

Format for Traditional and Abbreviated 510(k)s

Guidance for Industry and Food and Drug Administration Staff

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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 or by email at ocod@fda.hhs.gov.



**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-4014. 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 1567 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>.

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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

The main focus of this document is to provide guidance on how to format an original submission for a Traditional or Abbreviated premarket notification (510(k)) submission. This guidance document provides only a general framework for the format and content of a Traditional or Abbreviated 510(k). It does not describe our recommendations for any specific device types, [Special 510\(k\)s](#),¹ or other premarket submission types, such as premarket approval applications (PMAs), Humanitarian Device Exemption (HDE) applications, De Novo requests, or investigational device exemption (IDE) applications.

FDA believes the recommendations in this guidance document for a Traditional or Abbreviated 510(k) will conserve FDA and industry resources and facilitate timely review. This guidance document only supplements other FDA guidances on the 510(k) program and specific device types. It is not a replacement for those documents.

For the current edition of the FDA-recognized standard(s) referenced in this document, see the [FDA Recognized Consensus Standards Database](#).² For more information regarding use of consensus standards in regulatory submissions, please refer to the FDA guidance titled “[Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices](#)”³ and “[Standards Development and the Use of Standards in Regulatory Submissions Reviewed in CBER](#).”⁴

¹ For more information see “The Special 510(k) Program,” available at: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/special-510k-program>.

² Available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>.

³ Available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices>.

⁴ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/standards-development-and-use-standards-regulatory-submissions-reviewed-center-biologics-evaluation>.

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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

This document supplements other FDA guidance documents regarding the content for a 510(k) submission. For example, we recommend you compare your 510(k) submission's contents to FDA's acceptance checklist in "[Refuse to Accept Policy for 510\(k\)s](#)."⁵ You should also refer to 21 CFR 807 subpart E and the section on our web site [How to Prepare a 510\(k\) Submission](#).⁶

III. Definitions

Each person who proposes to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a device intended for human use, for which a PMA is not required, must submit a 510(k) to FDA at least 90 days before marketing unless the device is exempt from 510(k) requirements of the Federal Food Drug, and Cosmetic Act (FD&C Act) and does not exceed the limitations of exemptions in xxx.9 of the device classification regulation parts (e.g., 862.9, 864.9). There is no specific 510(k) form. 21 CFR 807.87 describes the information required in a 510(k) submission. This guidance recommends a format that will help you comply with these requirements.

A **Premarket Notification (510(k))** is a type of premarket submission that is intended to demonstrate that the device to be marketed is at least as safe and effective as a legally marketed device (21 CFR 807.92(a)(3)) that does not require PMA. In order to determine if a device is substantially equivalent (SE), FDA considers intended use, design, energy used or delivered, materials, chemical composition, manufacturing process, performance, safety, effectiveness, labeling, biocompatibility, standards, and other characteristics, as applicable.

A **510(k) submitter/holder** is the owner of the 510(k). Although a consultant or correspondent may submit the 510(k) on behalf of the 510(k) owner, that consultant or correspondent is not the 510(k) submitter/holder.

A **legally marketed device**⁷ is a device that was legally marketed prior to May 28, 1976 (i.e., preamendments), reclassified from class III to class II or class I, found substantially equivalent through a 510(k), or granted marketing authorization through the De Novo classification process. The legally marketed device(s) to which the submitter claims equivalence is commonly known as the "predicate."

⁵ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/refuse-accept-policy-510ks>.

⁶ <https://www.fda.gov/medical-devices/premarket-submissions/premarket-notification-510k>.

⁷ 21 CFR 807.92(a)(3).

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A **Traditional 510(k)** is the most common type of 510(k). In a Traditional 510(k), the submitter provides descriptive information about the indications for use and technology and results of performance testing to demonstrate substantial equivalence.

An **Abbreviated 510(k)** provides an effective means of facilitating the review of data in a 510(k) through a reliance on one or more:

- FDA guidance document(s);
- Special controls; or
- Voluntary consensus standard(s).

