of unapproved devices.

E. Can modifications to an existing 510(k)-cleared device be made under the custom device exemption?

Modifications to a 510(k)-cleared device that maintain its original intended use and could be clinically studied do not appropriately qualify as a custom device and should be handled in accordance with 21 CFR 807.81 and the guidance document "Deciding When to Submit a 510(k) for a Change to an Existing Device (K97-1)" (http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm080235.htm) (i.e., submission of a new 510(k) application, or documentation to the design history file explaining why the change does not require a new 510(k), as appropriate). However, 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.

It is worth noting that FDA reviews, clears, and approves for marketing many patient-specific devices (also referred to as patient-matched devices). Patient-specific devices are, in general, ones in which ranges of different specifications have been approved or cleared to treat patient populations that can be studied clinically. Premarket submissions for such devices are sometimes referred to as "envelope" submissions because their approval or clearance covers the entire range of specifications data they contain to support. The final manufacturing of these devices can be delayed until physicians provide imaging data or other information to the manufacturer to finalize device specifications within cleared or approved ranges. As a result, such devices are specifically tailored to patients.[7] For example, a manufacturer of an ankle replacement device could submit a 510(k) to cover a range of specifications for

[6] See Section 520(g) of the FD&C Act and 21 CFR Parts 50, 56, and 812, *Investigational Device Exemptions* (IDE), includes requirements for the conduct of clinical studies on human subjects with medical devices, such as the content of the IDE application, responsibilities of sponsors and investigators, labeling, recordkeeping, and reporting to FDA.

[7] CDRH has received 510(k)s and PMA applications for patient-specific/patient-matched medical devices in a number of different product areas including but not limited to TMJ implants, dental abutments, orthopedic surgical cutting guides, orthopedic joint replacement implants, and trauma and dental bone plates.

different system components to accommodate multiple patients with different anatomical characteristics. While some in industry have sometimes colloquially referred to these devices as "customized," they *are not custom devices* meeting the FD&C Act custom device exemption requirements unless they comply with all of the criteria of section 520(b). Marketing applications are required for these device types because the devices and patient populations can be defined and studied.

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

A device that meets all requirements of section 520(b) of the FD&C Act when initially distributed will not be counted against the five device units per year allotment if it has later been revised or serviced, *provided that* such revision or servicing is performed in furtherance of meeting the special needs of the person or physician for whom the custom device was intended before being revised and/or serviced. If you have any questions, you can contact CDRH's Office of Compliance to discuss the specifics of your situation prior to revising or servicing such device.

G. 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?

The component is only a custom device if it is designed to treat a unique pathology or physiological condition that no other device is domestically available to treat and meets all the other requirements of section 520(b). That the component is no longer being manufactured does not make the component a custom device. However, under these circumstances, a compassionate use request to allow the component to be manufactured and implanted could be submitted to FDA.

H. Are pediatric devices automatically custom devices, simply because they are for a pediatric population?

No. Pediatric patient populations may be studied just like adult populations, and, to the extent possible, they should be studied so that a device can be labeled properly. The proper labeling of a device can provide users a better understanding of the device's performance characteristics.

I. How should I label my custom device?

Custom devices remain subject to all device labeling requirements, among them requirements that the labeling bear adequate directions for use or may not be false or misleading, as well as many other labeling requirements, including those in 21 CFR 801.1. In addition, the labeling accompanying a custom device should include the following information: (1) a statement that the device is a custom device; (2) the name of the ordering physician, (3) identifying information for the patient (if applicable) whom the device is intended to treat; (4) indications for use; (5)

sterilization status; (6) relevant composition information (materials, components, etc.); and (7) storage conditions.[8]

J. Can I market my custom device to the general public?

No. A custom device is made at a physician's order on patients with a sufficiently rare condition or for a physician's special needs (e.g., unique pathology or unique physiologic condition). Section 520(b)(1)(C) specifies that, among other things, a custom device is not made generally available in finished form through labeling or advertising.

