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Multiple function device products — FDA clarifies its approach

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On April 27, 2018 FDA released a draft guidance describing the regulatory approach and policy for multiple function device products. The draft guidance, Multiple Function Device Products: Policy and Considerations, has been issued in response to the 21st Century Cures Act Sec. 3060(a) "Clarifying Medical Software Regulation." The guidance is available at https://bit.ly/2s4F3YX.

The term "function" is defined as "a distinct purpose of the product, which could be the intended use or a subset of the intended use of the product." Draft Guidance at 4.

The draft guidance is intended to clarify how FDA assesses the impact of functions that are not subject to FDA review when they are part of a multi-function product that includes at least one function that is subject to FDA review.

In short, the draft guidance indicates that FDA will not regulate functions of a multi-function product that do not meet the statutory device definition or are devices that are subject to an existing enforcement discretion policy.

The draft guidance is a positive step forward in providing clarity, even if it does not break new ground.

Also, though issued in relation to software functions, FDA states that they apply the same principles to the assessment of all multiple function products, not just those that contain software.

During review of premarket applications, FDA will assess the impact of "other functions" on a device function-under-review without reviewing the specifics of the other functions' design and performance not related to the device function-under-review.

In assessing the impact that these other functions may have on the device function-under-review, FDA will consider whether the other function(s) may impact the safety or effectiveness of the device function-under-review, by considering "whether there are shared computational resources, data dependencies, or any other type of relationship between the functions." *Id.* at 9.

If the other function(s) may impact the safety or effectiveness of the device function-under-review, FDA will consider whether there is an increased risk or adverse effect on performance.

Although sponsors may include information on other functions that positively impact the device function-under-review in their premarket submissions, FDA will only look for documentation on other functions in cases where the other function "could adversely impact the device function-under-review." *Id.* at 11.

A premarket submission for a multi-function device that includes other functions that could adversely impact the device function-under-review should include a description of the function, architecture and design information, risk analysis, requirements, and specifications.

Also, FDA intends to include language in the submission summary (e.g., 510(k) summary) to indicate that "FDA assessed functions not subject to premarket review only insofar as they might adversely impact the safety and effectiveness of the functions subject to FDA premarket review." *Id.* at 12.

This draft guidance should help those developing multiple function products to better understand how to limit their submissions to data and documentation for other functions only when they could adversely impact the device function-under-review. The boundaries have not always been clear in the past.

On the post-market side, general control requirements are not applicable to non-device functions and will not be enforced for functions for which FDA does not intend to enforce applicable regulatory controls.

This area of device regulation has always been somewhat murky. The draft guidance is a positive step forward in providing clarity, even if it does not break new ground.

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