Typically, an Abbreviated 510(k) includes one or more declarations of conformity to an FDA-recognized consensus standard (see Section (10) of this guidance), or cites general use of a standard. For more information about Abbreviated 510(k)s, see the FDA guidance document “[The Abbreviated 510\(k\) Program](#).”⁸

IV. Sections in a Traditional or Abbreviated 510(k)

In a Traditional or Abbreviated 510(k), we recommend that you include the section headings listed in the sequence below. In some instances, the information in a particular section may not apply to your device. In order to facilitate our reviews, 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. For example, if your device does not contain any software, we recommend you state this in Section 16 titled “Software.”

- (1) Medical Device User Fee Cover Sheet (Form FDA 3601)
- (2) Center for Devices and Radiological Health (CDRH) Premarket Review Submission Cover Sheet (Form FDA 3514)
- (3) 510(k) Cover Letter
- (4) Indications for Use Statement (Form FDA 3881)
- (5) 510(k) Summary or 510(k) Statement
- (6) Truthful and Accuracy Statement
- (7) Class III Summary and Certification
- (8) Financial Certification or Disclosure Statement
- (9) Declarations of Conformity and Summary Reports
- (10) Device Description
- (11) Executive Summary/Predicate Comparison
- (12) Substantial Equivalence Discussion
- (13) Proposed Labeling
- (14) Sterilization and Shelf Life
- (15) Biocompatibility
- (16) Software
- (17) Electromagnetic Compatibility and Electrical Safety

⁸ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/abbreviated-510k-program>.

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- (18) Performance Testing – Bench
- (19) Performance Testing – Animal
- (20) Performance Testing – Clinical

In the sections below, this guidance document describes the format we recommend for each of these sections and provides resources, such as regulations, guidance documents, and internet links that will be useful in preparing the sections.

V. Description of Each Section for Traditional or Abbreviated 510(k)s

In this section, we explain each section of a Traditional or Abbreviated 510(k) and include some resources for information.

(1) Medical Device User Fee Cover Sheet (Form FDA 3601)

The Medical Device User Fee Cover Sheet, receipt of the user fee payment, and a valid electronic copy (eCopy), allow FDA to begin processing your submission; therefore, you should provide a Medical Device User Fee Cover Sheet with your 510(k) submission, unless it is a third-party review submission. Third-party review submissions are exempt from user fees.

Although the following 510(k) submissions are also excepted from user fees pursuant to section 738(a)(2)(B) of the FD&C Act, we recommend you include a [Medical Device User Fee Cover Sheet](#),⁹ and use it to indicate the type of exception that applies in the case of 510(k) submissions:

- intended solely for pediatric use; or
- submitted by a state or Federal government entity (an exception from the FDA user fee unless the device is to be distributed commercially).

See also the FDA guidance “[User Fees and Refunds for Premarket Notification Submissions \(510\(k\)s\)](#).”¹⁰

(2) CDRH Premarket Review Submission Cover Sheet (FDA Form 3514)

The [CDRH Premarket Review Submission Cover Sheet](#)¹¹ is a voluntary form used to help provide basic administrative information for all types of premarket notification submissions.

⁹ <https://www.fda.gov/industry/medical-device-user-fee-amendments-mdufa/mdufa-cover-sheets>.

¹⁰ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/user-fees-and-refunds-premarket-notification-submissions-510ks>.

¹¹ <https://www.fda.gov/media/72421/download>.

(3) 510(k) Cover Letter

We recommend that you include a 510(k) Cover Letter with your submission. See Appendix A for more information on the suggested content of the 510(k) Cover Letter. Appendix A describes key information that may be useful to FDA in the initial processing and review of the 510(k) submission. In contrast with the CDRH Premarket Review Submission Cover Sheet from Section (2), the 510(k) Cover Letter is intended to be more descriptive of a 510(k) submission.

(4) Indications for Use Statement (FDA Form 3881)

We recommend that you use this section to provide the indications for use statement. FDA Form 3881 is a document where you should identify and describe the indications for use statement for the device(s) included in the 510(k) submission.