K. What are some examples of devices that are potential custom devices?[9]

A possible example of a custom device might be one manufactured for a patient with skeletal dysplasia requiring a total hip replacement procedure to treat her osteoarthritis. The patient's skeletal dysplasia could be characterized by abnormalities in the growth and/or remodeling of cartilage and bone, resulting in short stature and angular and torsional deformities of the patient's hip. In this particular case, it is possible that currently available total hip replacement devices marketed in the United States might not successfully treat the patient's unique pathological anatomy. Other elements of the custom device exemption—for example, too small a patient population to support a clinical study—would need to be met.

Another possible example of a custom device might be an artificial cervical disc replacement for reconstruction of the cervical disc following cervical discectomy to treat cervical radiculopathy in a 7'2" male patient. Under this hypothetical scenario, the osseous dimensions of this patient's cervical spine exceed those which an available artificial cervical disc available in the United States would accommodate, and the patient represents a population which, at this time, appears to be too small to support a clinical study.

An additional example of a possible custom device might be one manufactured for a toddler needing occipital condyle screws after surviving a severe car accident that left her paralyzed from the neck down and in need of instrumentation to help hold up her head. Her physician concludes that an occiput to C2 posterior cervical fusion would be best for her. In the United States, no cleared or approved screws for placement in the occipital condyle are available in the sizes needed for this pediatric patient. At this time the pediatric patient population requiring posterior occipital condyle fusion within the size range the toddler needed could be too small to support a clinical study. Because this scenario might satisfy the custom device exemption, her physician

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[8] For additional information on device labeling, refer to 21 CFR Part 801, 21 CFR 809.10, and "Guidance on Medical Device Patient Labeling" (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070782.htm).

[9] This is not intended to exhaustively list devices that might satisfy the custom device exemption and represents only a subset of the information needed to meet the statutory requirements for a valid custom device. If you question whether your scenario might satisfy the custom device exemption, we encourage you to contact CDRH's Office of Compliance at customdevice@fda.hhs.gov to discuss.

should request custom occipitocervical implants for non-standard, pediatric sized screws for use in the occiput, cervical spine and upper thoracic spine of this specific patient. The multiple screws used in this procedure would be considered one unit if the physician provided the manufacturer with either a statement that the unused devices were destroyed or returned them to the manufacturer. FDA expects the manufacturer to use appropriate quality system procedures to control returned product and ensure they are only redistributed under appropriate circumstance (i.e., another valid custom device case or U.S. marketing authorization).

FDA issued a call for comments[10] on the use of custom devices in developing this guidance document. We received no examples describing a potential physician-centric custom device. Assuming all other aspects of the custom device exemption in the FD&C Act are met, a potential example of a physician-centric medical device could be one for a surgical instrument requiring premarket review that needs to be modified to accommodate a deformity of a surgeon's hand.

L. What are some examples of a device that is not a custom device?

A primary total knee replacement (TKR) patient received company X's TKR device. Later, the patient needs a revision of one side of the TKR joint replacement, which use of company X's currently legally marketed off-the-shelf component for revision surgeries could accomplish. However, the hospital where the patient's doctor practices only uses company Y's products. The doctor would like to request that a custom company Y component be made to replace the patient's failing company X component. This hypothetical situation would not satisfy the requirements for a custom device exemption because a legally marketed device is domestically available to treat the patient. [See Section 520(b)(1)(D) of the FD&C Act.] This situation may be more appropriately addressed through application of the compassionate use program in order to distribute the device in interstate commerce without a cleared or approved marketing application.

VI. Annual Report

The statutory amendments to the custom device exemption under FDASIA added a new reporting requirement; namely, that *"… the manufacturer of such [custom] device notifies the Secretary on an annual basis, in a manner to be prescribed by the Secretary, of the manufacture of such device."* See 520(b)(2)(C) of the FD&C Act. In short, the manufacturer must report to FDA annually on the custom devices it supplied. The annual report should include the number of patients who received a new device or revisions of a previous custom device. Additionally, multiple custom devices or components used in one patient should be accounted for in the annual report. As noted in Section IV of this 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. Furthermore, the annual report should account for the number of custom devices physicians are provided, return to the manufacturer, or destroy.

