

Guidance for Industry and FDA Staff

Format for Traditional and Abbreviated 510(k)s

Document issued on: August 12, 2005

The information collection provisions in this guidance have been approved under OMB control number 0910-0120. This approval expires August 31, 2010. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.

For questions regarding this document contact Ms. Heather S. Rosecrans at 301-796-6571 or by email at heather.rosecrans@fda.hhs.gov.

This document was corrected on **November 17, 2005** to clarify recommendations about the user fee cover sheet, biocompatibility, clinical protocols, investigational device exemptions, and the 510(k) cover letter.



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

Office of Device Evaluation

Office of In Vitro Diagnostic Device Evaluation and Safety

Preface

Public Comment

Written comments and suggestions may be submitted at any time for Agency consideration to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852. When submitting comments, please refer to the exact title of this guidance document. Comments may not be acted upon by the Agency until the document is next revised or updated.

Additional Copies

Additional copies are available from the Internet at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM084365.htm>

You may also send an e-mail request to dsmica@fda.hhs.gov to receive an electronic copy of the guidance or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number (1567) to identify the guidance you are requesting.

Guidance for Industry and FDA Staff

Format for Traditional and Abbreviated 510(k)s

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

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 Submission (510(k)). 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 types¹, Special 510(k)s², or other types of documents, such as Premarket Approval Applications (PMAs) or Investigational Device Exemption Applications (IDEs).

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 guidance's on the 510(k) program and specific device types. It is not a replacement for those documents.

As an alternative to the submission format described in this document, you may submit your 510(k) in the globally harmonized format described in the document entitled “**Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices.**” The document was developed by Study Group 1 (SG1) of the Global Harmonization Task Force (GHTF) and issued as a proposed document in October 2002. See the FDA guidance, **A Pilot Program to Evaluate a**

¹ To search the CDRH web site for device specific guidance, see our web site at www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfggp/search.cfm.

² The option of a Special 510(k) allows a submitter to request clearance for changes to their own legally marketed device(s) which does not affect the device's intended use or alter the device's fundamental scientific technology. See also **The New 510(k) Paradigm Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications** at www.fda.gov/cdrh/ode/parad510.html.

Contains Nonbinding Recommendations

Proposed Globally Harmonized Alternative for Premarket Procedures³ for a description of the FDA pilot program and the eligible device types.

If you choose to submit a 510(k) in the STED format, the information about Traditional 510(k)s in this document may help you prepare your STED submission. Appendix C shows the correlation between the sections recommended in this guidance and the STED format.

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

The Least Burdensome Approach

We believe we should consider the least burdensome approach in all areas of device regulation. This guidance reflects our careful review of the relevant scientific and legal requirements and what we believe is the least burdensome way for you to comply with those requirements. However, if you believe that an alternative approach would be less burdensome, please contact us so we can consider your point of view. You may send your written comments to the contact person listed in the preface of this guidance or to the CDRH Ombudsman. Comprehensive information on CDRH's Ombudsman, including ways to contact him, can be found on the internet at www.fda.gov/cdrh/ombudsman/.

Background

This document supplements other FDA documents regarding the content requirements for a 510(k) submission. You should also refer to regulation 21 CFR 807 Subpart E and the section on our web site **How to Prepare a 510(k) Submission** www.fda.gov/cdrh/devadvice/314.html.

Definitions

Each person who wants to market in the United States, a class I, II, or III 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 (the act) and does not exceed the limitations of exemptions in xxx.9 of the device classification regulation chapters (e.g., 862.9, 864.9). There is no specific 510(k) form. However, 21 CFR 807 Subpart E describes requirements for a 510(k) submission. This guidance recommends a format that will help you comply with those requirements.

