Contains Nonbinding Recommendations

The Abbreviated 510(k) Program

Guidance for Industry and Food and Drug Administration Staff

Document issued on September 13, 2019.

This document supersedes the Abbreviated 510(k) content from "The New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications" issued March 20, 1998.

For questions about this document, contact ORP: Office of Regulatory Programs, DRP1: Division of Submission Support, Premarket Notification and Classification Team at 510K_Program@fda.hhs.gov or 301-796-5640.

For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach, and Development (OCOD) at 800-835-4709 or 240-402-8010.

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

Preface

Public Comment

You may submit electronic comments and suggestions at any time for Agency consideration to https://www.regulations.gov. Submit written comments to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852.

Identify all comments with the docket number FDA-2019-D-4015. Comments may not be acted upon by the Agency until the document is next revised or updated.

Additional Copies

CDRH

Additional copies are available from the Internet. You may also send an e-mail request to CDRH-Guidance@fda.hhs.gov to receive a copy of the guidance. Please include the document number 905 and complete title of the guidance in the request.

CBER

Additional copies are available from the Center for Biologics Evaluation and Research (CBER), Office of Communication, Outreach, and Development (OCOD), 10903 New Hampshire Ave., WO71, Room 3128, Silver Spring, MD 20903, or by calling 800-835-4709 or 240-402-8010, by email, ocod@fda.hhs.gov, or from the Internet at https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances.

The Abbreviated 510(k) Program

Guidance for Industry and Food and Drug Administration Staff

This guidance represents 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 recommendations on an optional approach that may be used to demonstrate substantial equivalence in premarket notifications (510(k)s). The Abbreviated 510(k) Program uses guidance documents, special controls, and/or voluntary consensus standards to facilitate FDA's premarket review of 510(k) submissions. The alternative approach described in this guidance document is intended to facilitate 510(k) submission preparation by manufacturers and review by FDA. FDA believes this voluntary program may conserve industry and Agency resources, while still protecting the public health, and not altering the statutory criteria for substantial equivalence.

For the current edition of the FDA-recognized standard(s), see the FDA Recognized Consensus Standards Database.[1] For more information regarding use of consensus standards in regulatory submissions, please refer to the FDA guidance document titled "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices"[2] and "Standards Development and the Use of Standards in Regulatory Submissions Reviewed in CBER."[3]

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.

[1] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm.
[2] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices.
[3] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/standards-development-and-use-standards-regulatory-submissions-reviewed-center-biologics-evaluation.

II. Background

Under section 510(k) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), each person required to register with FDA and who proposes to introduce a device into interstate commerce for commercial distribution is required to submit a 510(k) to FDA at least 90 days before commercial distribution is to begin. FDA established the Abbreviated 510(k) Program in 1998 and described the program and policy in the guidance document "The New 510(k) Paradigm: Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications." The Abbreviated 510(k) Program was intended to create an efficient submission preparation and review process that relies on guidance documents, special controls, and/or voluntary consensus standards. The Abbreviated 510(k) Program does not alter any statutory or regulatory requirements related to the premarket notification process under sections 510 and 513 of the FD&C Act, and 21 CFR 807 subpart E.

This guidance document supplements other FDA guidances regarding the specific content requirements and recommendations of a 510(k) submission. You should also refer to 21 CFR 807.87 and FDA's guidances "Refuse to Accept Policy for 510(k)s"[4] and "Format for Traditional and Abbreviated 510(k)s."[5]

III. The Abbreviated 510(k) Program

FDA issues guidance documents to communicate the Agency's recommendations to industry. FDA believes that, within the Abbreviated 510(k) Program, the use of guidance documents may facilitate the review of 510(k)s through a reliance on a "summary reports" that briefly describe and summarize the testing performed to support the submission as recommended in relevant guidance document(s). These reports summarize the device description, the manufacturer's device design requirements, risk management information, and a description of test methods used to address performance characteristics. A 510(k) submission that addresses the recommendations of an FDA guidance document should be easier to prepare by manufacturers and for FDA to review.

The Safe Medical Devices Act of 1990 (Public Law 101-629) introduced the concept of special controls to provide a reasonable assurance of safety and effectiveness for class II devices. Special controls are defined in section 513(a)(1)(B) of the FD&C Act as those controls, such as performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines, recommendations and other appropriate actions that provide reasonable assurance of the device's safety and effectiveness. As in the case of guidance documents, summary information that describes how a special control(s) has been used to address a specific risk or issue should reduce the time and effort to prepare and review 510(k)s.