[10] See 77 FR 69488 (Monday, November 19, 2012).

The annual report should summarize the number of custom devices manufactured and distributed in the United States during a 1-year reporting period. Each annual report should cover an entire calendar year (i.e., January 1-December 31 of a given year). The first report should contain information on custom devices manufacturered e from the date of enactment of FDASIA (July 9, 2012) through the date of the first report. For all subsequent reporting periods, the report should be submitted to FDA within the first quarter of the following calendar year (i.e., no later than March 31). FDA will not enforce the annual reporting requirement until the end of the calendar year following publication of the final guidance.

A complete annual report should include all of the information set forth below. FDA can review complete annual reports more efficiently, and FDA may be less likely to request additional information if a company submits a complete annual report. The following sections provide guidance on how to submit an annual report to FDA and the content of that report for both patient-centric and physician-centric custom devices.

A. Annual Report – General Contents

The following general information should be included in both patient-centric and physician-centric annual reports.

1. Cover Letter

Your report should include a cover letter that clearly states that the reason for the submission is a "Custom Device Annual Report" in the reference line. The cover letter should contain your complete contact information (i.e., the company name, company address, company website, contact person, contact person's title, contact person's phone number, contact person's fax number, and contact person's email address). The cover letter should also clearly identify the custom devices manufactured and distributed during the reporting period, and include the signature of the contact person or other responsible party within the company. The cover letter should also specify the reporting period (i.e., the dates the reporting period begins and ends).

2. Truthful and Accurate Statement

Your report should include a signed Custom Device Annual Report Truthful and Accurate statement that 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 your knowledge and that no material fact has been omitted. See Appendix II for a copy of the statement we recommend you use.

3. Other Logistical Information

Your Custom Device Annual Report should be written in English. Any material provided in a foreign language should be accompanied by an accurate and complete English translation. You should send two copies of your Custom Device Annual Report to the address below, including at least one hard copy:

Attn: Custom Device Annual Report Submission Coordinator
Division of Analysis and Program Operations
Office of Compliance
Center for Devices and Radiological Health
U.S. Food and Drug Administration
WO66, Room 2622
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Though not required for Custom Device Annual Reports, we strongly encourage you to submit one of the two required copies as an eCopy (i.e., a PDF file on a CD, DVD, or flash drive). See "eCopy Program for Medical Device Submissions: Guidance for Industry and Food and Drug Administration Staff" (http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM313794.pdf) for more information about submitting an eCopy.

B. Annual Report – Patient-Centric Custom Device Information

As described in Section V.B. of this guidance, a custom device is either patient-centric or physician-centric, but not both. In addition to the requested elements listed in Section VI.A. (above), the following elements should be provided to FDA in a Custom Device Annual Report for patient-centric devices to ensure the conditions listed in sections 520(b)(1) and 520(b)(2) are met.

1. Explanation of how the device satisfies the elements of Section 520(b) of the FD&C Act.

In your report, you should include a justification for how or why the device manufactured to treat an individual patient meets each of the following conditions contained in the FD&C Act:[11]

a) To explain how sections 520(b)(1)(B) and (b)(2)(A) are met, you should provide an explanation of why the device necessarily deviates from the premarket requirements, including treating a sufficiently rare condition, such that conducting clinical investigations on it are impractical. You may include information on the incidence or prevalence of the condition or disease the device is intended to diagnosis, treat, mitigate, prevent, or cure, or for which it is otherwise intended to affect the structure or any function of the body. References for the data provided should also be included. If the incidence or prevalence material referenced is not available in the published literature, you should include a copy of the reference in the annual report. If you believe that information on the incidence or prevalence of the condition or disease is not available, you