Your indications for use statement should be exactly the same as the indications for use listed throughout the rest of your 510(k) submission, including the indications for use in the device labeling. We recommend that you use the indications for use statement format in [FDA Form 3881](#).¹² We believe that in order for FDA to adequately review your submission, you should identify whether the device is intended for prescription use and/or over-the-counter use.

(5) 510(k) Summary or 510(k) Statement

In accordance with 21 CFR 807.87(h), each 510(k) submission must include either a 510(k) Summary (21 CFR 807.92) or 510(k) Statement (21 CFR 807.93). We recommend that you use this section to provide the 510(k) Summary or 510(k) Statement.

A 510(k) Summary provides a brief summary of the device included in the 510(k) and the supporting information. A 510(k) Statement is a certification that the 510(k) holder will provide a copy of the 510(k) submission, with certain exclusions, to any person within 30 days of a written request. Further information can be found on the FDA website regarding the content of the [510\(k\) Summary or 510\(k\) Statement](#).¹³

(6) Truthful and Accuracy Statement

In accordance with 21 CFR 807.87(l), all 510(k)s must include a statement certifying that all information submitted in the 510(k) is truthful and accurate and that no material fact has been omitted. A suggested format for the Truthful and Accuracy Statement can be obtained online at [Premarket Notification Truthful and Accurate Statement](#).¹⁴ The 510(k) holder, rather than a consultant or correspondent working for the holder, should sign and date the Truthful and Accuracy Statement.

¹² <https://www.fda.gov/media/86323/download>.

¹³ https://www.fda.gov/medical-devices/premarket-notification-510k/content-510k#link_7.

¹⁴ <https://www.fda.gov/medical-devices/premarket-notification-510k/premarket-notification-truthful-and-accurate-statement>.

(7) Class III Summary and Certification

If your 510(k) is for a device type classified into class III for which we have not called for PMAs, it must contain a Class III Summary and Certification pursuant to 21 CFR 807.87(k) and 807.94. The Class III Summary is a summary of the types of safety and effectiveness problems associated with the type of devices being compared and a citation to the information upon which the summary is based. The Class III certification ensures that a reasonable search of all information known or otherwise available about the class III device and other similar legally marketed devices has been conducted. We recommend that you use this [Class III Summary and Certification format](#).¹⁵

(8) Financial Certification or Disclosure Statement

In accordance with 21 CFR 807.87(i), if you submit information from clinical studies, you must submit a financial certification and/or a disclosure statement for each clinical investigator who participated in your study. The following forms are available on our web site:

- [Certification: Financial Interests and Arrangements of Clinical Investigators \(Form FDA 3454\)](#);¹⁶ and
- [Disclosure: Financial Interests and Arrangements of Clinical Investigators \(Form FDA 3455\)](#).¹⁷

See also 21 CFR part 54 and the guidance entitled, “[Financial Disclosure by Clinical Investigators](#).”¹⁸

(9) Declarations of Conformity and Summary Reports

If your 510(k) is a traditional 510(k) submission, we recommend that you use this section to provide information relating to your use of voluntary consensus standards, including any declarations of conformity or the basis of general use of such standards.

If your 510(k) is an Abbreviated 510(k) submission, we recommend that you use this section to provide the information regarding the use of standard(s), or a summary report that describes how the device complies with the special control(s) associated with the particular device type or that is recommended in any relevant device-specific guidance. As mentioned in the definitions section of this guidance, an Abbreviated 510(k) is a type of 510(k) in which you choose to rely on consensus standards, guidances, and/or special controls. See also the guidance titled “[The Abbreviated 510\(k\) Program](#).”¹⁹

¹⁵ <https://www.fda.gov/medical-devices/premarket-notification-510k/premarket-notification-class-iii-certification-and-summary>.

¹⁶ <https://www.fda.gov/media/70465/download>.

¹⁷ <https://www.fda.gov/media/69872/download>.

