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ALERTS

FDA Draft Guidance Revamps Assessment Of Multiple Function Devices

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The FDA recently issued a draft guidance titled, "Multiple Function Device Products: Policy and Considerations," which seeks to clarify FDA's policy for products with multiple functions that include at least one device function. Section 3060(a) of the 21st Century Cures Act, enacted last December, added Section 520(o)(2) to the Food, Drug & Cosmetic Act, which authorizes the FDA to assess the effect non-regulated functions of multiple function devices have on the device.

The FDA does not regulate certain software functions that do not meet the statutory device definition if they are contained in a multiple function product. The FDA may, however, assess the impact of the software function on the safety and effectiveness of the device under FDA's premarket review. Comments on the draft guidance can be submitted to the docket until June 26, 2018.

The draft guidance proposes that when assessing a multiple function device product, manufacturers and the FDA should determine if any other function may impact the safety or effectiveness of the device function subject to the FDA's premarket review. If so, the impact should be evaluated to determine whether the other function has a positive or negative impact on the device function in their premarket submission.

If the other function could adversely impact the device function subject to the FDA's premarket review, the guidance details what should be included in the premarket submission of a multiple function product, as follows:

- Indications for Use - The indications for use should only include the indications for use of the device-function-under review.
- Description of Functions - The device description should include a description of the other functions that impact the device function-under-review, and address how the device function-under-review is impacted by each of the other functions.
- Architecture and Design - The architecture and design documents included in the premarket submission for the device function-under-review should include adequate detail to understand how or if the other functions interact with or impact the device function-under-review.
- Risk Analysis - The risk analysis included in the premarket submission for the device function-under-review should include a risk-based assessment of any impact of the other function to the safety or effectiveness of the device function-under-review. The risk-based assessment should document any risk mitigations

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employed to mitigate increased risk resulting from the combination of functions.

- Requirements and Specifications - Documentation of requirements and specifications included in the premarket submission for the device function-under-review should include adequate detail to describe any expected relationship, utility, reliance, or interoperability with any other function.

- Submission Summary - Where the device function-under-review is not adversely impacted by another function, FDA does not intend to assess that other function (unless the Sponsor would like FDA to consider the positive impact of the other function in FDA's assessment of the device function-under-review). Therefore, an approved or cleared device may include functionality that FDA has not assessed. FDA intends to include a statement in the 510(k) Summary, PMA Summary of Safety and Effectiveness Data (SSED), De Novo Summary, or HDE Summary of Safety and Probable Benefit (SSPB, making the extent of the product's assessment clear.

The FDA recommends that, when possible, the device function subject to the FDA's premarket review should be separated from other functions of the device, and that the higher the degree of separation, the easier it is for the agency to independently review it for safety and effectiveness.

For more information, please contact the Barnes & Thornburg LLP attorney with whom you work or Lynn Tyler, the chair of the firm's Food, Drug and Device Practice Group, at lynn.tyler@btlaw.com or 317-231-7392.