Expansion of the Abbreviated 510(k) Program: Demonstrating Substantial Equivalence through Performance Criteria

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Draft Guidance for Industry and Food and Drug Administration

DRAFT GUIDANCE

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Preface

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Draft Guidance for Industry and Food and Drug Administration Staff

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.

I. Introduction

This guidance provides FDA's current thinking on expanding the use of the Abbreviated 510(k) program for demonstrating substantial equivalence for premarket notification (510(k)) submissions. The intent of the guidance is to describe an optional pathway for certain, well understood device types, where a submitter would demonstrate that a new device meets FDA-identified performance criteria to demonstrate that the device is as safe and effective as a legally marketed device.

FDA's guidance documents, including this draft guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required.

II. Background

For the purposes of determining substantial equivalence, section 513(i)(1)(A) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) provides that:

> [W]ith respect to a device being compared to a predicate device, that device has the same intended use as the predicate device and that the Secretary by order has found that the device –
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> (i) has the same technological characteristics as the predicate device, or
>
> (ii) –
>
> (I) has different technological characteristics and the information submitted that the device is substantially equivalent to the predicate device contains information, including appropriate clinical or scientific data if deemed necessary by the Secretary or a person accredited under section 523, that demonstrates that the device is as safe and effective as a legally marketed device, and
>
> (II) does not raise different questions of safety and effectiveness than the predicate device.

Through guidance, FDA has explained and clarified how it makes substantial equivalence decisions.[1] As described in that guidance, the 510(k) program has undergone a number of statutory changes since its inception, and FDA has adapted its implementation of the program in response to changing statutory requirements and the evolving medical device landscape. For example, FDA established alternative programs for demonstrating substantial equivalence, the Special 510(k) and the Abbreviated 510(k). The Abbreviated 510(k) submission program relies on the use of guidance documents, special controls, and FDA-recognized consensus standards to facilitate 510(k) review.[2] The current 510(k) program reflects the current statutory framework and FDA's implementation of that framework through regulation, guidance, and administrative practice.

Congress has also amended the FD&C Act to add what are known as the "least burdensome" provisions for medical devices,[3] some of which are specific to the 510(k) process.[4] Their general purpose is to ensure FDA requests the minimum information necessary to adequately address a regulatory question or issue through the most efficient manner at the right time.[5]

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[1] See "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)], Guidance for Industry and Food and Drug Administration Staff," available at https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM284443.pdf.

[2] See "The New 510(k) Paradigm: Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications" final guidance, available at https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080189.pdf.

[3] See sections 513(i)(1)(D)(i) – (iii), 513(a)(3)(D)(iii) – (iv), and 515(c)(5)(A) – (D) of the FD&C Act (21 U.S.C. §360c and §360e), established by the Food and Drug Administration Modernization Act of 1997 (FDAMA) (P. L. 105-115).

[4] See section 513(i)(1)(D)(i) – (iii) of the FD&C Act (21 U.S.C. §360c and §360e), established by FDAMA (P. L. 105-115) and amended by Congress through the Food and Drug Administration Safety and Innovation Act (Public Law 112-144) (FDASIA) and the 21st Century Cures Act (Public Law 114-255) (Cures Act).

[5] On December 16, 2017, FDA issued draft guidance on describing its proposed approach regarding the least burdensome provisions as amended by the Cures Act. When finalized, that guidance will describe the guiding principles and recommended approach for FDA staff and industry when applying least burdensome principles. See

This guidance focuses on the prong of the substantial equivalence analysis that requires a 510(k) submitter to demonstrate that, despite technological differences, its device is as safe and effective as a legally marketed device. FDA recognizes that, in some cases, demonstrating this through direct comparison testing may create burdens for 510(k) submitters that can be avoided. For example, it may be burdensome for submitters to conduct testing against a substantial number of the appropriate predicate devices to demonstrate equivalence for the necessary set of performance and technological characteristics. Sometimes these burdens are necessary in order to determine substantial equivalence. However, consistent with FDA's mandate in section 513(i)(1)(D) of the FD&C Act to consider the least burdensome means of demonstrating substantial equivalence, this guidance expands the potential use of the Abbreviated 510(k) program by explaining how substantial equivalence for certain device types may be demonstrated in a way that is less burdensome but at least as robust. Use of this expanded program may also streamline the review of 510(k) submissions, thereby reducing burdens on the Agency and possibly review times for individual submissions. In addition, this approach could facilitate healthcare professionals and patients making better informed decisions by ensuring that a device cleared through this pathway meets a transparent set of performance criteria. At the same time, this approach satisfies the statutory standard for demonstrating substantial equivalence.