³ <http://www.fda.gov/cdrh/ode/guidance/1347.html>

Contains Nonbinding Recommendations

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**, as described in 21 CFR 807.92(a)(3), is a device that was legally marketed prior to May 28, 1976, for which a PMA is not required, or a device which has been reclassified from class III to class II or I, or a device which has been found SE through the 510(k) process. The legally marketed device(s) to which the submitter claims equivalence is commonly known as the "predicate." Although devices recently cleared under 510(k) are often selected as the predicate to which equivalence is claimed, any legally marketed device may be used as a predicate

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, if not identical to the predicate, results of performance testing to demonstrate substantial equivalence.

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

- FDA-recognized consensus standards
- special controls established by regulation
- FDA guidance documents.

Typically, an Abbreviated 510(k) includes one or more declarations of conformity to a FDA-recognized consensus standard (see Chapter II, section 9 of this guidance), or part of a standard. For more information about Abbreviated 510(k)s, see **The New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications** at www.fda.gov/cdrh/ode/parad510.html.

Outline of the Guidance

This guidance describes the format that we recommend for a Traditional or Abbreviated 510(k) submission. This guidance is divided into three chapters as follows:

- Chapter I** Identifies the overall outline of the 510(k) format.
- Chapter II** Describes each section and identifies sources of information useful for that section.
- Chapter III** Provides a summary listing the individual sections and links to related resources.

Chapter I. Sections in a Traditional or Abbreviated 510(k)

In a Traditional or Abbreviated 510(k), we recommend that you include the sections headings listed, preferably in the sequence below. In some instances, the information in a particular section may not apply to your device. In order to speed 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. CDRH Premarket Review Submission Cover Sheet
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 or Disclosure Statement
9. Declarations of Conformity and Summary Reports
10. Executive Summary
11. Device Description
12. Substantial Equivalence Discussion
13. Proposed Labeling
14. Sterilization and Shelf Life

Contains Nonbinding Recommendations

15. Biocompatibility
16. Software
17. Electromagnetic Compatibility and Electrical Safety
18. Performance Testing – Bench
19. Performance Testing – Animal
20. Performance Testing – Clinical
21. Other

This document describes the format we recommend for each of these sections and provides resources, such as regulations, guidance documents, internet links that will be useful in preparing the sections. The guidance documents or other resources referred to in the links may be revised over time, but the links will remain the same. Therefore, by following the links in this document, you will be directed to the most current information for each section.

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

In this chapter, 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 and receipt of the user fee payment, 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 exempt from user fees, we recommend you include a Medical Device User Fee Cover Sheet, and use it to indicate the type of exemption that applies in the case of 510(k) submissions:.

- intended solely for pediatric use (a change in the intended use from pediatric use to adult use requires the submission of a new 510(k) in accordance with 21 CFR 807.81(a)(3); and an associated fee)
- submitted by a state or Federal government entity (exempt from the FDA user fee unless the device is to be distributed commercially).

The Medical Device User Fee Form may be obtained at www.fda.gov/oc/mdufma/coversheet.html. See also **Guidance for Industry and FDA Staff – User Fees and Refunds for Premarket Notification Submissions (510(k)s)** at www.fda.gov/cdrh/mdufma/guidance/1511.html.

2. CDRH Premarket Review Submission Cover Sheet

The CDRH Premarket Review Submission Cover Sheet is a voluntary form used to help provide basic administrative information for all types of premarket notification submissions. The Cover Sheet may be obtained at www.fda.gov/opacom/morechoices/fdaforms/FDA-3514.pdf.

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 proposed and 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 described in Section 3 is intended to be more descriptive of a 510(k) submission.

4. Indications for Use Statement

We recommend that you use this section to provide the indications for use statement, which is a document where you identify and describe the specific 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** at www.fda.gov/cdrh/devadvice/314312.html#link_6. 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 Section 5 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 regarding the content of the 510(k) Summary or 510(k) Statement may be obtained at www.fda.gov/cdrh/devadvice/314312.html#link_7.

6. Truthful and Accuracy Statement

In accordance with 21 CFR 807.87(k), 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. This form may be obtained at www.fda.gov/cdrh/manual/stmnt1.html.

