Contains Nonbinding Recommendations

Safety and Performance Based Pathway

Guidance for Industry and Food and Drug Administration

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The draft of this document, entitled "Expansion of the Abbreviated 510(k) Program: Demonstrating Substantial Equivalence through Performance Criteria" issued on April 12, 2018.

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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
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Preface

Public Comment

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Safety and Performance Based Pathway

Guidance for Industry and Food and Drug Administration Staff

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I. Introduction

This guidance provides FDA's current thinking on expanding the concept 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 – the Safety and Performance Based 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 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 –
>
> (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]

This guidance focuses on the decision point 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 greater burdens for 510(k) submitters than applying an alternative approach, such as the approach described in this guidance, if appropriate. For example, in some cases, it may be more burdensome for a submitter to conduct testing against an appropriate predicate device to demonstrate equivalence for the necessary set of performance and technological characteristics than to demonstrate their device meets appropriate performance

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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/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM284443.

[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] See FDA guidance "Least Burdensome Concept and Principles," which describes the guiding principles and recommended approach for FDA staff and industry when applying least burdensome principles. Available at https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM085999.

criteria established by FDA. Therefore, 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 concept 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 make the review of 510(k) submissions more efficient, thereby reducing burdens on the Agency and possibly review times for individual submissions. 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 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 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 that the device's performance meets established performance criteria. Performance expectations may be described in FDA guidance, FDA-recognized consensus standards,[7] and/or special controls.[8] In some cases, these performance criteria may be explicitly defined, while in others, the acceptable outcomes may be described qualitatively, such as for biocompatibility. Device types that are eligible for third party review in addition to being appropriate for the Safety and Performance Based Pathway (see Section III.A) would remain eligible for the 510(k) Third Party Review Program.[9]

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 represent performance that meets the performance of one or more existing, legally marketed devices of that device type. 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)

[6] See 21 CFR 807.87(f).

[7] A submitter may base a Declaration of Conformity on testing and analysis performed in-house or on testing performed by a third party, such as a testing laboratory or certification body. See FDA Guidance "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices," available at https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM077295.

[8] A device must comply with any applicable special controls 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.

[9] The 510(k) Third Party Review Program is described at the following Web Site: https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ThirdParyReview/default.htm. The list of devices eligible for Third Party Review is available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfThirdParty/current.cfm#4.

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 or Special 510(k) pathway, as appropriate, including for those devices also eligible for the 510(k) Third Party Review Program.

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 Safety and Performance Based Pathway, a submitter would use robust versions of those same mechanisms, which contain all the performance characteristics necessary to support a finding of substantial equivalence for a device type, rather than using direct predicate comparison testing to support a finding of substantial equivalence for some of the performance characteristics.

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 all the performance criteria. Although FDA may recommend test methodology for the performance criteria, a submitter may choose to use an appropriate testing methodology other than what is specified or recommended to demonstrate the performance characteristics. (See Section III.C for discussion on FDA review of protocols and underlying data in such circumstances.) All performance criteria for use of the Safety and Performance Based Pathway will be publicized through FDA guidance developed for purposes of this program, which may reference FDA-recognized consensus standards, FDA guidance, 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 Abbreviated 510(k)s, remain available to submitters.

A. Devices Appropriate for the Safety and Performance Based Pathway: 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(s), appropriate intended uses, and appropriate indications for use. FDA also intends to maintain a list of device types appropriate for the Safety and Performance Based Pathway on the FDA website (see Section III.B. for additional information). In addition, in individual submissions for the Safety and Performance Based Pathway, FDA will continue to require the identification of predicate device(s) for the intended use and technological characteristics decision points 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 the Safety and Performance Based Pathway, 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 from the appropriate Office or Division on the appropriateness of using the performance criteria. 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 Safety and Performance Based Pathway.

B. Identification of performance criteria

FDA intends to maintain a list of device types appropriate for the Safety and Performance Based Pathway on the FDA website for the Safety and Performance Based Pathway,[10] 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 and relevant FDA guidance. Performance criteria in FDA-recognized consensus standards that have not been identified in FDA guidance for use in the Safety and Performance Based Pathway should not be used in this program. 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 available to FDA 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 ensure 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 Abbreviated 510(k)s, remain available to submitters, as appropriate.

