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Client Alert

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FDA Holds Webinar Discussing Final Guidance on Custom Device Exemptions

Restrictions Loosened but Exemption Remains Narrow

On October 14, 2014, the U.S. Food and Drug Administration (FDA or "the Agency") held a webinar for industry to explain the guidance document, Custom Device Exemption: Guidance for Industry and Food and Drug Administration Staff ("Custom Device Exemption Guidance"), that issued on September 24, 2014.[1] During the webinar, FDA discussed the new guidance and answered questions from stakeholders. Slides from the webinar, as well as a complete recording of the webinar, are available on FDA's website.[2]

The webinar and the Custom Device Exemption Guidance describe FDA's thinking associated with implementation of section 520(b) of the Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 360j(b), as modified by the 2012 Food and Drug Administration Safety and Innovation Act (FDASIA).[3] Specifically, the guidance and webinar provide FDA's interpretation of the statutory criteria for exemption of custom devices from premarket review requirements, focusing in particular on how the Agency construes the annual limit of five custom devices per device type for each manufacturer and the information that must be included in an annual report to be submitted to FDA. The final guidance contains some key differences from the draft guidance, including clarification of the term "product type" as it relates to the five device cap. Although the guidance, as finalized, contains some added flexibility, the custom device exemption remains a narrow exemption to standard premarket approval or clearance requirements. Comments on the guidance may be submitted at any time and should reference docket number FDA-2013-D-1601.

Background

Section 520(b) of the FDCA, which provides a narrow exemption from pre-market review requirements for certain custom devices, was modified by FDASIA in 2012. The FDASIA amendments provided for use of the exemption for both new and modified existing devices, whereas the provision had previously been limited to new, one-off devices. The amendments also prohibited manufacturers from selling more than five custom units of a device type per year and established an annual reporting requirement for manufacturers who made use of the exemption.

Under the custom device provision of the FDCA (§520(b)), as modified by FDASIA, a device will only be considered a custom device, and therefore exempt from premarket review requirements, if it meets all the following criteria:

- it is created or modified based on an order from a physician or dentist;
- it "necessarily deviates" from a performance standard or PMA requirement;
- it is "not generally available" in the United States in finished form;
- it is designed to treat a unique pathology or physiological condition that no other domestically available device can treat;
- it is intended to meet the special needs of a physician or dentist ("physician-centric"); or is intended for use by an individual patient named in the physician or dentist's order ("patient-centric"); and
- it is assembled from components or manufactured on a case-by-case basis. [4]

In addition, the custom device exemption from premarket review will apply only if the following conditions are met:

- the device is for the purpose of treating a "sufficiently rare condition" that "conducting clinical investigations on such device would be impractical;"
- production of the device is "limited to no more than 5 units per year of a particular device type, provided that such replication otherwise complies" with these requirements; and
- the manufacturer provides annual reports to FDA regarding production of custom devices.[5]

Notably, under the FDASIA amendments, a custom device may have common, standardized design characteristics, chemical and material compositions, and manufacturing processes as commercial devices.[6]

The Custom Device Exemption Guidance includes definitions for several key terms included in the statutory exemption requirements. Most importantly, the guidance modifies and finalizes the definition of "device type."

Clarification of "Five Units per Year of a Particular Device Type"

Given that products will not be eligible for the custom device exemption if they are produced in a quantity greater than "5 units per year of a particular device type," the definition of "device type" is pivotal. In the draft guidance, FDA incorporated the definition of "generic type of device" from 21 C.F.R. § 860.3(i): "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."[7] In an attempt to further distill the meaning of "device type," FDA elaborated that the term "describes devices with common design characteristics and indication/intended use, such as those devices defined by an FDA classification regulation or product code."[8] This additional language raised serious concerns among stakeholders.

In finalizing the Custom Device Exemption Guidance, FDA clarified that it would approach the definition of "device type" with greater flexibility, not necessarily classifying all devices in a given product code or classification regulation as falling within the same "device type." FDA deleted the language describing "device type" as dependent on "common design characteristics and indication/intended use, such as those devices defined by an FDA classification regulation or

product code." Instead, the guidance defines "device type" by simply adopting the definition of "generic device type" in 21 C.F.R. § 860.3(i). FDA further explained that the definition of device type takes into account "multiple considerations such as anatomical location, disease state, material, technology, and indications."[9] FDA elaborated with an example of knee replacement device systems, which the Agency explained can comprise multiple device types, despite being used in the same anatomical location, if different technological characteristics, materials, or disease state uses apply.[10] FDA reiterated this view in its October 14, 2014 webinar, explaining that knee replacement devices could span multiple types of devices for purposes of the five devices per year cap based on the materials used to produce the product and the type of replacement device (*e.g.*, metal, polymer, constrained, unconstrained). "Device type" would not create distinctions between component pieces of a knee replacement system, however. For example, femoral and tibial components of a single knee replacement system would not be classified as two different device types.

