May 14, 2018

FDA Issues Draft Guidance on Devices with Multiple Functions

On April 27, 2018, FDA issued draft guidance on the regulation of devices with multiple functions. The draft guidance implements a requirement of the 21st Century Cures Act (Cures Act), signed into law on December 13, 2016, prohibiting FDA from directly regulating non-"device" software functions in digital health products. FDA did not limit the scope of the draft guidance to cover only the Cures Act mandate, however. Instead, the draft guidance addresses any type of product that includes both device and other functions, regardless of whether those functions involve software. Therefore, any manufacturer of a product that includes both FDA-regulated device functions and non-FDA-regulated functions should be familiar with the draft guidance.

The Cures Act's Limitation on FDA Regulation of Software Devices with Multiple Functions

As described in a previous Ropes & Gray Alert, Section 3060 of the Cures Act established boundaries around FDA's legal authority to regulate health-related software by removing certain software functions from the definition of "device" under section 201(h) of the Federal Food, Drug, and Cosmetic Act. The Cures Act also provided that, in the case of a product that contains at least one function that meets the definition of a device and one software function that does not meet that definition, FDA is prohibited from regulating the non-device software function as a device. Despite this restriction, the Cures Act expressly permits FDA to assess the impact of the non-device software function on the device function when assessing the safety and effectiveness of the device function. FDA had previously announced that it would issue guidance on its interpretation of this statutory change.

The Draft Guidance

According to FDA, the same principles set out in the Cures Act with respect to software functions apply to the assessment of *all* multiple function products that contain at least one device function. The draft guidance, entitled "Multiple Function Device Products: Policy and Considerations," recognizes that a product may contain multiple functions, not all of which are subject to FDA premarket review because the product contains: (i) a function that does not meet the statutory definition of "device," (ii) a function that is a "device" but is exempt from or otherwise not subject to FDA premarket review, or (iii) a function over which FDA has expressed an intention to exercise enforcement discretion (collectively referred to as "other" functions). For purposes of the draft guidance, a multiple function device contains at least one device function and one function not subject to premarket review.

FDA asserts that, when assessing a multiple function device under premarket review, it may assess the impact of the function(s) not subject to premarket review on the safety and effectiveness of the device function under premarket review. In determining the impact that a function not subject to premarket review may have on a device function that is subject to premarket review, FDA notes that sponsors would benefit from separating the functions in design and implementation. The higher the degree of separation between the device and other functions in the product's architecture, design, and functionality, the easier it would be for FDA to review the safety and effectiveness of the device function under premarket review independently of the other function. FDA intends to assess a product with multiple functions according to (i) whether the other function not subject to premarket review would impact the safety or effectiveness of the device function under premarket review, and (ii) whether the impact would result in an increased risk or an adverse effect on performance. When evaluating the potential impact, sponsors should consider whether there are shared computational resources, data dependencies, or other types of relationships between the functions.

If the sponsor determines that there could be an adverse impact on the device function under review, the sponsor should undertake a risk mitigation assessment and appropriate verification and validation testing to characterize the safety and performance of the device function under premarket review. Accordingly, a premarket submission for such a product should include additional documentation describing, among other things, the other functions not under premarket review, how those functions interact with the device function under review, and any safety or effectiveness issues resulting from the impact.

The draft guidance also clarifies that postmarket general controls, such as the quality system regulation (including design controls) and medical device reporting, apply to device functions that FDA regulates, but not to device functions over which FDA intends to exercise enforcement discretion or to functions that do not meet the definition of "device." Thus, a multiple function device can be subject to general control requirements as applied to some, but not all, of the product's functions.

Current Lessons from the Draft Guidance

Although only in draft form, the guidance provides insight into how FDA conceives of its authority to regulate multiple function devices consistent with the Cures Act. The document may be useful not only for manufacturers of products that contain software functions that meet the definition of a device, but also multiple function devices where the other function involves hardware, not software. In particular, the draft guidance emphasizes the need to think carefully about product design and architecture early in product development. Where possible, designing device architecture with clear lines of demarcation between the device and other functions of the product can be valuable. Where the device and other functions are necessarily interdependent, risk mitigation assessment and documentation become paramount.

When developing a multiple function device, companies should consider how to operationalize FDA's approach. For example, a company's design control procedures could describe the manner in which the company will handle design documentation for such products. In addition, or in the alternative, project-specific design documentation could address that question. Similarly, manufacturers may want their medical device reporting procedures to describe how they will handle evaluation and regulatory reporting of adverse events associated with multiple function devices.

FDA will be accepting comments on the draft guidance until June 26, 2018.

Ropes & Gray will continue to monitor developments in this area. For further information about how the issues described in this Alert may affect your interests, please contact a member of Ropes & Gray's FDA regulatory practice or your usual Ropes & Gray advisor.