FDA U.S. FOOD & DRUG ADMINISTRATION

Software Precertification Program:
Regulatory Framework for Conducting the Pilot Program within Current Authorities

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The FDA plans to implement the Software Precertification (Pre-Cert) Pilot Program under the De Novo pathway initially, as described below. The goal of this phase of the pilot is to determine the contours of a possible regulatory model that provides efficient regulatory oversight of certain software-based medical devices from manufacturers who have demonstrated a robust culture of quality and organizational excellence (CQOE) and are committed to monitoring real-world performance while assuring that these devices are safe and effective. The pilot also will inform FDA as to whether it should seek other regulatory authorities to implement a modern, more effective, proactive, and efficient regulatory framework for software-based medical devices.

As described in version 1.0 of the Software Precertification Program: A Working Model (January 2019), the pilot program is limited to software as a medical device (SaMD), which is defined as software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device.[1] As FDA gains experience with implementation of version 1.0, we hope to develop in the future an expanded program that could leverage a software manufacturer's precertification status to the review of all its medical device software products. Ultimately, the product types that may benefit from precertification might include all software that meets the definition of a device in section 201(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) including Software as a Medical Device (SaMD), software in a medical device (SiMD), and other software that could be considered accessories to hardware medical devices. However, for version 1.0 of the program, the current focus is to establish processes for SaMD technologies, which may include software functions that use artificial intelligence and machine learning algorithms.

Utilization of De Novo Pathway for Pre-Cert Pilot

Pathway for De Novo-eligible SaMD Product

FDA intends to utilize the De Novo classification process (section 513(f)(2) of the FD&C Act) for the next phase of the Software Pre-Cert Pilot Program under its current authorities.

The De Novo classification process is a pathway for certain new types of low to moderate risk devices for obtaining marketing authorization as class I or class II, rather than remaining automatically designated as a class III device that would require premarket approval. Pilot participants who have a SaMD product eligible for the De Novo classification process could participate in an Excellence Appraisal conducted by FDA.

During the Excellence Appraisal, FDA intends to evaluate an organization according to the elements of excellence principles identified in the working model. These elements correspond to certain De Novo Request content or special control requirements or Quality System Regulation (QSR) requirements. FDA intends to document the results of the Excellence Appraisal and collect the records supporting the appraisal in a device master file; this information would support the De Novo Request and could also be used in a future premarket submission.

The excellence-appraised sponsor may opt to submit a Review Determination Pre-Submission to discuss whether the SaMD product is appropriate for a De Novo Request. During this optional

[1] http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-131209-samd-key-definitions-140901.pdf

Review Determination Pre-Sub, the manufacturer may discuss product-level information with FDA, including the product-level elements outlined in section 6 of the Working Model. The information discussed during this Pre-Sub would be documented so that FDA can reference it during the review of the subsequent De Novo Request.

The excellence-appraised manufacturer would submit a De Novo Request containing required submission content that was not already received by FDA through the Excellence Appraisal and documented in the device master file. This streamlined "Pre-Cert De Novo Request" would include those applicable submission elements of a traditional De Novo that, in addition to the elements reviewed and documented during the Excellence Appraisal, provide the required information necessary to determine that the device is of low to moderate risk and that general controls or general and special controls can provide a reasonable assurance of safety and effectiveness. (See sections 3.5 and 6.1 of the Working Model, which describe the proposed elements of a Pre-Cert submission, and the proposed Test Plan.) The Pre-Cert De Novo Request would include the submitter's certification that it is following the processes and procedures that FDA reviewed and documented during the Excellence Appraisal. All applicable elements required for a De Novo Request under the FD&C Act will, therefore, be satisfied by information submitted to FDA at different times; i.e., during the Excellence Appraisal, Review Determination, and Streamlined Review phases.

After a substantive review, if FDA finds that all De Novo premarket requirements have been met, FDA would classify the device by written order and if the device is class II, establish special controls necessary to provide reasonable assurance of safety and effectiveness for the device type. The special controls may include, for organizations who opt to pursue certification, certain Excellence Appraisal elements or include requirements for notifying FDA if certain appraisal elements are changed after the Excellence Appraisal is conducted. The special controls may also include postmarket data collection requirements, as deemed necessary for the device type. Certain special controls, such as Excellence Appraisal elements or postmarket real-world performance requirements, may permit certain modifications to the device without premarket review when the special controls effectively mitigate risks associated with such modifications.

Premarket Review of 510(k) Submissions following Classification of the Device

The De Novo order would establish a device classification that, if appropriate, enables sponsors to submit 510(k) submissions to market a device of the same type. Excellence-appraised sponsors may opt to submit a Review Determination Pre-Sub to confirm that their SaMD product is eligible for a 510(k) under the classification created by the De Novo order. During this Pre-Sub, FDA and the sponsor may also discuss which special controls are satisfied by the Excellence Appraisal, in accordance with the De Novo order. The excellence-appraised sponsor would submit a "Pre-Cert 510(k)" that includes product-specific submission requirements and leverages other submission requirements already documented during the Excellence Appraisal and optional Pre-Sub. Accordingly, FDA expects that review of a "Pre-Cert 510(k)" would be more efficient than the review of a traditional 510(k) submission.

Sponsors who have not been excellence appraised and who wish to market a device within the class established by the De Novo order would submit a traditional 510(k) submission, which includes all required elements of a 510(k) under the FD&C Act and its implementing regulations, including demonstration of meeting all applicable special controls established for the classification.

Modifications to the Device in the De Novo Classification

After the classification of the device through the De Novo order, modifications to that manufacturer's device would be assessed to decide whether the modification could significantly affect safety and effectiveness or is a change to the intended use of the software (see 21 CFR 807.81(a)(3)). A manufacturer of a device may opt to submit a Review Determination Pre-Sub to discuss the modification with FDA. In accordance with the FDA guidance Deciding When to Submit a 510(k) for a Software Change to an Existing Device, submission of a new 510(k) is likely not required when implementing redundant risk control measures or enhancing existing risk control measures if the risk control measures in the most recently cleared device effectively mitigate the hazardous situation.

In addition, if the special controls established for the device class effectively mitigate risk caused by the modification to the device, and the modification does not change the intended use, a new 510(k) would not be required. If the special controls do not mitigate the risks caused by the modification, a new 510(k) would be required.

Sponsors who have been excellence appraised may submit a "Pre-Cert 510(k)" that would contain product-level information regarding the modification while leveraging the documented Excellence Appraisal to satisfy some required elements of a 510(k) submission (through reference to the device master file documenting the appraisal elements). The FDA expects that review of a "Pre-Cert 510(k)" would be more efficient than the review of a traditional 510(k) submission, because certain elements would have already been discussed with the manufacturer, reviewed, and documented through the Excellence Appraisal and optional Review Determination Pre-Sub. If a 510(k)-cleared device is modified so as to change the intended use of the device or in a manner that could significantly affect its safety or effectiveness, sponsors who have been excellence appraised may submit a "Pre-Cert 510(k)" or "Pre-Cert De Novo Request," whichever is appropriate, that similarly leverages the Excellence Appraisal and optional Pre-Sub to provide an efficient review of the modified device.

Conclusion

After testing and validating the framework provided in the Working Model, FDA plans to utilize the De Novo pathway to authorize marketing and establish special controls for SaMD products and to further test the Total Product Life Cycle approach of the Pre-Cert program. In this way, FDA will, consistent with its current authorities, continue to explore the possibilities of precertification through an innovative pilot program while also providing reasonable assurance of the safety and effectiveness of software devices.