Contains Nonbinding Recommendations

The submitter should sign and date the statement. The 510(k) holder rather than a consultant or correspondent working for the holder should sign the Truthful and Accuracy 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 in accordance with 21 CFR 807.87(j) and 807.94. The Class III Summary and Certification provide a review of the risks and adverse events known and associated with the general category of devices into which the proposed device falls. We recommend that you use the Class III Summary and Certification format at www.fda.gov/cdrh/manual/stmnciii.html.

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:

- FORM FDA 3454, Certification: Financial Interests and Arrangements of Clinical Investigators, www.fda.gov/opacom/morechoices/fdaforms/FDA-3454.pdf
- FORM FDA 3455, Disclosure: Financial Interests and Arrangements of Clinical Investigators, www.fda.gov/opacom/morechoices/fdaforms/FDA-3455.pdf.

See also 21 CFR Part 54 and the guidance entitled, **Financial Disclosure by Clinical Investigators** at www.fda.gov/oc/guidance/financialdis.html.

9. Declarations of Conformity and Summary Reports

If your 510(k) is an Abbreviated 510(k) submission, we recommend that you use this section to provide the information regarding any declarations of conformity to a standard or a summary report 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 declare conformance to a recognized standard for any part of the device design or testing or you choose to prepare a summary report to a guidance. More information about the FDA standards program, including a current list of FDA recognized standards may be obtained at www.fda.gov/cdrh/stdsprog.html. See also the guidances titled **The New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications - Final Guidance** at www.fda.gov/cdrh/ode/parad510.html and **Use of Standards in Substantial Equivalence Determinations** at www.fda.gov/cdrh/ode/guidance/1131.html.

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

Contains Nonbinding Recommendations

- declaration of conformity to the standard⁴ or summary report recommended in any relevant device-specific guidance; or
- a statement that testing will be conducted and meet specified acceptance criteria before the device is marketed.

Because a declaration of conformity is based on results from testing, we believe you cannot properly submit a declaration of conformity until you have completed the testing the standard describes. For more information, please refer to section 514(c)(1)(B) of the act. Additional information regarding the use of declarations of conformity may be obtained at www.fda.gov/cdrh/devadvice/3145.html#link_9.

10. Executive Summary

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
- 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. 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.

11. 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 or components, 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, accessory or component included in the 510(k) submission. We also recommend that you provide a list of all patient contacting components and their respective materials.

⁴ See Required Elements for a Declaration of Conformity to a Recognized Standard (Screening Checklist for All Premarket Notification (510(k)) Submissions) at www.fda.gov/cdrh/ode/reqrecstand.html.

12. Substantial Equivalence Discussion

In the substantial equivalence section, we recommend that you identify the predicate and identify its trade name, model number, 510(k) submitter/holder, and 510(k) number, if available. You may choose to identify, compare, and test against more than one predicate, if, for example, your device has two features or indications not previously combined in a single predicate. Our substantial equivalence determination is based on the **510(k) Substantial Equivalence Decision-Making Process Flowchart**. The flowchart can be found at www.fda.gov/cdrh/ode/dd510kse.pdf.

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 background on making determinations of substantial equivalence we recommend that you refer to Blue Book Memorandum K86-3 entitled **Guidance on the Center for Devices and Radiological Health's Premarket Notification Review Program #K86-3** at www.fda.gov/cdrh/k863.html.

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 should additionally satisfy the requirements of 21 CFR 809.10. Generally, the term “labeling” includes the device label, instructions for use, and any patient labeling. See also **Labeling Requirements**, at www.fda.gov/cdrh/devadvice/314312.html#link_10 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 follow the guidance, **Updated 510(k) Sterility Review Guidance K90-1; Final Guidance for Industry and FDA**, at www.fda.gov/cdrh/ode/guidance/361.html.

For devices that are reprocessed single use devices, please refer to **Guidance for Industry and FDA Staff – Medical Device User Fee and Modernization Act of 2002 Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed Single-Use Medical Devices** at www.fda.gov/cdrh/ode/guidance/1216.html.

