DuVal Client Alert

Passing on Tribal Knowledge of FDA Law

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2021 Retrospection Highlight

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De Novo Program

In October, FDA issued a final rule on the De Novo Classification Process. The new regulation is 21 CFR Part 860 and becomes effective on January 3, 2022 (90 days after publication of the rule). In association with this update, FDA released multiple guidance documents to assist with the preparation of these submissions.

The De Novo program may be used for commercialization of a new low or moderate risk device for which no acceptable predicate device exists. The submission includes a request for classification of the device type as either Class I (low risk) or Class II (moderate risk), including justification for the selection, recommended special controls (if Class II is recommended), and evidence to support a reasonable assurance of safety and effectiveness for the device. Once the De Novo request is granted, the product is eligible for commercialization in the United States and may be used by future products as a predicate device for clearance through the 510(k) Premarket Notification program. The final rule permits De Novo submission either after submitting a 510(k) and receiving a not substantially equivalent (NSE) determination, or without submission of a 510(k) but following determination that there is no appropriate predicate device.

An important difference between the 510(k) program and the De Novo program as defined in the new rule is that manufacturing and Quality System Regulation (QSR) activities are outside the scope of a 510(k) review, so 510(k)s are not associated with "pre-clearance" manufacturing site inspections. The new rule provides FDA with the ability to determine that an inspection may be required to determine whether general controls would be sufficient to provide an adequate assurance of safety and effectiveness, or whether special controls will be necessary. Although this inspection is not intended for compliance review with the QSR and FDA states these will not be required for most De Novo submissions, time will tell how these inspections are handled and assigned.

Because the De Novo path does not include evaluation of substantial equivalence compared to a predicate device (which can provide the scope of testing required), submitters should be aware of the range FDA will have in asking for more test data which may include human clinical studies. It is critical for these submissions to ensure the submission advocates for the product and the verification and validation that has been followed. Ensure that risks of the product are well-characterized and provide support for the adequacy and sufficiency of the data provided.

Finally, De Novo submissions are associated with significant User Fees, even for small companies. The standard De Novo fee for FY22 (through September 30, 2022) is $112,457. For a company with a small business determination, the fee is still $28,114. Due to the significant range in expectations and this fee that is significantly higher than for a 510(k) submission***, we strongly recommend requesting a Pre-Sub through the FDA Q-Submission program to obtain feedback on the testing strategy prior to submission.*** See our Client Alert series on the Q-Submission program: *Navigating the Strange Pre-Sub Experience* for tips on success with that program.

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Drug, Device and Food Law

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