¹⁸ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/financial-disclosure-clinical-investigators>.

¹⁹ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/abbreviated-510k-program>.

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More information about the FDA standards program, including a current list of FDA recognized standards may be obtained at the [Standards and Conformity Assessment Program website](https://www.fda.gov/standards-and-conformity-assessment-program-medical-devices)²⁰ and the guidance titled “[Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices).”²¹

If you choose to rely on an FDA-recognized standard or a guidance for any part of the device design or testing, you should include either a:

- declaration of conformity to the standard or summary report²² recommended in any relevant device-specific guidance; or
- the basis of general use of the standard along with the underlying information or data that supports how the standard was used.

If you choose to rely on a consensus standard that is not FDA-recognized for any part of the device design or testing, you should include the basis of general use of the standard along with the underlying information or data that supports how the standard was used. Additional information regarding the use of declarations of conformity and general use of standards may be found in the FDA guidance “[Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices).”²³

(10) Device Description

We recommend that you describe the performance specifications and include a brief description of the device design requirements in this section. We also recommend that you identify all models, as well as all accessories included in the submission.

If diagrams, dimensions, tolerances, and/or schematics are useful to fully describe and characterize the device, we recommend that you include them for each device and accessory included in the 510(k) submission. We also recommend that you provide a list of all tissue-contacting components and their respective materials.

(11) Executive Summary/Predicate Comparison

In this section of your 510(k), we recommend that you provide an executive summary of the 510(k), which should include a:

- concise description of the device, including the indications for use and technology;
- device comparison table; and

²⁰ <https://www.fda.gov/standards-and-conformity-assessment-program-medical-devices>.

²¹ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices>.

²² The FDA guidance “The Abbreviated 510(k) Program” provides an overview of summary reports that are identified in device-specific guidances.

²³ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices>.

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- concise summary for any performance testing in the submission.

The description, although concise, should be sufficient to provide an overall understanding of the device. The device comparison table should outline the differences and similarities between your device and the predicate. Table 1 is a sample of the predicate comparison table. Table 1 is provided for illustrative purposes only and does not represent the information that may be necessary for FDA to establish substantial equivalence. We recommend that you also provide a discussion of how this comparison supports substantial equivalence. The summary for each performance testing section (i.e., sections (18), (19), and (20)) should be sufficient to provide a broad understanding of the type of testing performed, the methods used, and your conclusion from the results.

Table 1. Sample predicate comparison table to outline differences and similarities between the subject and predicate devices

Description	Subject Device	Predicate Device (Kxxxxxx)
Indications for use		
Prescription/over-the-counter use		
Size(s)		
Battery or mains powered		
[comparison x]		
[comparison y]		
[comparison z]		

(12) Substantial Equivalence Discussion

In this section, we recommend that you identify the predicate device and identify its trade name, model number, 510(k) submitter/holder, and 510(k) number, if available. We recommend that you provide a detailed comparison between your device and the predicate sufficient to demonstrate the substantial equivalence of the devices, as applicable, in terms of:

- indications for use;
- technology; and
- performance specifications, including any testing.

For additional information on how FDA determines substantial equivalence, we recommend that you refer to the FDA guidance “[The 510\(k\) Program: Evaluating Substantial Equivalence in Premarket Notifications \[510\(k\)\]](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-program-evaluating-substantial-equivalence-premarket-notifications-510k).”²⁴

²⁴ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-program-evaluating-substantial-equivalence-premarket-notifications-510k>.

(13) Proposed Labeling

The 510(k) must include proposed labeling in sufficient detail to satisfy the requirements of 21 CFR 807.87(e). If the device is an in vitro diagnostic device, the labeling must satisfy the requirements of 21 CFR 809.10. Generally, the term “labeling” includes the device label, instructions for use, and any patient labeling. See the FDA guidances “[Device Labeling Guidance #G91-1](#),”²⁵ “[Labeling – Regulatory Requirements for Medical Devices](#),”²⁶ “[Guidance on Medical Device Patient Labeling](#),”²⁷ and device-specific guidance, where available, for more information about labeling your device.

