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Custom Device Exemption Remains Narrow, but FDA's Final Guidance Addresses Industry Concern About "Device Type" Definition

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The FDA announced the availability of its final guidance on the "custom device exemption" on September 24, 2014 and held a webinar on this topic on October 14, 2014. The final guidance contains several changes from the draft guidance. Most significantly, FDA has broadened its interpretation of "device type," thereby reducing the severity of the statutory limit of five custom devices per "device type" per year.

Under section 520(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) (21 U.S.C. § 360j(b)), custom devices are exempted from FDA's premarket approval and clearance requirements (but not other device requirements). The custom device exemption was included in the 1976 Medical Device Amendments, but was significantly changed when Congress enacted the Food and Drug Administration Safety and Innovation Act (FDASIA) in 2012. FDCA § 520(b) currently provides that a custom device must meet the following criteria:

- Be created or modified to comply with the order of a physician;
- Deviate necessarily from a performance standard or requirement for cleared or approved devices;
- Not be generally available in finished form in the United States;
- Be designed to treat a unique pathology or condition that no other domestically available device can treat;
- Meet the special needs of a physician/patient;
- Be assembled from components or manufactured on a case-by-case basis to accommodate the unique needs of the physician or patient;
- Be "for the purpose of treating a sufficiently rare condition, such that conducting clinical investigations on such device would be impractical."

- Production must be “limited to no more than 5 units per year of a particular device type.”

Uncertainty over the scope of these limitations has caused considerable anxiety among medical device firms.

Most critically, firms have wondered: What is a “device type”? Is it a narrow or a broad category? Incorporating comments from industry, the final guidance creates a flexible standard for determining whether devices constitute different “device types.”

Like the draft guidance, the final guidance defines “device type” with reference to the definition of “generic type of device” in FDA regulations at 21 C.F.R. § 860.3(i). In wording identical in the regulation and guidance, a generic device type is:

“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.”

Unlike the final guidance, the draft guidance had further limited “device type” to devices with “common design characteristics and indication/intended use, such as those devices defined by an FDA classification regulation or product code” (emphasis added). Industry reacted strongly to this supplemental language about FDA classification regulations and product codes.

For example, AdvaMed, the largest trade association of medical device companies, submitted a comment on the draft guidance in which they argued that this additional language would sweep too broadly and undercut the purpose of FDASIA. As AdvaMed explained, a single FDA classification regulation or product code may encompass different device types with different compositions and functions. AdvaMed argued that limiting manufacturers to five products within a single FDA classification regulation or product code would drastically reduce the ability of manufacturers to meet the needs of patients with unique conditions. AdvaMed provided the example of FDA code KWP (registration number 888.3050), which includes a posterior cervical spine system, iliac screws for the lumbar spine, and pedicle screws for the lumber, thoracic, and sacral spine — different uses for different parts of the body.

Addressing this concern, the final guidance omits references to FDA classification regulations or product codes in its definition of “device type,” and instead adheres to the regulatory definition of generic device type. This regulatory definition is flexible and allows for consideration of different materials and function and other features related to safety and effectiveness in deciding whether devices fall within the same “device type.” Although much uncertainty remains, FDA has backed away from its proposal to use product codes as a criterion for defining device types.

During the webinar’s question-and-answer session, FDA explained that the five-per-device-type limit is also specific to the disease. For example, a manufacturer could make five knee device systems per year to treat one disease of the knee and five to treat another knee disease, provided both knee diseases are sufficiently rare.

Additionally, the final guidance provides that an unused custom device is subtracted from the 5-device-per-year tally if it is destroyed by a physician, whereas only devices returned to the manufactured could be subtracted from the tally under the draft guidance.

Like the draft guidance, the final guidance encourages physicians to consider FDA's guidance on "compassionate use," suggesting that devices that fail a criterion for custom devices may still qualify for "compassionate use." This would be applicable to unapproved and uncleared devices when the use complies with the investigational device exemption regulations.

FDA's final guidance also describes the content of the Custom Device Annual Report that must be submitted to FDA. FDA is asking for detailed information on patients, physicians, and the justification for the custom device. Physicians and manufacturers should note that FDA continues to interpret the custom device exemption narrowly and will be monitoring uses under the annual reporting requirement.

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