Special 510(k) Program Pilot Overview

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On October 1, 2018, the Food and Drug Administration (FDA) launched the Special 510(k) Program Pilot, which aims to expand on the types of changes eligible for the program to improve the efficiency of 510(k) review.

The FDA periodically pilots programs to help improve consistency and efficiency in 510(k) review and help reduce total time to decision. MDUFA IV (Medical Device User Fee Amendments) shared outcome goals include decreasing 510(k) total time to decision to 108 days by fiscal year 2022. Special 510(k) updates are part of CDRH's plan to reduce total time to decision.

Purpose

The purpose of the Special 510(k) Program Pilot is to determine whether updated factors for eligibility in the Special 510(k) Program will improve FDA staff's efficiency in reviewing 510(k) submissions

Scope

This pilot includes all 510(k) submissions received on or after October 1, 2018 that are identified and eligible for review as a Special 510(k). This pilot does not include submissions reviewed by the Center for Biologics Evaluation and Research (CBER)

Eligibility

- The proposed change is made and submitted by the manufacturer authorized to market the existing device
- Performance data are unnecessary, or if performance data are necessary, **well-established methods** are available to evaluate the change, and
- All performance data necessary to support substantial equivalence can be reviewed in a summary or risk analysis format

Well established methods are defined as:

- Those used in the previously-cleared 510(k)
- Methods in an FDA recognized consensus standard
- Widely available and accepted methods published in the public domain, scientific literature, or found acceptable by the FDA

The FDA may still convert a Special 510(k) Program Pilot submission to a Traditional 510(k) if:

- The 510(k) is submitted for a change that is not to the manufacturer's own existing device
- Testing is needed to evaluate the change and there is no well-established method to evaluate the change
- The data cannot be reviewed in a summary or risk analysis format

Special 510(k) Pilot Process

There is no change from existing Special 510(k) policy

- Special 510(k) leverages information already submitted to the FDA and existing design controls procedures
- The predicate device should be the manufacturer's own device

- Can the data be reviewed in a summary or risk analysis format?
  - Complete test reports should not be submitted in a Special 510(k)
  - The FDA intends to assess whether information can be summarized, but will convert the submission to a Traditional 510(k) as necessary
  - Data cannot be summarized when substantial equivalence determination depends on the FDA's interpretation of the underlying data, such as images, raw graphs, or line item data. Small numbers of representative images can be submitted

When a Special 510(k) may not be appropriate

- Changes that involve several different scientific review disciplines
- Multiple devices with unrelated changes
- Common scenarios when a complete test report will be necessary to establish substantial equivalence (clinical data, novel sterilization methods, certain Magnetic Resonance compatibility labeling changes, when validation data should be provided (human factors, reprocessing), chemical characterization for biocompatibility)
- When validation data is required for reprocessed single- use devices and reusable devices identified in Federal Register notices

Submitting the 510(k)

- The following best practices still apply for Special 510(k) submission preparation:
  - Tabular summary of design control activities
  - Summary or table listing changes, which could include redlined versions of previously submitted information
- Send by mail to CDRH's Document Control Center
- Valid eCopy required
- Hard copy duplicate not needed
- Include a hard copy of the cover letter
- MDUFA User Fees apply

Review process

- Pilot Refuse to Accept (RTA) form has pilot eligibility factors
- The Elements of a Complete Submission (Refuse to Accept items) have not changed
- The FDA intends to process Special 510(k)s in 30 days
- The review should be interactive
- The FDA may request additional information through an email with an attached document identifying deficiencies when warranted

If found inappropriate as a Special 510(k)

- The Special 510(k) will be converted to a Traditional 510(k)
- Same concurrence process for conversions as existing program
- The FDA will email the official contact of the 510(k) to state the reason for conversion

Pilot Assessment
The FDA will collect the following:

- Number of Special 510(k) submissions received
- 510(k) number
- The FDA Day it was placed on hold, if applicable
- Total time to decision
- If a submission was found not appropriate for a Special 510(k):
    - The reason
    - The FDA Day on which it was concurred upon as inappropriate
    - Total number of submissions that were converted from Special 510(k) to Traditional 510(k)
    - The pilot began October 1, 2018

Pilot Benefits

- All 510(k) submissions marked and eligible as a Special 510(k) will be considered for the pilot program. No additional designation is necessary
- Expand on the types of changes eligible for the Special 510(k) program
- Improve the efficiency of 510(k) review
- Decrease total time to decision for 510(k) submissions to meet MDUFA shared outcome goals
- Promote timely access to safe, effective, and high- quality medical devices