FDA In Brief: FDA launches new interactive, PDF-based, template to promote greater efficiency and consistency in preparation and review of 510(k) medical device applications

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The following quote is attributed to Jeffrey Shuren, M.D., J.D., director of the FDA's Center for Devices and Radiological Health:

"As technology advances, the FDA must keep pace with the increasing complexity of rapidly developing technology and continue to modernize and evaluate our programs and processes, ensuring they continue to be efficient, consistent and scientifically rigorous.

"To promote these goals, we're launching a new optional 510(k) submission template that allows pilot participants to submit applications to the FDA using a more dynamic electronic format capable of organizing the complex information necessary for a robust scientific review. Without changing our statutory or data requirements, this highly-interactive submission template is intended to allow manufacturers to provide information to the FDA that's complementary to CDRH internal review templates currently used to review 510(k)s, allowing us to receive information and evaluate the submission more efficiently and consistently.

"The template, referred to as the electronic Submission Template And Resource (eSTAR), will be released as part of an eSTAR Pilot Program. eSTAR is intended to improve our overall productivity, enabling the agency's review staff to put more of our time and resources into evaluating applications for devices that pose the highest potential risks to patients. Additionally, eSTAR is a step toward fulfilling our Medical Device User Fee Amendments of 2017 (MDUFA IV) commitment to streamline the premarket notification review submission process, which is also part of the FDA's ongoing effort to ensure that we're giving patients more timely access to safe, effective and high-quality medical devices."

- Today, the U.S. Food and Drug Administration is announcing (https://www.federalregister.gov/documents/2020/02/27/2020-03945/request-for-comments-improving-510k-submission-preparation-and-review-voluntary-electronic) the voluntary electronic Submission Template And Resource (eSTAR) Pilot Program (/medical-devices/premarket-notification-510k/510k-program-pilots) as an alternate method available for selected industry participants in the pilot to prepare a 510(k) submission. The FDA will select up to nine participants who provide a holistic representation of the medical device industry and meet the pilot selection criteria.
- With an eSTAR, the content of the premarket submission is embedded within a PDF document, which allows applicants more dynamic functionality when developing, viewing and editing a 510(k). eSTAR templates are designed and structured in a similar format as the FDA reviewers' template, thereby improving consistency in FDA's review of these premarket submissions.
- Submissions using an eSTAR do not change any statutory or data requirements for device sponsors to demonstrate their devices are substantially equivalent to a predicate

device. However, a Refuse to Accept (/regulatory-information/search-fda-guidance-documents/refuse-accept-policy-510ks) review (a preliminary review used to ensure the submission is complete) will not be conducted on eSTAR templates submitted as part of the pilot.

Related Information

- FDA: 510(k) Program Pilots (/medical-devices/premarket-notification-510k/510k-program-pilots)
- FDA: 510(k) Submission Process (/about-fda/510k-submission-process)
- FDA: 510(k) Clearances (/medical-devices/device-approvals-denials-and-clearances/510k-clearances)

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.