

Welcome to today's FDA/CDRH Webinar

*Thank you for your patience while additional
time is provided for participants to join the call.*

**Please connect to the audio portion of the
webinar now:**

U.S. Callers: 888-390-1068

International Callers: 1-212-547-0152

Conference Number: PWXW9502204

Passcode: 6352340

Special 510(k) Program

Angela DeMarco
510(k) Program Expert

Josh Silverstein
Regulatory Advisor

Office of Product Evaluation and Quality
Center for Devices and Radiological Health

October 31, 2019

Agenda

This presentation will cover:

- Background on the Special 510(k) Program
- Results from the Special 510(k) Program Pilot
- Overview of the Special 510(k) Program
- Related 510(k) Program Updates
- Resources and Questions

Objectives

After this training, you should know:

- The results of the U.S. Food and Drug Administration's (FDA) Special 510(k) Pilot
- How to determine if your submission is appropriate for the Special 510(k) Program
- What to submit and expect from the review process
- How the FDA updated other guidances to reflect the updated Special 510(k) Program, improved alignment between the related 510(k) guidances, and current policies
- How to find Resources

Special 510(k) Background

1998

- The Special 510(k) Program was established in the FDA guidance “The New 510(k) Paradigm – Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications” (The New 510(k) Paradigm).

2018

- The FDA issued the draft guidance “The Special 510(k) Program.”
- The Special 510(k) Program Pilot launched.

2019

- The FDA issued the final guidances, “The Special 510(k) Program” and “The Abbreviated 510(k) Program,” to supersede the New 510(k) Paradigm guidance.
- The FDA withdrew the guidance “Frequently Asked Questions on the New 510(k) Paradigm”.

The Special 510(k) Program

The Special 510(k) Program is an optional pathway for certain well-defined device modifications where a manufacturer modifies its own legally marketed device, and design control procedures produce reliable results that can form—in addition to other 510(k) content requirements—the basis for substantial equivalence.

Summary of Special 510(k) Program Pilot

- The Pilot allowed the FDA and industry to test an expansion to the Special 510(k) Program
- The goal of the Special 510(k) Program Pilot was to determine whether updated factors for the Special 510(k) Program would improve the efficiency of the FDA's review of 510(k) submissions
- The FDA wanted to increase the number of 510(k) submissions that are appropriate for the Special 510(k) Program
- All Special 510(k)s received on or after October 1, 2018 were included in the Pilot. Our analysis reflects data from October 1, 2018 – July 1, 2019

Pilot Assessment

The FDA collected the following information:

- Number of Special 510(k) submissions received
- 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 found not appropriate
 - Total number of submissions that were converted from Special 510(k) to Traditional 510(k)

Pilot Data

Item Assessed	Pilot (10/18-7/19)	Prior Year (10/17-7/18)
Total number of Special 510(k)s received	476	464
Average Total Time to Decision of cleared files	43 days	49 days
Average FDA Day cleared file was placed on hold, if applicable	28 days	27 days
If converted to a Traditional 510(k):	--	--
- Reason	--	--
- Not manufacturer's own device	5%	1%
- (pilot) Lack of well-established method	59%	--
- (pre-pilot) Change in IFU	--	21%
- (pre-pilot) Change in technology	--	61%
- Cannot be placed into summary or risk-analysis format	23%	13%
- Other	13%	4%
- The average FDA days to conversion	15 days	16 days
- Conversion rate	25%	34%

Comments on the Draft Guidance

- Draft guidance issued on September 28, 2018
- 13 groups or individuals submitted approximately 130 comments
 - Medical device manufacturers
 - Trade associations
 - Patient advocacy groups
 - Consulting firm

Changes Reflected in Final Guidance

Special 510(k) Factors

- Updated examples of well-established methods to include those found in FDA guidance and Medical Device Development Tools (MDDTs)
- Clarified that a Special 510(k) is not appropriate if change generally involves more than 3 scientific disciplines

Examples

- Added new examples, including those for in vitro diagnostic devices
- Made minor changes to existing examples

Minor Policy Changes

- Clarified that the final guidance does not supersede other guidance document recommendations
- Recommended how to describe changes from predicate
- Clarified reprocessed single-use devices policy
- Referenced Bundling Policy for multiple unrelated changes