(14) Sterilization and Shelf Life

For devices sold as sterile, we recommend that you consider the guidance “[Submission and Review of Sterility Information in Premarket Notification \(510\(k\)\) Submissions for Devices Labeled as Sterile](#).”²⁸

For devices that are reprocessed single use devices, refer to the FDA guidance “[Medical Device User Fee and Modernization Act of 2002 Validation Data in Premarket Notification Submissions \(510\(k\)s\) for Reprocessed Single-Use Medical Devices](#).”²⁹

For a submission that identifies a shelf life for the device, your shelf life should be supported by appropriate bench tests and/or sterilization (packaging) validation.

(15) Biocompatibility

If your device contains components that come into direct or indirect contact with tissue, you should evaluate the biocompatibility of the tissue-contacting materials. Refer to the FDA guidance document “[Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process."](#)”³⁰

(16) Software

This section should include the appropriate software documentation as described in the guidance titled “[Guidance for the Content of Premarket Submissions for Software Contained](#)

²⁵ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/device-labeling-guidance-g91-1-blue-book-memo>.

²⁶ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/labeling-regulatory-requirements-medical-devices-fda-89-4203>.

²⁷ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-medical-device-patient-labeling>.

²⁸ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/submission-and-review-sterility-information-premarket-notification-510k-submissions-devices-labeled>.

²⁹ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-device-user-fee-and-modernization-act-2002-validation-data-premarket-notification>.

³⁰ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-international-standard-iso-10993-1-biological-evaluation-medical-devices-part-1-evaluation-and>.

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[in Medical Devices](#).”³¹ As discussed in the guidance, we recommend that you identify the “Level of Concern,” (minor, moderate, or major) associated with your device and provide documentation consistent with that level.

We recommend this section also include appropriate cybersecurity information as described in the FDA guidance document “[Content of Premarket Submissions for Management of Cybersecurity in Medical Devices](#).”³²

(17) Electromagnetic Compatibility and Electrical Safety

If your device is electrically powered, we recommend that you evaluate its electromagnetic compatibility (EMC). EMC encompasses both emissions (interference with electronic products) and immunity (interference with device performance created by emissions from other electronic products). You should refer to the FDA guidance “[Information to Support a Claim of Electromagnetic Compatibility \(EMC\) of Electrically-Powered Medical Devices](#).”³³ FDA also recommends that you use the currently FDA-recognized version of American National Standards Institute (ANSI)/Association for the Advancement of Medical Instrumentation (AAMI) Electrical Safety (ES) 60601-1: *Medical electrical equipment - Part 1: General requirements for basic safety and essential performance* or an equivalent method.

(18) Performance Testing – Bench

If you submit bench test results to support substantial equivalence, we recommend you include the following information in this section. If the device is an in vitro diagnostic device (IVD), refer to the applicable sections of the FDA guidance “[Refuse to Accept Policy for 510\(k\)s](#)”³⁴ and device-specific guidances for IVDs that can be found on [FDA’s guidance website](#).³⁵

FDA recommends that your non-clinical bench performance testing include the relevant information described in the FDA guidance document “[Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions](#).”³⁶

³¹ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-content-premarket-submissions-software-contained-medical-devices>.

³² <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/content-premarket-submissions-management-cybersecurity-medical-devices-0>.

³³ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/information-support-claim-electromagnetic-compatibility-emc-electrically-powered-medical-devices>.

³⁴ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/refuse-accept-policy-510ks>.

³⁵ <https://www.fda.gov/search-fda-guidance-documents>.

³⁶ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recommended-content-and-format-non-clinical-bench-performance-testing-information-premarket>.