C. FDA review of data

The amount and type of information necessary to support a finding of substantial equivalence under the Safety and Performance Based Pathway are summarized in Table 1. 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

[10] Available at https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm629679.htm

Declaration of Conformity to an FDA-recognized consensus standard,[11] testing protocols, a summary of the data, and/or underlying data, as appropriate. When the performance criteria and testing methodologies are in an FDA-recognized standard (identified in the relevant FDA guidance) and the submitter uses the specified methods to establish that its new device meets the performance criteria, a Declaration of Conformity should be sufficient to support a finding of substantial equivalence, unless noted otherwise in the relevant Safety and Performance Based Pathway guidance. When FDA establishes performance criteria 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 demonstrating that the FDA-identified performance criteria have been met in addition to a Declaration of Conformity for the methodology. When FDA establishes performance criteria and recommends or specifies testing methodologies that are not in existing FDA-recognized consensus standards, and the submitter uses such methods, the submitter should also submit a test report that includes the testing protocol describing the test methodology and a summary of the data demonstrating that the FDA-identified performance criteria have been met. 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 the underlying data to FDA as well as the testing protocols.

Consistent with FDA policy for all 510(k) submissions, for all 510(k) submissions under the Safety and Performance Based Pathway, FDA may request and review underlying data demonstrating that a new device meets the FDA-identified performance criteria and testing methodology, as necessary.

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.

[11] See section 514(c)(1)(B) of the FD&C Act and FDA Guidance FDA Guidance Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices

Table 1. FDA Review of Information Provided to Demonstrate that a Device Meets Performance Criteria and Methodology Indicated in FDA Guidance for Submissions using the Safety and Performance Based Pathway

Type of Performance Criteria and Methodology FDA identified in the relevant Safety and Performance Based Pathway Guidance		Safety and Performance Based Pathway 510(k) Submission should Include
Performance Criteria	***Testing Methodology***	
FDA-recognized standard[12]	FDA-recognized standard[12]	Declaration of Conformity[13]
FDA-established	FDA-recognized standard[12]	Summary of Data and Declaration of Conformity to recognized standard for methodology
FDA-established	FDA-recommended or specified	Summary of Data and Testing Protocol
FDA-established	None specified/recommended or alternative to FDA-specified methodology used	Summary of Data, underlying data and Testing Protocol

D. Modifications to the list

As discussed above, FDA intends to maintain a list of device types appropriate for the Safety and Performance Based Pathway on the FDA website, accompanied by the guidances that identify the performance criteria and testing methods recommended for each device type, and any other relevant information. FDA intends to revise the list of appropriate device types on our website with additional device types and may revise the corresponding performance criteria and testing methodology in guidance over time as appropriate and in accordance with FDA's Good Guidance Practices (21 CFR 10.115). FDA intends to periodically review the applicable criteria and guidances in order to ensure they remain appropriate to the device type. 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, i.e., when a device type is removed from the list or an updated final guidance is issued, would apply prospectively to devices for which a 510(k) has not yet been submitted. The clearance for devices that have been cleared via the Safety and Performance

[12] This refers to FDA-recognized consensus standards indicated in the relevant Safety and Performance Based Pathway guidance for use for a particular device type. As stated in section III.B., performance criteria in FDA-recognized consensus standards that have not been identified in FDA guidance for use in the Safety and Performance Based Pathway should not be used in this program.

[13] See Table 1 in FDA Guidance Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices for details on FDA Review of Declarations of Conformity and Supplemental Documentation.

Based Pathway prior to the removal of a device type from the list of appropriate device types would not be affected by the change to the list. Such devices may be subject to other action, as appropriate, to address the reason for the modification or removal from the list, for example, if there was a safety concern.

Appendix. Submission Recommendations for a 510(k) in the Safety and Performance Based Pathway

Safety and Performance Based 510(k)s must comply with the content requirements for premarket notifications submitted in support of substantial equivalence decisions at 21 CFR 807.87. This appendix provides recommendations on how to apply the recommendations in the general 510(k) Format Guidance to the format and content of a Safety and Performance Based 510(k) that uses the 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)[14] are appropriately included in your submission.

Consistent with the RTA Policy Guidance, we recommend that you include the section headings listed, preferably in the sequence outlined below, when submitting a Safety and Performance Based 510(k) in accordance with this guidance. In some instances, the information in a particular section may not apply to your device. 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

[14] https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM315014

The RTA Policy Guidance provides recommendations for each of these sections. In addition, 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 described in Section III.C.:

- A declaration of conformity to the standard;[15]
- summary data or a summary report if recommended in any relevant device-specific guidance;
- testing protocols; 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 performance criteria and testing methods, including whether they are contained in an FDA-recognized standard identified in the relevant Safety and Performance Based Pathway guidance or established or recommended/specified by FDA in such guidance (See Table 1).

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 Safety and Performance Based Pathway, 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 510(k)s through the Safety and Performance Based Pathway provide the information as you would in a traditional 510(k) for the sections on Proposed Labeling, Sterilization and Shelf Life, Biocompatibility, Software, Electromagnetic

[15] See FDA Guidance Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices.

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, testing protocols and/or underlying data, as applicable, demonstrating the new device meets the performance criteria using appropriate testing methods.