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 patients, you should evaluate the biocompatibility of the patient-contacting materials. Please refer to the guidance documents titled **Blue Book Memo, G95-1, Use of International Standard ISO-10993, and Biological Evaluation of Medical Devices Part 1: Evaluation and Testing** at www.fda.gov/cdrh/g951.html. You should select biocompatibility tests for the duration and type of contact appropriate to your device design and submit the pass/fail criteria or in some cases, a summary of the results.

If identical materials are used in a predicate with the same type and duration of patient contact, you may identify the predicate in lieu of performing biocompatibility testing and state that your device is comprised of identical materials and that are processed by identical manufacturing methods. This is most appropriate if you are the manufacturer of the predicate and you have complete documentation with respect to the manufacturing methods and materials employed.

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 in Medical Devices** at www.fda.gov/cdrh/ode/guidance/337.html. 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.

17. Electromagnetic Compatibility and Electrical Safety

If your device design includes an electronic component, 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). We recommend you test your device according to IEC 60601-1-2 Medical Electrical Equipment -- Part 1: General Requirements for Safety; Electromagnetic Compatibility -- Requirements and Tests (Second Edition, 2001) or equivalent method to demonstrate the EMC characteristics of your device.

If your device design results in patient contact with any electrically powered component, FDA recommends that you follow IEC 60601 1 (1988): Medical electrical equipment - Part 1: General requirements for safety, including Amendment 1 (1991) and Amendment 2 (1995) 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, refer to Appendix B.

Contains Nonbinding Recommendations

You should describe the bench testing and provide the results that support the performance characteristics of your device. Generally, all submissions should include the information below; however, if a relevant device-specific guidance is available, you should follow the recommendations in that guidance document.

- list the specific bench tests conducted
- describe each test protocol
- summarize the results
- describe your analysis
- 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
- 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 in terms of substantial equivalence.

19. Performance Testing – Animal

If you submit animal 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, refer to Appendix B.

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 branch or team 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

Contains Nonbinding Recommendations

- 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
- 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, refer to Appendix B.

FDA will always 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 branch or team responsible for the review of your device is also available to assist you with any questions about studies.

Contains Nonbinding Recommendations

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)
- 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.

If your study is considered significant risk⁵, the study must be conducted under the IDE regulation, 21 CFR Part 812 if it is conducted in the United States.⁶ If, however, your study is considered non-significant risk, the study is subject to the abbreviated requirements of 21 CFR Part 812.2(b) only.

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).

Chapter III. 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.

Table 2: Sections Recommended in a Traditional or Abbreviated 510(k) and Related Information

Section	Title	Related Information
1	MDUFMA Cover Sheet	Medical Device User Fee Cover Sheet www.fda.gov/oc/mdufma/coversheet.html
2	CDRH Premarket Review Submission Cover Sheet	CDRH Premarket Review Submission Cover Sheet www.fda.gov/opacom/morechoices/fdaforms/FDA-3514.pdf
3	510(k) Cover Letter	Appendix A of this guidance
4	Indications for Use Statement	Device Advice “Content of a 510(k)” Section D www.fda.gov/cdrh/devadvice/314312.html#link_6
5	510(k) Summary or 510(k)	Device Advice “Content of a 510(k)” Section E

⁵ Significant risk devices are defined in 21 CFR 812.3(m)(4). See also **Significant Risk and Nonsignificant Risk Medical Device Studies** at www.fda.gov/oc/ohrt/irbs/devices.html#risk.

⁶ Only studies conducted in the US are subject to the requirements of 21 CFR Part 812.