(19) Performance Testing – Animal

If you submit animal test results to support substantial equivalence,³⁷ we recommend you include the following information in this section. If the device is an in vitro diagnostic device (IVD), refer to the applicable sections of the FDA guidance “[Refuse to Accept Policy for 510\(k\)s](#)”⁵ and device-specific guidances for IVDs that can be found on [FDA’s guidance website](#).³⁵

If you conducted animal testing, we recommend that you describe the tests and provide the results that support the performance characteristics of your device. Generally, all submissions that describe animal testing should include the information below; however, if a relevant device-specific guidance is available, you should follow the recommendations in that guidance document. The Division responsible for the review of your device is also available to assist you with any questions about animal testing.

- list the specific animal tests conducted;
- describe each test protocol;
- summarize the results;
- describe your analysis; and
- discuss your conclusions.

The description of test protocols should identify the:

- objective of the test;
- test articles used in the test;
- test methods and procedures (including any specific test conditions);
- study endpoint, i.e., the specific parameter measured; and
- pre-defined acceptance or pass/fail criteria.

In the summary of your results and analysis, we recommend that you briefly present the data derived from testing in a clear and concise form, such as a table.

We also recommend that your conclusions describe any comparison testing with the predicate device in terms of substantial equivalence.

(20) Performance Testing – Clinical

If you submit results from clinical studies to demonstrate substantial equivalence, we recommend you include the following information in this section. If the device is an in vitro diagnostic device (IVD), refer to the applicable sections of the FDA guidance “[Refuse to](#)

³⁷ FDA supports the principles of the “3Rs,” to reduce, refine, and replace animal use in testing when feasible. We encourage sponsors to consult with us if they wish to use a non-animal testing method they believe is suitable, adequate, validated, and feasible. We will consider if such an alternative method could be assessed for equivalency to an animal test method.

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[Accept Policy for 510\(k\)s](#)³⁸ and device-specific guidances for IVDs that can be found on [FDA's guidance website](#).³⁵

FDA will consider alternatives to clinical studies when the proposed alternatives are supported by an adequate scientific rationale. Our recommendations for clinical testing typically depend on many factors including device type, intended use, design, safety profile, and clinical experience.

Generally, all submissions that describe clinical studies should include the information below; however, if a relevant device-specific guidance is available, you should follow the recommendations in that guidance document. The Division responsible for the review of your device is also available to assist you with any questions about studies.

If your submission describes clinical studies, we recommend that you provide the clinical protocol that identifies the:

- objective of the test;
- test methods and procedures (including any specific test conditions);
- study endpoints (usually both safety and effectiveness); and
- statistical methodology used.

In addition, we recommend that you discuss the study results, analyses performed (including statistical, as appropriate), and conclusions. We also recommend that your conclusions discuss any comparison testing with the predicate device in terms of substantial equivalence.

For each applicable device clinical trial included in your submission, you must include the Certification of Compliance with the requirements of ClinicalTrials.gov Data Bank ([FDA Form 3674](#))³⁹ (42 U.S.C. 282(j)(5)(B)).

If your study is considered significant risk,⁴⁰ the study must be conducted under the IDE regulation, 21 CFR Part 812. If, however, your study is considered non-significant risk, the study is subject to the abbreviated requirements of 21 CFR Part 812.2(b).

In all cases, sponsors of clinical trials must comply with the regulations governing institutional review boards (21 CFR Part 56) and informed consent (21 CFR Part 50).

When data from clinical investigations conducted outside the United States are submitted to FDA, the requirements of 21 CFR 812.28 may apply. 21 CFR 812.28 outlines the conditions for FDA acceptance of clinical data from investigations conducted outside the US when submitted to support premarket submissions. For more information, see the FDA guidance

³⁸ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/refuse-accept-policy-510ks>.

³⁹ <https://www.fda.gov/media/69901/download>.

⁴⁰ Significant risk devices are defined in 21 CFR 812.3(m)(4). See also "Significant Risk and Nonsignificant Risk Medical Device Studies," available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/significant-risk-and-nonsignificant-risk-medical-device-studies>.

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[“Acceptance of Clinical Data to Support Medical Device Applications and Submissions: Frequently Asked Questions.”](#)⁴¹

VI. Summary: Sections Recommended in a Traditional or Abbreviated 510(k) and Related Information

The table below lists the sections we recommend for a Traditional or Abbreviated 510(k) submission. The table also includes related information and additional resources (e.g., links to guidance documents) specific to that section.