FDA retained provisions in the draft guidance related to production of multiple devices for sizing, or use of multiple devices within a single patient (*e.g.*, for bilateral conditions).[11] In both the guidance and the webinar, however, FDA stressed that, although it 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, the additional devices, not used for the patient, will be counted against a manufacturer's quota if they are not returned to the manufacturer or destroyed (with appropriate documentation) by the physician. FDA will count the unused units toward the five unit limit if a manufacturer cannot produce adequate documentation of either the physician's destruction of the units or the manufacturer's receipt and holding of the additional units until valid marketing authorization is provided or a subsequent custom device case requires their use. Additionally, when a patient requires multiple custom devices of the same type, in cases such as a bilateral condition or treatment, FDA will count the multiple devices as one unit for purposes of calculating the annual limit so long as all are provided to or implanted in the patient within the same reporting year.

In the webinar, FDA clarified that, even if a custom device is used for short-term or temporary purposes, it cannot be returned to the manufacturer after patient use to avoid counting as a custom device in the manufacturer's annual quota. Once a device has been used in customer care, it will be counted toward the five-unit annual quota.

FDA finalized without alteration the exclusion from the five unit limit actions to revise and service existing, valid custom devices, "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."[12] The finalized guidance also makes note of compassionate use provisions for devices that do not meet the requirements for the custom device exemption but for which there is an identified patient for whom no alternative therapy exists. Manufacturers would need to comply with the requirements for compassionate use of medical devices should they follow this route.

Annual Reports

Under the FDASIA amendments, manufacturers must submit annual reports regarding the custom devices they have supplied. Specifically, section 520(b)(2)(C) of the FDCA states, "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." The first report, however, must contain information on custom devices manufactured from the date of enactment of FDASIA (July 9, 2012). Accordingly, the first manufacturer report should include information relating to custom devices manufactured between July 9, 2012 and December 31, 2014.[13] It will be due March 31, 2015. Subsequent annual reports should cover an entire calendar year, and be submitted by March 31 of the following year.

Each annual report should include a cover letter, a signed certification statement, and detailed information about the custom devices distributed by the manufacturer that year. The summary data table and the model certification statement included in the guidance appendices provide examples of how FDA suggests the annual report be formatted. For both physician-centric and patient-centric custom devices, specific reporting requirements apply. The basic information to

convey, however, is largely similar. In one section of the annual report, manufacturers are required to explain how each device supplied meets each of the custom device provision requirements. FDA explained during the custom device webinar that, to the extent that it may be difficult to prove or explain that there is no domestic alternative or that a clinical trial would be impractical, the Agency expects manufacturers to make a good faith effort to find appropriate information and to document their research efforts.[14] A second section of the annual report should include the number of all custom devices distributed, an account of the custom devices that are returned or destroyed, the number of patients who receive a device or revisions of a previous custom device, and, if multiple devices were used in one patient, each custom device used must be accounted for. The third section of the report should include details about the use of the custom device, including patient information, physician information, the number of devices used, and any applicable product name, brand name, model number, catalog number, product code, and classification regulation. FDA views this latter information as useful, primarily to identify the device, whether it is a modified existing device or a new device.

Custom device manufacturers should submit two copies of their annual report, including at least one hard copy. FDA encourages manufacturers to submit the second report copy as an eCopy (*i.e.*, PDF file on a CD, DVD, or flash drive).

FDA will use annual reports to identify where industry requires further clarification in order to interpret and apply the exemption appropriately. The Agency will also use annual reports to monitor compliance with the custom device exemption and track the number and types of custom devices to respond to inquiries from Congress and others.

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King & Spalding will continue to monitor FDA guidance and policy regarding custom devices. Please let us know if you would like assistance applying the final guidance to your policies and procedures for custom devices.

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[1] *Custom Device Exemption: Guidance for Industry and Food and Drug Administration Staff; Availability*, 79 Fed. Reg. 57,112 (Sept. 24, 2014), Guidance available at: http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm415799.pdf [hereinafter Custom Device Guidance]
[2] Food and Drug Administration, *Custom Device Exemption*, http://www.fda.gov/downloads/Training/CDRHLearn/UCM418838.pdf (slides); http://www.fda.gov/downloads/Training/CDRHLearn/UCM419432.wmv (recording).
[3] Pub. L. No. 112-144, § 617, 126 stat. 993, 1062 (2012).
[4] FDCA § 520(b)(1) [21 U.S.C. § 360j(b)(1)].
[5] FDCA § 520(b)(2) [21 U.S.C. § 360j(b)(2)].
[6] FDCA § 520(b)(1)(G) [21 U.S.C. § 360j(b)(1)(G)].
[7] *Custom Device Exemption: Draft Guidance for Industry and Food and Drug Administration Staff* 2 (Jan. 14, 2014). [hereinafter Draft Guidance]
[8] *Id.*at 2.
[9] Custom Device Guidance at 3.
[10] *Id.*
[11] *Id.* at 4.

[12] *Id.* at 7.
[13] *Id.* at 10.
[14] FDA Custom Device Exemption Guidance Webinar (Oct. 14, 2014).