Significant Changes to the Special 510(k) Program

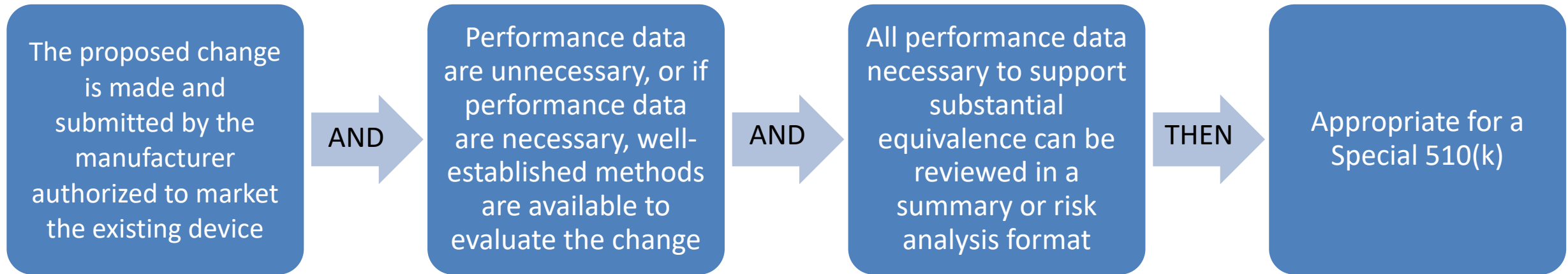
The New 510(k) Paradigm (now superseded)

- Change(s) do not affect intended use; and
- Change(s) do not alter the fundamental scientific technology

The Special 510(k) Program (now final guidance)

- Performance data are unnecessary, or if performance data are necessary, well-established methods are available to evaluate the change; and
- All data necessary to support substantial equivalence can be reviewed in a summary or risk analysis format

Special 510(k) Eligibility Factors



Special 510(k) Eligibility Factors

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

- Special 510(k) relies on the FDA's previous review of detailed information and existing design controls procedures
- The submitter should be the manufacturer legally authorized to market the predicate device

Special 510(k) Eligibility Factors

B. Are performance data needed to evaluate the change?

- If testing is not necessary, appropriate for a Special 510(k). If testing is necessary, proceed to the next Special 510(k) factor
- If there's a disagreement about the need for performance data, the FDA intends to continue with the additional Special 510(k) factors

Special 510(k) Eligibility Factors

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

- Well established methods:
 - The submitter’s methods, protocols, and acceptance criteria used to support the previously cleared 510(k) that can be applied to the subject 510(k)
 - Methods in an FDA-recognized consensus standard or FDA guidance document
 - Qualified medical device development tools (MDDTs) **OR**
 - Widely available and accepted methods, or those found acceptable by the FDA in another marketing submission by the same submitter
- All methods used in 510(k) should be well-established
 - If one does not exist, the FDA intends to convert to a Traditional 510(k)
- Submissions that use methods that rely on clinical studies or animal data are not typically appropriate for the Special 510(k) Program

Special 510(k) Eligibility Factors

D. 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 to 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

Additional Considerations

E. When a Special 510(k) may not be appropriate:

- Changes that involve generally greater than three different scientific review disciplines
- Multiple devices with unrelated changes (see [Bundling guidance](#))
- 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 a Special 510(k)

- The following recommended content apply when preparing Special 510(k) submissions, as noted in Appendix A of the guidance:
 - A detailed description of changes
 - A tabular comparison of the modified device to the cleared device
 - Clean and redlined copies of documents that were updated since the predicate device's submission (such as labeling, risk analysis)
 - Tabular summary of design control activities, such as your risk analysis
 - Based on the risk analysis, an identification of verification and validation activities, including a summary of test methods, acceptance criteria, and results, and why each is adequate to support substantial equivalence
 - Indications for Use form (the FDA Form 3881)
 - A signed statement on design controls activity

Example 1 – Appropriate for a Special 510(k)

Change: Labeling change to environment of use for a transcutaneous electrical nerve stimulation (TENS) from a professional healthcare facility only to both professional healthcare facility and home use. The device is still intended to be used under the direction and supervision of a healthcare professional.

- **A - Is it a change to the manufacturer's own device?** Yes.
- **B - Are performance data needed to evaluate the change?** Yes. There are different acceptance criteria for electrical safety and electromagnetic compatibility (EMC) to address home use.
- **C - Is there a well-established method to evaluate the change?** Yes. For example, the FDA-recognized standard methods ANSI/AAMI ES60601-1 35 and IEC 60601-2-1036 address basic safety and essential performance, IEC 60601-1-2 addresses EMC, and basic safety for home use devices (ANSI/AAMI HA60601-1-1138 or IEC 60601-1-1139), along with the CISPR 1140 emission limits for Group 1 and Class B. The manufacturer provided their statement of essential performance and associated device-specific acceptance criteria.
- **D - Can the data be reviewed in a summary or risk analysis format?** Yes. The particular standard used was identified. The acceptance criteria and results were summarized in a tabular format. A justification was provided for all results that were outside the bounds of an acceptance range or differed from the predicate. The results can be summarized because the substantial equivalence determination does not depend on the Agency's interpretation of the underlying data, such as images, raw graphs, or line item data.

Decision: Change can be reviewed in a Special 510(k).

Example 2 – Not appropriate for a Special 510(k)

Change: Modify the general indications for delivering illumination and laser energy for photocoagulation to include specific clinical applications for treatment of retinopathy.