[4] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/refuse-accept-policy-510ks.
[5] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/format-traditional-and-abbreviated-510ks.

In addition to guidance documents and special controls, the appropriate use of voluntary consensus standards can increase predictability of the premarket review process, provide clearer regulatory expectations, and facilitate market entry of safe and effective medical products. Section 204 of the FDA Modernization Act of 1997 (FDAMA, Public Law 105-115) introduced voluntary consensus standards into section 514(c) of the FD&C Act. FDAMA also introduced changes to the 510(k) Program, such as increased reliance on postmarket controls to expedite device classification under section 205 of FDAMA (section 513(i)(1)(C) of the FD&C Act).

Therefore, device manufacturers may choose to submit an Abbreviated 510(k) when the submission relies on one or more:

- FDA guidance document(s);
- Demonstration of compliance with special controls for the device type, either in a device-specific classification regulation or a special controls guidance document; and/or
- Voluntary consensus standard(s).

An Abbreviated 510(k) submission must include the required information identified in 21 CFR 807.87. In addition, manufacturers submitting an Abbreviated 510(k) that relies on an FDA guidance document and/or special control(s) should include a summary report that describes how the guidance document(s) were used to demonstrate substantial equivalence and/or how the device complies with special control(s). If recommendations in guidance document(s) are used to support substantial equivalence, the summary report should include information regarding any deviations, that is any alternative methods used to demonstrate substantial equivalence that are not described in the guidance. For more information about summary reports, see Appendix A.

Manufacturers submitting an Abbreviated 510(k) that relies on a voluntary consensus standard(s) should provide the information described in Appendix A and a declaration of conformity as recommended by the guidance document "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices."[6] Manufacturers submitting an Abbreviated 510(k) that relies on general use of a voluntary consensus standard should include the basis of such use along with the underlying information or data that supports how the standard was used.

The incentive for manufacturers to provide summary reports describing the use of guidance documents, special controls, or the appropriate use of voluntary consensus standards is intended to facilitate 510(k) submission preparation of 510(k) submissions. FDA believes that its review of Abbreviated 510(k)s may be more efficient than that of Traditional 510(k) submissions. In addition, by allowing FDA staff to rely on a manufacturer's summary report on the use of an FDA guidance document(s), special control(s), and/or voluntary consensus standard(s), FDA's review resources can be used in an efficient manner.

[6] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices.

Subject to FDA's acceptance review in accordance with the guidance "Refuse to Accept Policy for 510(k)s,"[7] FDA intends to review Abbreviated 510(k) submissions within FDA's 90-day statutory deadline under section 510(n)(1) of the FD&C Act and Medical Device User Fee Amendments (MDUFA) performance goals for 510(k) submissions. If a manufacturer submits an Abbreviated 510(k) that FDA does not believe is appropriate for review under the Abbreviated 510(k) Program, FDA intends to convert the submission to a Traditional 510(k) and notify the submitter.

[7] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/refuse-accept-policy-510ks.

Appendix A. Abbreviated 510(k) Content

An Abbreviated 510(k) should include:

- A coversheet clearly identifying the submission as an "Abbreviated 510(k)";
- Information required under 21 CFR 807.87, including a description of the device, the intended use and the indications for use of the device,[8] and the proposed labeling for the device. For further information about the suggested format and content of an Abbreviated 510(k), see the FDA guidance "Refuse to Accept Policy for 510(k)s"[9] and "Format for Traditional and Abbreviated 510(k)s."[10]
- For a submission that relies on an FDA guidance document(s) or is subject to special controls, a summary report that describes how the guidance(s) were used to demonstrate substantial equivalence and/or how the device complies with the special control(s). These reports summarize the device description, the manufacturer's device design requirements, risk management information, and a description of test methods used to address performance characteristics. If a manufacturer chooses to use an alternative approach to address a particular issue, sufficient detail should be provided to justify that approach;
- For a submission that relies on voluntary consensus standards, we recommend that you consult the FDA guidance "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices;"[11]
- Data/information to address issues not covered by guidance documents, special controls, and/or voluntary consensus standards; and
- Indications for Use form (FDA Form 3881[12]).

[8] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-program-evaluating-substantial-equivalence-premarket-notifications-510k.
[9] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/refuse-accept-policy-510ks.
[10] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/format-traditional-and-abbreviated-510ks.
[11] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices.
[12] https://www.fda.gov/media/86323/download.