III. Policy

Under section 513(i)(1)(A) of the FD&C Act, substantial equivalence is rooted in comparisons between new devices and predicate devices. However, the FD&C Act does not preclude FDA from using performance criteria to facilitate this comparison. If a legally marketed device performs at certain levels relevant to its safety and effectiveness, and a new device meets or exceeds those levels of performance for the same characteristics, FDA could find that the new device is as safe and effective as the legally marketed device. Instead of reviewing data from direct comparison testing between the two devices, FDA could support a finding of substantial equivalence based on data showing the new device meets or exceeds the level of performance of appropriate predicate device(s). Under the approach expanded in this guidance, a submitter could satisfy the requirement to compare its device with a legally marketed device[6] by, among other things, demonstrating conformance to objective performance criteria established in FDA guidance, FDA-recognized consensus standards, and/or special controls.[7] In order to identify the specific set of performance criteria appropriate to satisfy a submitter's comparison to an appropriate predicate for a given device-type, FDA would ensure that those performance criteria

https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM588914.pdf.

[6] See 21 CFR 807.87(f).

[7] A device must comply with any applicable special controls to be within the type to which the special controls apply regardless of which 510(k) pathway is used, see section 513(a)(1)(B) of the FD&C Act, but there may be instances where conformance to special controls, FDA-recognized standards, and/or FDA-established criteria would also be sufficient to demonstrate a device is as safe and effective as a legally marketed device.

represent performance that is equivalent to or exceeds the performance of one or more existing, legally marketed devices of that device type, using equivalent test methodology. Thus, by demonstrating that a new device meets the identified performance criteria, a submitter could demonstrate that the new device is at least as safe and effective, as a legally marketed device, in accordance with sections 513(i)(1)(A)(ii)(I) and 513(i)(1)(D) of the FD&C Act. Note that direct comparison of a new device with a legally marketed device would remain available under a Traditional 510(k).

The policy in this guidance is an expansion of the approach FDA has long applied through the Abbreviated 510(k) program. When submitting an Abbreviated 510(k), a submitter uses conformity to FDA-recognized consensus standards, FDA guidance, and/or special controls to demonstrate some of the performance characteristics necessary to support a finding of substantial equivalence. In the optional program described here, the Expanded Abbreviated 510(k) program, a submitter would use robust versions of those same mechanisms to demonstrate *all* of the performance characteristics necessary to support a finding of substantial equivalence for a given device type.

FDA believes that use of performance criteria is only appropriate when FDA has determined that (1) the new device has indications for use and technological characteristics that do not raise different questions of safety and effectiveness than the identified predicate, (2) the performance criteria align with the performance of one or more legally marketed devices of the same type as the new device, and (3) the new device meets the performance criteria. All performance criteria for use of the Expanded Abbreviated 510(k) program will be publicized through FDA guidance developed for purposes of this program, which may reference FDA- recognized consensus standards and special controls. If a device cannot rely entirely on performance criteria identified by FDA to demonstrate substantial equivalence for its submission, it is not appropriate for this program; however, we emphasize that the previously established 510(k) programs in which direct performance comparisons against appropriate predicates are conducted, including Traditional, Special, and (non-expanded) Abbreviated 510(k)s, remain available to submitters.

A. Devices Appropriate for the Expanded Abbreviated 510(k) program: Intended use and technological characteristics

FDA plans to provide information about the types of devices to which the performance criteria would apply in the guidance establishing the performance criteria. Such information may include the relevant product code, appropriate intended uses, appropriate indications for use, and expectations for technological characteristics. In addition, in individual submissions for the Expanded Abbreviated 510(k) program, FDA will continue to require the identification of predicate device(s) for the intended use and technological characteristics prongs of the substantial equivalence analysis. Clarifying the set of devices for which the performance criteria are appropriate in guidance and having submitters identify a predicate of the same device type will help ensure that a new device that utilizes this program has (1) the same intended use as, and (2) technological characteristics that do not raise different questions of safety and effectiveness from the predicate device.