Contains Nonbinding Recommendations

Section	Title	Related Information
	Statement	www.fda.gov/cdrh/devadvice/314312.html#link_7
6	Truthful and Accuracy Statement	Device Advice “Content of a 510(k)” Section G www.fda.gov/cdrh/devadvice/314312.html#link_9
7	Class III Summary and Certification	Class III Summary and Certification Form www.fda.gov/cdrh/manual/stmnciii.html
8	Financial Certification or Disclosure Statement	FORM FDA 3454, Certification: Financial Interests and Arrangements of Clinical Investigators www.fda.gov/opacom/morechoices/fdaforms/FDA-3454.pdf FORM FDA 3455, Disclosure: Financial Interests and Arrangements of Clinical Investigators www.fda.gov/opacom/morechoices/fdaforms/FDA-3455.pdf Financial Disclosure by Clinical Investigators www.fda.gov/oc/guidance/financialdis.html
9	Declarations of Conformity and Summary Reports	Use of Standards in Substantial Equivalence Determinations www.fda.gov/cdrh/ode/guidance/1131.html . FDA Standards program www.fda.gov/cdrh/stdsprog.html . Declaration of conformity www.fda.gov/cdrh/devadvice/3145.html#link_9 Required Elements for Declaration of Conformity to Recognized Standard www.fda.gov/cdrh/ode/reqrecstand.html
10	Executive Summary	See section 10 in Chapter II of this guidance
11	Device Description	See section 11 in Chapter II of this guidance
12	Substantial Equivalence Discussion	Guidance on the CDRH Premarket Notification Review Program 6/30/86 (K86-3), www.fda.gov/cdrh/k863.html
13	Proposed Labeling	Device Advice “Content of a 510(k)” Section H www.fda.gov/cdrh/devadvice/314312.html#link_10
14	Sterilization/Shelf Life	Updated 510(k) Sterility Review Guidance (K90-1) www.fda.gov/cdrh/ode/guidance/361.html For reuse of single use devices, see Guidance for Industry and FDA Staff – Medical Device User Fee and Modernization Act of 2002 Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed Single-Use Medical Devices www.fda.gov/cdrh/ode/guidance/1216.html
15	Biocompatibility	FDA Blue Book Memo, G95-1, Use of International Standard ISO-10993, “Biological Evaluation of Medical Devices Part 1: Evaluation and Testing” www.fda.gov/cdrh/g951.html
16	Software	Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices www.fda.gov/cdrh/ode/software.html

Contains Nonbinding Recommendations

17	Electromagnetic Compatibility/Electrical Safety	CDRH Medical Device Electromagnetic Compatibility Program www.fda.gov/cdrh/emc See also IEC 60601-1- 2 Medical Electrical Equipment -- Part 1: General Requirements for Safety; Electromagnetic Compatibility -- Requirements and Tests (Second Edition, 2001)
18	Performance Testing – Bench	See section 18 in Chapter II of this guidance
19	Performance Testing – Animal	See section 19 in Chapter II of this guidance
20	Performance Testing – Clinical	See section 20 in Chapter II of this guidance Certification/Disclosure Forms: Financial Interests and Arrangements of Clinical Investigators www.fda.gov/opacom/morechoices/fdaforms/FDA-3454.pdf www.fda.gov/opacom/morechoices/fdaforms/FDA-3455.pdf

Responding to Requests for Additional Information

FDA may request additional information from the submitter, and in many cases, will place the submission on hold by issuing a hold letter. For more information please see Guidance for Industry and FDA Staff - FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment at www.fda.gov/cdrh/mdufma/guidance/1219.html.

All responses to requests for additional information should:

- identify the submission as a response to a request for additional information to a 510(k);
- reference the date of FDA’s request for additional information;
- include firm name and 510(k) number; and
- identify each question, as it appears in the additional information request followed by a complete response.

Appendix A – 510(k) Cover Letter

Purpose

Traditionally, 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 in order to ensure the most 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. 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;
- at least one contact person, by name, title, and phone number;
- your preference for continued confidentiality (21 CFR 807.95);
- your recommended 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,” at www.fda.gov/cdrh/devadvice/313.html. An unclassified device is a legally marketed pre-amendment 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, pre-IDE, 510(k), PMA, request for designation (RFD), related to your device.