- **A - Is it a change to the manufacturer's own device?** Yes.
- **B - Are performance data needed to evaluate the change?** Yes. Clinical testing is typically provided to support marketing clearance for such a change in the indications for use. The requested change in the indications for use now identify a specific disease condition. The clinical outputs have changed from general coagulation of blood vessels to treatment of retinopathy. Clinical testing should be conducted to assess new outcomes such as decrease in vision impairment, whereas the predicate assessed the general outcome of successful vessel coagulation.
- **C - Is there a well-established method to evaluate the change?** No. There is no well-established method identified in the predicate's submission or a consensus standard to evaluate clinical endpoints for this device. The substantial equivalence determination rests on a review of the underlying clinical performance data.
- **D - Can the data be reviewed in a summary or risk analysis format?** N/A.

Decision: Change cannot be reviewed in a Special 510(k).

Example 3 – Not appropriate for a Special 510(k)

Change: Change the labeling of a blade-form endosseous dental implant from “Safety in MRI Not Evaluated” to “MR Conditional.”

- **A - Is it a change to the manufacturer’s own device?** Yes, the submitter is the manufacturer of the predicate device.
- **B - Are performance data needed to evaluate the change?** Yes. Non-clinical performance testing to support substantial equivalence should be provided by manufacturers seeking MR Conditional labeling for a device that contains metallic components. The FDA guidance document Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment provides recommendations for such testing.
- **C - Is there a well-established method to evaluate the change?** Yes. There are FDA-recognized voluntary consensus standards such as ASTM F2503, 58 ASTM F2052, 59 ASTM F2213, 60 ASTM F2182, 61 and ASTM F211962 for MR compatibility testing of passive implants.
- **D - Can the data be reviewed in a summary or risk analysis format?** No. Although there are consensus standards for all test methods, FDA does not believe this data can be summarized because the SE determination will depend on FDA’s interpretation of the underlying data to support the MR Conditional label. This includes interpretation of device-specific pass/fail criteria and results that are not addressed in the standard.

Decision: Change cannot be reviewed in a Special 510(k).

Example of Summary of Design Control Activities

- Recommended content as noted in Appendix C of the guidance:
 - Device change
 - Risks associated with the device change
 - Verification/Validation (V&V) method(s) used to evaluate the change
 - Acceptance criteria
 - Deviations to the V&V method(s) and/or acceptance criteria with justifications
 - Summary of results
 - Description rather than just stating pass/fail for non-binary tests
 - If leveraging results from another study or test, or citing a risk analysis, include a justification for why this is acceptable

What to Expect During Special 510(k) Review

- Subject to the [Refuse to Accept Policy for 510\(k\)s](#), the FDA generally reviews Special 510(k)s within 30 days of receipt
- If a Special 510(k) is found to be inappropriate for review in this program, the FDA intends to convert to a Traditional 510(k). If converted:
 - Management concurrence occurs prior to conversion
 - The FDA intends to explain the reasons for conversion using the Special 510(k) factors
 - This may delay the review process because the FDA will likely request complete test reports

Related Guidance Updates: Refuse to Accept Policy for 510(k)s

- Reflects the updated Special 510(k) Program, improve alignment between the related 510(k) guidances, and reflect current policies

Other Guidance Update: Format for Traditional and Abbreviated Premarket Notifications

- The recommended format of a Traditional and Abbreviated 510(k) now aligns with the order of the Refuse to Accept (RTA) Checklist
- Contemporary guidance and website links
- These updates are not intended to reflect new policy

Stakeholder Considerations

- The Special 510(k) Program guidance was operationalized upon issuance of the final guidance (September 13, 2019)
- We recognize that both the FDA and industry may need up to 60 days to operationalize changes to the guidance [Refuse to Accept Policy for 510\(k\)s](#). If a 510(k) is received by the FDA before or up to 60 days after the publication of this guidance and does not include all criteria necessary to meet a minimum threshold of acceptability, the FDA may decide not to refuse to accept.
- Until November 13, 2019, once FDA has determined a submission is appropriate for review as a Special 510(k) as described in [the Special 510\(k\) Program guidance](#), and for all other 510(k) submission types, FDA intends to utilize [the prior final RTA guidance](#) to assess whether a 510(k) submission meets a minimum threshold of acceptability and should be accepted for substantive review.

Resources

- The Special 510(k) Program
<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/special-510k-program>
- The Abbreviated 510(k) Program
<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/abbreviated-510k-program>
- Format for Traditional and Abbreviated 510(k)s
<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/format-traditional-and-abbreviated-510ks>
- Refuse to Accept Policy for 510(k)s
<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/refuse-accept-policy-510ks>

Questions?

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;

Sub-Heading: Premarket Notification

Please complete a short survey about your FDA CDRH webinar experience. The survey can be found at www.fda.gov/CDRHWebinar immediately following the conclusion of the live webinar.