If you have questions about whether your new device is within a type identified by FDA as appropriate for an Expanded Abbreviated 510(k), specifically (1) whether your new device is within the scope of devices to which the FDA-identified performance criteria are intended to apply, or (2) whether its indications for use or technological characteristics raise different questions of safety and effectiveness than a predicate device, we recommend that you seek feedback through the Q-Submission program on the appropriateness of using the performance criteria.[8] FDA believes that it will typically be able to make these determinations without reviewing data, as long as the device clearly falls within the types FDA has identified as appropriate for utilizing this program. However, where FDA determines that additional data are necessary to make these determinations, the Agency may, on a case-by-case basis, review that data before determining whether or not the device is appropriate for this Expanded Abbreviated 510(k) program.

B. Identification of performance criteria

FDA intends to maintain a list of device types appropriate for the Expanded Abbreviated 510(k) program on the FDA website, accompanied by the guidance documents that identify the performance criteria for each device type, as well as the testing methods recommended in the guidances where feasible, and any other relevant information. These guidance documents may reference consensus standards, or portions of consensus standards, recognized by FDA under section 514 of the FD&C Act, as well as special controls established for that device type. When selecting from established performance criteria and test methodology in standards or guidance and when establishing new performance criteria and test methodology through guidance, FDA intends to rely on the experience and expertise of FDA staff, information in literature, and analyses of data on existing devices within a device type to determine the performance criteria and associated testing methods that could support a finding of substantial equivalence for a given device type. FDA will assure that these criteria represent performance levels that are at least equivalent to the performance of legally marketed devices of the type to which they apply. However, because it is FDA's responsibility to determine whether a new device reviewed under the 510(k) program is substantially equivalent, the final determination will be FDA's. We reemphasize that the previously established 510(k) programs in which direct performance comparisons against predicates are conducted, including Traditional, Special, and (non-expanded) Abbreviated 510(k)s, remain available to submitters, as appropriate.

C. FDA review of data

To support an FDA finding of substantial equivalence through this program, FDA expects a submitter to demonstrate that the new device meets the FDA-identified performance criteria by submitting a declaration of conformity, a summary of the data, and/or underlying data, as appropriate. When the performance criteria and testing methodologies are in an FDA-recognized

[8] See "Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff - Guidance for Industry and Food and Drug Administration Staff," available at https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm311176.pdf.

standard and the submitter uses the specified methods to establish that its new device meets the performance criteria, a declaration of conformity should be sufficient. When FDA establishes performance criteria, through guidance and/or special controls, and recommends or specifies testing methodologies, and the submitter uses the method recommended or specified by FDA, submitters should submit a summary of the data. When FDA establishes performance criteria through guidance and/or special controls and recommends or specifies the use of testing methodologies from an FDA-recognized standard, submitters using the recommended or specified testing methodologies should provide a summary of the data in addition to a declaration of conformity.

FDA may request and review underlying data demonstrating that a new device meets the FDA-identified performance criteria as necessary. When no testing methodology is specified or recommended, or when a submitter chooses to use a testing methodology other than the methodology specified or recommended, submitters should submit underlying data to FDA.

If data provided by the submitter do not show that the new device meets the performance criteria FDA has identified for the device type, FDA would not be able to find that the new device is substantially equivalent through this program. As previously mentioned, submitters could still use other available 510(k) programs to demonstrate substantial equivalence.

D. Modifications to the list

FDA intends to revise the list of appropriate device types with additional device types and corresponding performance criteria and testing methodology in guidance and on our website over time as appropriate and in accordance with FDA's Good Guidance Practices (21 CFR 10.115). FDA may modify or remove an entry from the list, particularly where new information indicates that the performance criteria in the identified guidance do not fully support a substantial equivalence determination. In such a case, we intend to either remove that device type from the list or note on the list that additional testing may be necessary while the underlying source(s) of the performance criteria are updated. Changes to the list would apply prospectively to devices for which a 510(k) has not yet been submitted.

Appendix. Submission Recommendations for an Expanded Abbreviated 510(k)

Expanded Abbreviated 510(k)s must comply with the content requirements for premarket notifications submitted in support of substantial equivalence decisions at 21 CFR 807.87. FDA's Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s (510(k) Format Guidance) provides a general framework for the format and content of an Abbreviated 510(k). This appendix provides recommendations on how to apply the recommendations in the general 510(k) Format Guidance to the format and content of an Abbreviated 510(k) that uses the expanded approach described in this guidance. These recommendations are also intended to ensure that the elements recommended in FDA's guidance "Refuse to Accept Policy for 510(k)s" (RTA Policy Guidance) (https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm315014.pdf) are appropriately included in your submission.

