BARNES & THORNBURG LLP

ALERTS

FDA Launches Limited Pilot Program For Interactive 510(K) Application

March 2, 2020

The Food and Drug Administration (FDA) recently announced that it is soliciting participation for its voluntary Electronic Submission Template and Resource (eSTAR) Pilot Program for 510(k) applications. The goal of the program is to improve consistency and efficiency in the industry's preparation and the FDA's review of premarket notification submissions.

To be considered for the eSTAR Pilot Program, a company must submit a statement of interest to esubpilot@fda.hhs.gov, which should include 1) the company's agreement to the selection criteria and 2) a description of the device in enough detail to confirm that it is a software-enabled tissue contacting device and that it is not a combination product.

The eSTAR Pilot Program will select up to nine participants who provide a "holistic representation of the medical device industry" and meet the following selection criteria:

- Intent to submit a traditional, special, or abbreviated 510(k) for a medical device (not a combination product) using eSTAR within three months of acceptance into the voluntary program
- Agree to provide feedback on eSTAR as outlined in the Federal Register notice
- Intent to submit at least one 510(k) for a device that contacts body tissue and includes software

In addition to the benefits of its existing eSubmitter platform, which is an

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electronic template that that guides a user through preparation of a 510(k) submission, the FDA states that eSTAR will also offer the following benefits:

- More intuitive interface
- No special software installation (if the user has Adobe Acrobat or similar software already installed)
- Support for images and dynamic pop-up messages
- Mobile device and Apple iOS support
- Ability to comment when converted to a static PDF
- Ability to share (e.g., email) an eSTAR file that is in the process of being constructed
- No necessary packaging process

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