Section	Title	Related Information
1	Medical Device User Fee Amendments (MDUFA) Cover Sheet	Medical Device User Fee Cover Sheet ⁹
2	CDRH Premarket Review Submission Cover Sheet	CDRH Premarket Review Submission Cover Sheet ¹¹
3	510(k) Cover Letter	Appendix A of this guidance
4	Indications for Use Statement	Indications for Use (FDA Form 3881) ¹²
5	510(k) Summary or 510(k) Statement	Device Advice “Content of a 510(k)” Section E ⁴²
6	Truthful and Accuracy Statement	Device Advice “Content of a 510(k)” Section G ⁴³
7	Class III Summary and Certification	Class III Summary and Certification format ⁴⁴
8	Financial Certification or Disclosure Statement	<ul style="list-style-type: none">• Certification: Financial Interests and Arrangements of Clinical Investigators (Form FDA 3454)¹⁶• Disclosure: Financial Interests and Arrangements of Clinical Investigators (Form FDA 3455)¹⁷• “Financial Disclosure by Clinical Investigators”¹⁸

⁴¹ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/acceptance-clinical-data-support-medical-device-applications-and-submissions-frequently-asked>.

⁴² https://www.fda.gov/medical-devices/premarket-notification-510k/content-510k#link_7.

⁴³ https://www.fda.gov/medical-devices/premarket-notification-510k/content-510k#link_9.

⁴⁴ <https://www.fda.gov/medical-devices/premarket-notification-510k/premarket-notification-class-iii-certification-and-summary>.

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Section	Title	Related Information
9	Declarations of Conformity and Summary Reports	<ul style="list-style-type: none"> • “Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices”³ • Standards and Conformity Assessment Program website⁴⁵
10	Device Description	See Section (10) of this guidance
11	Executive Summary/Predicate Comparison	See Section (11) of this guidance
12	Substantial Equivalence Discussion	“The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]” ²⁴
13	Proposed Labeling	Device Advice “Content of a 510(k)” Section H ⁴⁶
14	Sterilization and Shelf Life	<p>“Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile”²⁸</p> <p>For reuse of single use devices, see “Medical Device User Fee and Modernization Act of 2002 Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed Single-Use Medical Devices.”²⁹</p>
15	Biocompatibility	“Use of International Standard ISO 10993-1, “Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process”” ³⁰
16	Software	“Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices” ³¹

⁴⁵ <https://www.fda.gov/standards-and-conformity-assessment-program-medical-devices>.

⁴⁶ https://www.fda.gov/medical-devices/premarket-notification-510k/content-510k#link_10.

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Section	Title	Related Information
17	Electromagnetic Compatibility and Electrical Safety	<p>“Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically-Powered Medical Devices”³³</p> <p>See also the FDA-recognized version of ANSI/AAMI ES 60601-1: <i>Medical electrical equipment - Part 1: General requirements for basic safety and essential performance</i> or an equivalent method.</p>
18	Performance Testing – Bench	See Section (18) of this guidance
19	Performance Testing – Animal	See Section (19) of this guidance
20	Performance Testing – Clinical	<p>See Section 20 in Chapter II(20) of this guidance. Certification Form: Financial Interests and Arrangements of Clinical Investigators</p> <p>Disclosure Form: Financial Interests and Arrangements of Clinical Investigators</p>

Appendix A. 510(k) Cover Letter

Purpose

Cover letters have been prepared in a wide range of formats and have varied in terms of the information they contain. This appendix identifies the information we recommend that you include in your cover letter to ensure an efficient review of your submission.

Content

The cover letter should be prepared by the submitter on company letterhead and clearly identify who the submitter is and, if applicable, who is the official contact person authorized by the submitter (i.e., primary correspondent). The cover letter must include the designation “510(k) Notification” (21 CFR 807.90(e)).

