Customization is a fact of life. As consumers, we insist on customizing many of the products we purchase. As learners, we want a program geared to our individual needs. Even in medicine, patients expect a personalized treatment program that addresses their specific needs. As orthopaedic surgeons, we often find ourselves in situations that are best addressed by a customized device or implant, particularly if we have a practice focused on reconstructive surgery (including spine, arthroplasty, oncology, and pediatrics). It may be that the patient’s anatomy is such that only a truly custom device is appropriate. Or, it may be that the patient has comorbid conditions that prevent him or her from participating in the clinical trial of a device that would otherwise be suitable.

The U.S. Food and Drug Administration (FDA) has recently made multiple changes to the rules and regulations governing how end users may acquire devices necessary to treat patients who have unique or unusual circumstances. These changes maintain the agency’s commitment to providing consumers with a reasonable assurance of safety and effectiveness of devices, while also recognizing that some patients may have a higher tolerance of risk. Each of these pathways has unique circumstances and variables that must be understood so approval through the proper channels can be obtained. This article reviews the three pathways—the custom device exemption (CDE), compassionate use request (CUR), and humanitarian device exemption (HDE)—that we as surgeons may use in treating our patients.

**Custom devices**

Physicians have been able to request a CDE since the initial 1976 amendments establishing medical device regulation. However, the passage of the Food and Drug Administration Safety and Innovation Act in 2012 sparked several changes to the regulatory structure surrounding custom devices. According to two court decisions regarding orthopaedic devices (2008 and 2009) and the FDA, “custom devices should represent a narrow category for which, because of the rarity of the patient’s medical condition or physician’s special need, requiring compliance with premarket review requirements and performance standards under sections 514 and 515 of the Food, Drug, and Cosmetic Act is impractical.”

Fig. 1 shows the specific set of circumstances that must be met to obtain a CDE. Note that all the requirements must be met; if the answer to any one question is “No,” a CDE is not available and some other pathway must be used. Changes to the custom device provision set the number of occurrences for which a manufacturer could use the custom device pathway at five per year. They also include a provision clarifying that the FDA would consider devices on a per-patient—rather than a per-use—criterion. Thus, if a patient requires bilateral custom implants, the manufacturer can consider this as one occurrence rather than two. This expands the availability of a device for treating a sufficiently rare condition by giving both manufacturers and physicians more opportunity to have a five-time occurrence-per-year limit before the point is reached where conducting clinical investigations on such a device may be considered to become practical.

The new provisions amended the existing CDE regulations and introduced new aspects and procedures, such as the following:

- the potential for multiple units of a device type (not to exceed five units per year) qualifying for the custom device exemption
- annual reporting requirements by the manufacturer to FDA about custom devices
- the inclusion of devices that are for a patient’s unique physiologic or pathologic needs as well as for the unique practice needs of a physician, surgeon, or dentist

The physician must find a manufacturer willing to supply the custom device and start the application process with that manufacturer. FDA has no premarket role in determining if a device is custom or not. The decision is up to the manufacturer. The manufacturer documents the decision and reports it in its annual report to FDA.

**Compassionate use**

Recognizing that the custom pathway may not be appropriate for some individual needs of patients, the FDA also has a “compassionate use” pathway that enables unique and unusual circumstances to be handled in a timely fashion once submitted by the manufacturer on behalf of the surgeon. Although not well known, the CUR can be helpful in many circumstances that do not meet all the criteria for a custom device exemption.

Regardless of the status of an investigational device exemption (IDE), the CUR submitted to FDA by a manufacturer on behalf of a surgeon is another way that surgeons can obtain an unapproved device needed for a patient. If a CUR is filed outside an IDE, a monitoring schedule should be designed to meet the needs of the patients while recognizing the investigational nature of the device. Follow-up information on the use of a compassionate use device should be submitted in a report after patients have been treated. In addition, the CUR may be used in a situation that requires the use of an investigational device in a manner inconsistent with the approved investigational plan or by a physician who is not part of the clinical study for the device. CUR can also be applied when a physician wishes to treat a group of patients who have a serious disease or condition for which no alternative therapy (typically a legally marketed device) adequately meets their medical need.

In this case, the physician should...