Your identification of the device classification regulation, classification, panel, or product code for your device may differ from the final classification, panel or product code that appears on FDA’s SE or Not Substantially Equivalent (NSE) determination letter.

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)⁷
- new indication for use
- new device design
- a submission for a reprocessed, single use, disposable device⁸
- 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** at www.fda.gov/cdrh/ode/510kmod.html.

If your device is comprised of finished device components that are assembled into a convenience kit, we recommend that you identify your device as a convenience kit and list all the device components of the kit. See also **Convenience Kits Interim Regulatory Guidance** at www.fda.gov/cdrh/ode/convkit.html. In 510(k) submissions for convenience kits, we recommend that you provide the kit certification statement, which can be obtained at www.fda.gov/cdrh/ode/odecl874.html.

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** www.fda.gov/cdrh/mdufma/guidance/1215.html for information about bundling.

⁷ If a new 510(k) is required for a modification (807.81(a)(3)) and the modification does not affect the intended use or alter the fundamental scientific technology of the device, then a Special 510(k) may be appropriate. Otherwise, we believe a Traditional or Abbreviated 510(k) is appropriate. For more information see **The New 510(k) Paradigm Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications** at www.fda.gov/cdrh/ode/parad510.html.

⁸ See Section 510(o) of the Act and the guidance titled, **Medical Device User Fee and Modernization Act of 2002, Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed Single-Use Medical Devices** www.fda.gov/cdrh/ode/guidance/1216.html.

Contains Nonbinding Recommendations

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 the table below.

Table 3 –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.

Appendix B – Performance Characteristics for In Vitro Diagnostic Devices

If your device is an in vitro diagnostic device, refer to the OIVD website at <http://www.fda.gov/cdrh/oivd/regulatory-guidance.html> for the availability of device-specific guidance documents that describe the recommended information on performance characteristics.

General information on the content of 510(k) submissions for in vitro diagnostic devices may also be found in Appendix 3 of the **Guidance for Third Parties and FDA Staff – Third Party Review of Premarket Notifications** at www.fda.gov/cdrh/ode/guidance/2237a3a.html.

OIVD also has a pilot program that allows submitters to electronically complete and submit 510(k) submissions. Please refer to <http://www.fda.gov/cdrh/oivd/turbo510kcesub1.html> for more information.

Appendix C – Comparison with STED Format

The table below provides a comparison between the document format sections described in the draft STED document as outlined in the FDA guidance document “A Pilot Program to Evaluate a Proposed Globally Harmonized Alternative for Premarket Procedures” and the document format section described in this document. We believe this information will be useful to you if you are preparing a STED 510(k) submission.

510(k) Section described in this document	Corresponding STED 510(k) section
Section 1: MDUFMA Cover Sheet	same
Section 2: CDRH Premarket Review Submission Cover Sheet	same
Section 3: 510(k) Cover Letter	Executive summary
Section 4: Indications for Use Statement	same
Section 5: 510(k) Summary or 510(k) Statement	same
Section 6: Truthful and Accuracy Statement	same
Section 7: Class III Summary and Certification	same
Section 8: Financial Certification or Disclosure Statement	same
Section 9: Declarations of Conformity and Summary Reports	Not applicable
Section 10: Executive Summary	Executive summary
Section 11: Device Description	Device Description
Section 12: Substantial Equivalence Discussion	Essential principles and evidence of conformity
Section 13: Proposed Labeling	same
Section 14: Sterilization/Shelf Life	Essential principles and evidence of conformity
Section 15: Biocompatibility	Essential principles and evidence of conformity
Section 16: Software	Essential principles and evidence of conformity
Section 17: Electromagnetic Compatibility/Electrical Safety	Essential principles and evidence of conformity

Contains Nonbinding Recommendations

Section 18: Performance Testing – Bench	Essential principles and evidence of conformity
Section 19: Performance Testing – Animal	Essential principles and evidence of conformity
Section 20: Performance Testing – Clinical	Essential principles and evidence of conformity
Not applicable	Risk Analysis
Not applicable	Manufacturing