Consistent with the 510(k) Format Guidance and the RTA Policy Guidance, we recommend that you include the section headings listed, preferably in the sequence outlined below, when submitting an Expanded Abbreviated 510(k) in accordance with this guidance. In some instances, the information in a particular section may not apply to your device. In order to assist review staff, we recommend you retain the section headings in the sequence listed. If you believe a section does not apply, we recommend you include the section and state "This section does not apply" or "N/A" under that heading with a rationale for why the section does not apply. For example, if your device does not contain any software, we recommend you state, "This section is not applicable because the subject device does not contain software" in Section 17 titled "Software."

1. Medical Device User Fee Cover Sheet (Form FDA 3601)
2. CDRH Premarket Review Submission Cover Sheet (Form FDA 3514)
3. 510(k) Cover Letter
4. Indications for Use Statement
5. 510(k) Summary or 510(k) Statement
6. Truthful and Accuracy Statement
7. Class III Summary and Certification
8. Financial Certification and/or Disclosure Statement (Form FDA 3454)
9. Certification of Compliance with requirements of ClinicalTrials.gov Data Bank (Form FDA 3674)
10. Declarations of Conformity and Summary Reports
11. Executive Summary
12. Device Description
13. Substantial Equivalence Discussion
14. Proposed Labeling
15. Sterilization and Shelf Life
16. Biocompatibility
17. Software

18. Electromagnetic Compatibility and Electrical Safety
19. Performance Testing – Bench
20. Performance Testing – Animal
21. Performance Testing – Clinical
22. Other

Together, the 510(k) Format Guidance and the RTA Policy Guidance provide recommendations for each of these sections. In addition to the recommendations found in the 510(k) Format Guidance, we recommend the following for sections 10, 13, and 14-21:

10. Declarations of Conformity and Summary Reports

To demonstrate your device meets the relevant performance criteria, you should include, depending on the circumstances:

- A declaration of conformity to the standard;[9]
- a summary report recommended in any relevant device-specific guidance; and/or
- underlying data demonstrating that the new device meets the FDA-identified performance criteria.

Which of these approaches is appropriate will depend on the underlying source for the criteria and testing methods, including whether they are contained in an FDA-recognized standard or identified by FDA in guidance and/or special controls, and whether the testing methodology used is recommended or recognized by FDA for this purpose.

In general, we expect submitters to submit a summary report when criteria are established by guidance and/or special controls. In general, FDA expects submitters to submit a declaration of conformity when using standards. However, if the guidance, special control, or standard does not recommend or specify testing methodologies, FDA expects submitters to submit underlying data.

It is possible that FDA-identified performance criteria in a guidance or special control would recommend or specify use of an FDA-recognized standard for testing methodology. In this case, FDA would expect submitters to submit a summary report in addition to a declaration of conformity.

If a submitter chooses not to use FDA-recommended or recognized testing methods, FDA expects the submitter to submit underlying data.

Finally, FDA may request and review underlying data as necessary.

[9] See "Required Elements for a Declaration of Conformity to a Recognized Standard (Screening Checklist for All Premarket Notification (510(k)) Submissions)" available at https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142706.htm.

13. Substantial Equivalence Discussion

In the substantial equivalence section, we continue to recommend that you identify the predicate by providing its trade name, model number, name of the 510(k) submitter/holder, and 510(k) number, if available.

We recommend that you provide a comparison between your device and the predicate in terms of indications for use and technology.

If you choose to use the Expanded Abbreviated 510(k) program, we do not expect you to provide direct comparison testing against a legally marketed device for performance specifications. Any testing you conduct in accordance with standards or guidance should be as described in sections 10, 13, and 14-21, as applicable.

14 - 21. Proposed Labeling, Sterilization and Shelf Life, Biocompatibility, Software, Electromagnetic Compatibility and Electrical Safety, and Performance Testing – Bench, Animal, and Clinical, as applicable

We continue to recommend that submitters of Abbreviated 510(k)s through this expanded program provide the information described in the 510(k) Format Guidance for the sections on Proposed Labeling, Sterilization and Shelf Life, Biocompatibility, Software, Electromagnetic Compatibility and Electrical Safety, and Performance Testing, except that FDA would not expect your information to describe direct comparison testing against the predicate device. Instead, FDA recommends that you include a declaration of conformity, summary of the data, and/or underlying data, as applicable, demonstrating the new device meets the performance criteria using appropriate testing methods.