Administrative Information

We recommend that your cover letter identify:

- Type of 510(k) submission, Abbreviated or Traditional;
- Your device type in plain terms, i.e., by its common name;
- 510(k) submitter;
- One primary correspondent, by name and title, with their current phone number and email address. Additional correspondents may be identified;
- Your preference for continued confidentiality (21 CFR 807.95);
- Your proposed classification regulation;
- Class (i.e., whether it is unclassified or a class I, II, or III device). For more information regarding classification see “[Classify Your Medical Device](#).”⁴⁷ An unclassified device is a legally marketed preamendments device for which a classification regulation has yet to be finalized and for which a PMA is not required.;
- Panel;
- Product code; and
- Any FDA document numbers associated with prior formal correspondence with FDA (e.g., IDE, Q-Submissions, 510(k), PMA, request for designation (RFD)) related to your device.

Basis for the Submission

We recommend that you explain the basis for your submission. For example, an appropriate basis for a Traditional or Abbreviated 510(k) is a:

- new device
- modification of a legally marketed device that would not otherwise qualify for a Special 510(k)⁴⁸

⁴⁷ <https://www.fda.gov/classify-your-medical-device>.

⁴⁸ If a new 510(k) is required for a modification (21 CFR 807.81(a)(3)) and the method(s) to evaluate the change(s) are well-established, and the results can be sufficiently reviewed in a summary or risk analysis format, then a Special 510(k) may be appropriate. Otherwise, we believe a Traditional or Abbreviated 510(k) is

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- new indication for use
- new device design
- a submission for a reprocessed, single use, disposable device⁴⁹
- an exempt device which exceeds the limitations for exemption.

For guidance about submitting a 510(k) when you modify your legally marketed device, see “[Deciding When to Submit a 510\(k\) for a Change to an Existing Device](#).”⁵⁰

If your device is comprised of finished devices that are assembled into a convenience kit, we recommend that you identify your device as a convenience kit and list all the devices included in the kit. See also “[Convenience Kits Interim Regulatory Guidance](#).”⁵¹ In 510(k) submissions for convenience kits, we recommend that you provide the [kit certification statement](#).⁵²

If you are bundling more than one device in your submission, we recommend that you identify all the devices you are bundling and discuss why you believe bundling is appropriate. See also “[Bundling Multiple Devices or Multiple Indications in a Single Submission](#)”⁵³ for information about bundling.

Design and Use of the Device

We recommend that your cover letter address the principal factors about the design and use of your device in a tabular format, for example, by answering questions shown in Table 2 below.

appropriate. For more information see “The Special 510(k) Program,” available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/special-510k-program>.

⁴⁹ See section 510(o) of the FD&C Act and the guidance “[Medical Device User Fee and Modernization Act of 2002, Validation Data in Premarket Notification Submissions \(510\(k\)s\) for Reprocessed Single-Use Medical Devices](#),” available at <https://www.fda.gov/media/71482/download>.

⁵⁰ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/deciding-when-submit-510k-change-existing-device>.

⁵¹ <https://www.fda.gov/medical-devices/guidance-documents-medical-devices-and-radiation-emitting-products/convenience-kits-interim-regulatory-guidance>.

⁵² <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/kit-certification-510ks>.

⁵³ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/bundling-multiple-devices-or-multiple-indications-single-submission>.

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Table 2. Design and Use of the Device

Question	YES	NO
Is the device intended for prescription use (21 CFR 801 subpart D)? ^A		
Is the device intended for over-the-counter use (21 CFR 807 subpart C)? ^A		
Does the device contain components derived from a tissue or other biologic source?		
Is the device provided sterile?		
Is the device intended for single use?		
Is the device a reprocessed single use device?		
If yes, does this device type require reprocessed validation data?		
Does the device contain a drug?		
Does the device contain a biologic?		
Does the device use software?		
Does the submission include clinical information?		
Is the device implanted?		

^A A device may be intended for both prescription and over-the-counter use. If so, the answer to both of these questions is yes.