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ALERTS

Food, Drug & Device Law Alert - FDA Proposes Expedited Approval Program For PMA Medical Devices For Unmet Needs

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The FDA recently released a draft guidance document titled “Expedited Approval Program for Premarket Approval Medical Devices Intended for Unmet Medical Need for Life-Threatening or Irreversibly Debilitating Diseases or Conditions.” FDA states that the program, dubbed the “Expedited Access PMA” or “EAP,” will “help patients have more timely access to these medical devices by expediting their development, assessment and review, while preserving the statutory standard of reasonable assurance of safety and effectiveness for premarket approval.”

Participation in the EAP program is only at the request of the sponsor and with FDA’s agreement. EAP devices may offer a potential for clinically meaningful benefit as compared to existing alternatives (preventative, diagnostic, or therapeutic) or provide a breakthrough technology over currently available devices for patients with life-threatening or irreversibly debilitating diseases or conditions.

The draft guidance states “FDA intends to engage with sponsors of EAP devices earlier and more interactively during the device’s development, assessment and review.” FDA further “intends to work closely with sponsors of EAP Devices to develop a Data Development Plan for the device that provides, among other elements, a description of the premarket and postmarket data collection and an explanation and justification for the proposed balance of premarket and postmarket data collection, with the goal of significantly reducing the time and cost from device development to FDA marketing decision.”

To help expedite approval, the sponsor may rely on data based on surrogate endpoints in the pre-market phase. In addition, in some cases, FDA may allow a sponsor to provide less manufacturing information in its PMA application. FDA may also forego pre-market inspection of certain manufacturing sites and instead conduct those inspections after product approval. Finally, FDA states that it “intends to impose certain postmarket requirements as part of the EAP program, including conditioning the approval of EAP Devices on continuing evaluation and periodic reporting on the safety, effectiveness, and reliability of these devices for their intended uses, in accordance with 21 CFR 814.82(a)(2).” These postmarket data will be designed to assess the risks and benefits of these devices with a higher degree of certainty and, if appropriate to protect patient safety, take appropriate enforcement action.

A pdf copy of the draft guidance is available here.

For more information, please contact the Barnes & Thornburg LLP

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