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**US Callers Dial: 1-888-469-0942;
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Special 510(k) Program Pilot

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Agenda

This presentation will cover:

- Purpose of the Special 510(k) Program pilot
- Background
- Differences between the Program pilot and the existing Program
- Effect on current review of Special 510(k) submissions

Objectives

After this training, you should know:

- How to determine whether your submission is appropriate for the Special 510(k) Program pilot using the updated eligibility factors
- What to expect from the review process

Purpose of the Special 510(k) Program Pilot

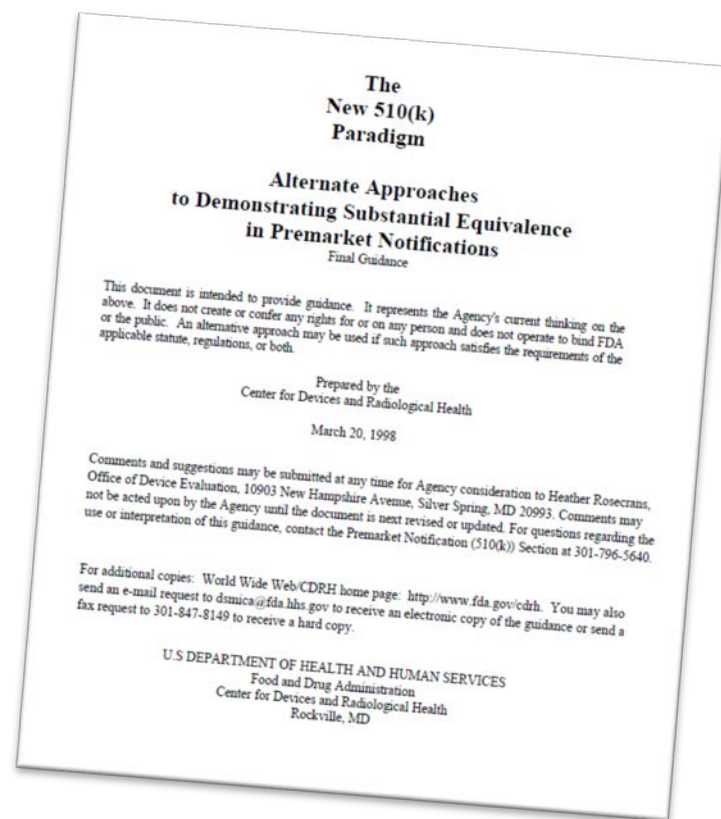


The purpose of the Special 510(k) Program Pilot is to:

- Determine whether updated factors for eligibility in the Special 510(k) Program will improve FDA staff's efficiency in reviewing 510(k) submissions

Background

- The New 510(k) Paradigm guidance established the Special 510(k) program in 1998
- Summary of the Special 510(k) program:
 - Leverages design controls and previously submitted information so that FDA can do a summary-level review for certain 510(k)s in 30 days
 - Does not alter the requirements for premarket notification under sections 510 and 513 of the Federal Food, Drug, and Cosmetic Act and 21 CFR 807 Subpart E



What Prompted this Pilot?

The FDA periodically pilots programs to help improve consistency and efficiency in 510(k) review, and help reduce total time to decision.

- [MDUFA IV](#) 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
- The FDA intends to process Special 510(k)s in 30 days, rather than the 90 days required by section 510(n)(1) of the Federal Food, Drug, and Cosmetic Act

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)



Changes Being Piloted

**Remains the same:
The proposed change is made and submitted by the
manufacturer authorized to market the existing device**