[11] See Section VII of this guidance document for the complete text contained in section 520(b) of the FD&C Act.

should provide an explanation why you believe the information is not available.

b) To explain how section 520(b)(1)(A) is met, you should 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.

c) To explain how section 520(b)(1)(C) is met, you should 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.

d) To explain how part of section 520(b)(1)(D) and section 520(b)(2)(B) are met, you should provide a complete description of the device, including device type (e.g., product code, as applicable), as well as the patient's unique pathology or physiological condition the device was designed to treat.

e) To show that section 520(b)(1)(D) is met, you should provide a statement that no other device is domestically available to treat the patient's unique pathology or physiological condition. You should maintain records of the evaluation that you used to determine that no other device is domestically available to treat the patient's unique pathology or physiological condition.

f) To explain how section 520(b)(1)(E)(ii) is met, you should provide a unique patient identifier for the individual patient in the physician's order.

g) To explain how section 520(b)(1)(F) is met, you should 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. Additionally, you should explain under section 520(b)(1)(G) whether the device or device components have common, standardized design characteristics, chemical and material compositions, and the same manufacturing processes as commercially distributed devices.

2. Summary of Custom Devices Shipped, Used, Returned, and Destroyed

You should provide a summary of all the custom devices the ordering physician supplied, used, returned, and destroyed during the reporting period. This includes the name or description of the device and product code (if available). This summary should also include information on the number of each type of device that was shipped, used/remaining with the patient (e.g., implanted) in new and revision patients, and the number of custom devices that were returned to the manufacturer/distributor or the ordering physician destroyed. To facilitate FDA's review of your summary report, we recommend using the format described in Table 1 of Appendix I for reporting this information.

3. Details on Custom Device Use

You should provide the following detailed information on custom devices manufactured during the reporting period.

a) Patient Information. You should indicate 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 and a description of the condition that necessitated use of a custom device.

b) Physician information. You should provide the name, address, and other contact information for the treating physician for each patient procedure.

c) Custom device or custom device components. For each custom device or device component remaining with the patient, you should provide details on each device or device component. 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 product code (if applicable).

To facilitate FDA's review of your detailed custom device report, FDA recommends the format described in Table 2 in Appendix I for presenting patient, physician, and device information.

C. Annual Report – Physician-Centric Custom Device Information

As described in Section V of this guidance, a custom device is considered to be patient-centric or physician centric, but not both. In addition to the requested elements listed in Section VI.A. (above), the following elements should be provided to FDA in a Custom Device Annual Report for a physician-centric device to ensure that the conditions listed in sections 520(b)(1) and 520(b)(2) are met.

1. Explanation of how the device satisfies the elements of Section 520(b) of the FD&C Act

In your report, you should include a justification for how or why the device manufactured meets the special needs of a physician in the course of his/her professional practice and satisfies each of the following conditions contained in the FD&C Act:[12]

a) To explain how sections 520(b)(1)(B) and (b)(2)(A) are met, you should provide an explanation of why the device necessarily deviates from the premarket requirements including addressing a sufficiently rare condition, such that conducting clinical investigations are impractical. You may include information on the incidence or prevalence of the condition

[12] See Section VII of this guidance document for the complete text contained in section 520(b) of the FD&C Act.

or disease the device is intended to diagnose, treat, mitigate, or prevent. References for the data provided should be included. If the incidence or prevalence material referenced is not available in the published literature, you should include a copy of the reference in the annual report. In addition, you should include an explanation of why conducting clinical investigations on such device would be impractical. If you believe that information on the incidence or prevalence of the condition or disease is not available, you should identify why you believe the information is not available.

b) To explain how section 520(b)(1)(A) is met, you should indicate if the device was a newly created device or modified from an existing legally marketed device in order to comply with the order of an individual physician, as well as the name of the individual doctor in the order.

c) To explain how section 520(b)(1)(C) is met, you should 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.

