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Parsing products: FDA regulatory policy for multi-function medical devices

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On April 27, 2018, the U.S. Food and Drug Administration (FDA or the Agency) released a draft guidance, Multiple Function Device Products: Policy and Considerations, addressing the Agency's regulatory approach to medical devices that include both regulated and unregulated functions. Documenting the Agency's existing informal policy and building on changes enacted by the 21st Century Cures Act (Cures Act), the guidance focuses on the impact of unregulated functions on regulated functions built into the same software or hardware device.

In brief, the draft guidance provides clarity on FDA's planned implementation of Section 520(o)(2) of the FD&C Act, added by the Cures Act, which explicitly directed that otherwise unregulated software functions would not become regulated solely because they are included in a product with a regulated function. Consistent with existing FDA policy, the draft guidance, however, broadens the scope of the policy to all multiple function products (not just software products) that contain at least one device function. It also treats product functions which may be 510(k)-exempt or subject to enforcement discretion in a similar way as non-device functions (collectively referred to as "other functions"). For such "other functions," FDA will focus on any impact on the medical device function under review, as determined by the company. The draft guidance also outlines the considerations for premarket submissions associated with multiple function products.

In general, the guidance is consistent with the way FDA has been treating multiple function products for several years. Because there has been some inconsistency in this approach between review groups, the draft guidance is expected to be helpful in encouraging consistency across the Agency. The historical approach was to assess medical devices holistically during premarket review, rather than first assessing the regulatory status of each function of a product. Although the current guidance is still in draft form, because it implements existing law, it is likely that the Agency will follow this guidance more consistently in the interim.

Key principles and considerations

Scope and terminology

The draft guidance proposes several key terms for understanding concepts associated with product functions.

- **Function**. The draft guidance defines the term "function" as "a distinct purpose of the product, which could be the intended use or a subset of the intended use of the product."

- **Other functions**. Those functions that (1) do not meet the definition of a device; (2) are exempt from premarket review; or (3) are subject to enforcement discretion.
- **Multiple function device products**. Products with at least one device function. The draft guidance provides the example of a product with an intended use to store, transfer, and analyze data – an intended use that includes three distinct functions, i.e., storage, transfer, and analysis, with the device function being analysis.

The term "device function", while used extensively, is never specifically defined in the draft guidance, although it appears to be a function that is known to meet the statutory definition of a medical device and to be actively regulated.

Importantly, while the language of section 520(o)(2) of the FD&C Act applies to the regulation of multiple function device products that contain at least one device function and at least one *non-device software function,* in the draft guidance, FDA intends to apply the principles to both software and hardware multi-function products.

FDA notes that the policies in the draft guidance also apply to the device component of combination products.

FDA review of multiple function device products

The draft guidance is clear that FDA does not intend to review (e.g., in a 510(k) submission) "other functions", but states that the Agency will assess the impact of the other functions (including those subject to enforcement discretion) on the safety and effectiveness of the device function. Approval or clearance decisions would then be limited to the device function.

FDA cautions that the other functions should be separated from the device functions if possible, and if not possible, controls should be in place to reduce any potential adverse impact of the other functions on the device functions-under-review.

In assessing the impact of the other functions, FDA intends to ask two questions:

1. Does the other function impact the safety or effectiveness of the device function-under review?
2. Does the impact result in increased risk or have an adverse effect on performance?

If there are increased risks or adverse impact introduced by the other functions, appropriate verification and validation should be performed to ensure risk is mitigated and to assess any effect on device function performance.

Content of premarket submissions for multiple function device products

FDA provides some guidance regarding what information should be included in a premarket submission for a device function-under-review <u>if</u> the sponsor determines that another function could *adversely* impact the device function. FDA also notes that the company can voluntarily provide such information on the other function if it *positively* impacts the device function and the company wishes for FDA to take this into account during the review. This seems to imply that if the other functions do not adversely impact the device function-under-review, they do not need to be discussed in the premarket submission. However, it appears from some of the language in the draft guidance that FDA may well want documentation that the other functions do not impact the device function-under-review as part of the product specifications and risk analysis. This is an area that may be further clarified in a final version of the guidance.

FDA provides the following guidance on the content of such a premarket submission:

- **Indications for use:** The indications for use should cover only the device function-under-review.
- **Device information:** The device description should include a description of the other functions which impact the device function-under-review, and how they impact it. The design documents should include "adequate detail to understand how or if the other functions interact with or impact the device function-under-review." Requirements and specifications should include "adequate detail to describe any expected relationship, utility, reliance, or interoperability with any other function."
- **Risk analysis:** This should include an assessment of the impact of the other functions on the device function-under-review, and any risk mitigations.

FDA notes that it will make clear in the summary document (e.g., 510(k) Summary, PMA Summary of Safety and Effectiveness Data (SSED), etc.) "the extent of the product's assessment," presumably meaning which specific functions were reviewed.

Other Controls

FDA states that there are no postmarket controls for non-device functions. The draft guidance also confirms that the Agency does not intend to enforce general regulatory control requirements for device functions that are under enforcement discretion.

Conclusions

In sum, for companies preparing premarket submissions for multiple function device products, it will be important to clearly define device functions versus other functions of the product, assess the impact of the other functions on the device function in terms of safety and efficacy, and the introduction of new risks or adverse effects, and provide documentation that those risks have been mitigated. It would be advisable for these distinctions be carried through and highlighted in all documentation and in particular during design and development and risk management.

Because the draft guidance implements provisions of the Cures Act, it is reasonable for companies to rely on the general policy articulated by the guidance, in consultation with the relevant review branch.

Comments on the draft guidance may be submitted here by June 26, 2018, referencing Docket No. FDA-2018-D-1339.

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