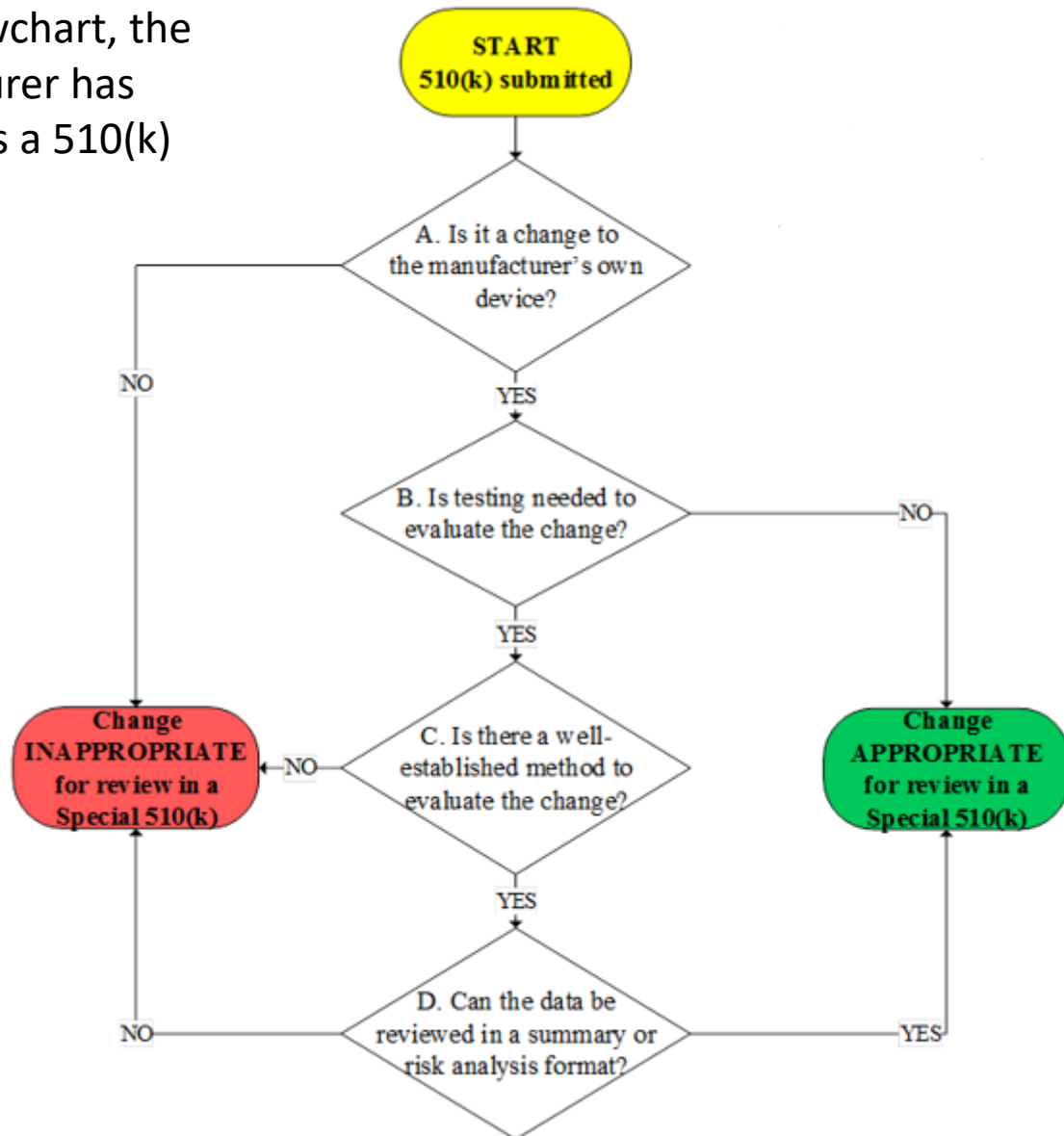
1998 Final Guidance	Special 510(k) Program Pilot
<p>Changes(s) do not affect intended use; and</p> <p>Change(s) do not alter the fundamental scientific technology</p>	<p>Performance data are unnecessary, or if performance data are necessary, well-established methods are available to evaluate the change; and</p> <p>All data necessary to support substantial equivalence can be reviewed in a summary or risk analysis format</p>

Special 510(k) Pilot Process



For the purposes of this flowchart, the FDA assumes the manufacturer has made a change that requires a 510(k) per 21 CFR 807.81(a)(3)

Note: Flowcharts are provided as a visual aid, but do not capture all necessary considerations



Eligibility Factors

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

Special 510(k) Pilot Process

Is it a change to the manufacturer's own device?

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

Special 510(k) Pilot Process

**Is testing needed to evaluate the change?
(indications for use, labeling or technology)**

- Moving away from automatic conversions for non-clerical changes to the indications for use
- If testing is not necessary, appropriate for a Special 510(k)
- If testing is necessary, proceed to the next question

Special 510(k) Pilot Process

Is there a well-established method to evaluate the change?

- Well established methods:
 - 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
- All methods used in subject 510(k) should be well-established
- If there is not a well-established method, the FDA intends to convert the submission to a Traditional 510(k)

Special 510(k) Pilot Process

Can the data be reviewed in a summary or risk analysis format?

No change from existing Special 510(k) policy.

- 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

Special 510(k) Pilot Process

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

Preparing 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
- See the FDA guidance [Frequently Asked Questions on the New 510\(k\) Paradigm](#) and [How to Prepare a Special 510\(k\)](#) webpage for an example and more information

Submitting the 510(k)

No change from current method

- 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

No impact on substantive or scientific review

- Pilot Refuse to Accept (RTA) form has pilot eligibility factors on page 1
- 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)

Stakeholder Considerations

- The pilot began October 1, 2018
- All 510(k) submissions marked and eligible as a Special 510(k) will be considered for the pilot program
 - No additional designation is necessary

Benefits

- 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

Resources

- 510(k) Program Pilot webpage
<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm618561.htm>
- Frequently Asked Questions on The New 510(k) Paradigm
<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073946.htm>



Questions?

For Questions Specific to the 510 Program, email:
510k_Program@fda.hhs.gov

For General Questions, email: Division of Industry and
Consumer Education: DICE@fda.hhs.gov

Slide Presentation, Transcript and Webinar Recording will be
available at:

<http://www.fda.gov/training/cdrhlearn>

Under Heading: How to Study and Market Your Device;
Subheading: Premarket Notification 510 (K)

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