d) To explain how part of section 520(b)(1)(D) and section 520(b)(2)(B) are met, you should provide a complete description of the device,; including device type (e.g., product code, as applicable), as well as the doctor's special need that the device was designed to meet.

e) To show that sections 520(b)(1)(D) and 520(b)(1)(E)(i) are met, you should provide a statement that no other device is domestically available to address the doctor's special need in the course of conducting his/her practice. You should maintain records of the evaluation that you used to determine that no other device is domestically available to address the doctor's or dentist's special needs are met.

f) To explain how section 520(b)(1)(F) is met, you should 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, per 520(b)(1)(G), you should explain whether the device or device components have common, standardized design characteristics, chemical and material compositions, and manufacturing processes as commercially distributed devices.

2. Accommodating a Physician's Special Need

You should provide an annual summary of all the custom devices a physician is supplied and/or returns or destroys to accommodate a special need. This information should include the name or description of the device and product code (if applicable). This summary should also include information on the number of each type of device that was shipped/used during the reporting period and the number of custom devices that were returned to the manufacturer/distributor or the ordering physician destroyed. To facilitate

FDA's review of your summary custom device report, we recommend you use the format described in Table 1 in Appendix I.

3. Details on Custom Device Use

You should provide the following detailed information on custom devices distributed during the reporting period:

a) Physician information. You should provide the name, address, and other contact information for the physician ordering the custom device.

b) Custom device or custom device components. You should provide information on 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. This includes the date of manufacture, the product name, brand name, product model number, product catalog number, or other product identifier information, and product code (if applicable).

To facilitate FDA's review of your detailed custom device report, FDA recommends the format described in Table 3 in Appendix I for presenting physician and device information.

D. FDA's Review of Your Annual Report

FDA's review of annual reports allows the agency to assess several important issues related to the manufacture and distribution of custom devices. These issues include the adequacy of report documentation and fulfillment of the requirements of section 520(b) of the FD&C Act. If we find that the information provided in your annual report is insufficient to allow a complete review, we may request additional information by letter, telephone, or e-mail.[13] If we only need clarification of an issue, we may communicate on such issues either via telephone or e-mail, whichever we believe will be the most efficient.

VII. Complete Text of Section 520(b) of the Food, Drug and Cosmetic Act

Section 520(b) (21 U.S.C. 360j(b)) is amended to read as follows:
(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);

[13] Section 520(b)(2)(C) of the FD&C Act now requires that custom device manufacturers submit annual reports for all devices distributed under the custom device exemption. Without submission of the required annual report to FDA, devices distributed as "custom devices" would not be exempted from any applicable premarket requirements.

(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;
(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
(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.

(3) GUIDANCE.—Not later than 2 years after the date of enactment of this section, the Secretary shall issue final guidance on replication of multiple devices described in paragraph (2)(B).

Please see Appendix III for a flow diagram of the decision tree needed to implement the custom device provisions in the FD&C Act.

VIII. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520).

The time required to complete this information collection is estimated to average forty hours per response, including the time to review instructions, search existing data sources, gather the data needed, and complete and review the information collection. Send comments regarding this burden estimate or suggestions for reducing this burden to:

FDA PRA Staff,
Office of Operations,
Food and Drug Administration,
PRAStaff@fda.hhs.gov

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this information collection is 0910-0767 (To find the current expiration date, search for this OMB control number available at https://www.reginfo.gov).

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	

Table 3. Physician-Centric Devices - Summary of Physician and Device Information

Physician name, degree and address	**Date(s) of procedures**	**Description of special need necessitating custom device**	**Custom device name or custom device components**	**Other relevant information**
			Product name, Brand name, Product model number, Product catalog number, Other product identifier information, Product code, Product classification regulation, Material composition	

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Appendix II

Custom Device Annual Report 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.

_____

(Signature)

_____

(Typed Name)

_____

(Date)

Appendix III
Custom Device Decision Tree

Note the term physician in the decision tree stands for physician, dentist or specially qualified person as noted in Section 520(b) of the FD&C Act.

