FDA 510(k) Process

OVERVIEW

Delphi Consulting Group (DCG)

www.delphiconsulting.com

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Successful commercialization of medical devices in the United States requires careful attention to regulatory issues. The FDA Guidance, rules, and regulations [Law] is always in a state of change. It is important to be aware of the latest updates and modifications of these Guidance, rules and regulations. In January, 2014, the FDA published a number of documents that review, explain and provide guidance for 510(k)s going forward. This booklet is a compilation of these documents. However, before starting any new 510(k) Submission check for new or modifications to the Guidance, rules, and regulations.

The sections of this booklet that were taken from Government publications do not constitute endorsement by the US Federal Government or any of its agencies.

The application of any of these documents or any other Delphi Consulting Group recommended practice is solely within the discretion and judgment of the user of the document.

Additional copies, printed or electronic of this booklet may be obtained by contacting Delphi Consulting Group. The following is contact information:

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Introduction

Premarket Notification (510(k)) submissions for medical devices are reviewed by FDA’s Center for Devices and Radiological Health (CDRH), specifically, the Office of Device Evaluation (ODE) and the Office of In Vitro Diagnostics and Radiological Health (OIR). The Divisions in these offices are organized according to medical device specialties. 510(k) submissions are reviewed by ODE and OIR staff, including biomedical engineers, physicians, microbiologists, chemists, and other scientific professionals.

Log-in and Acknowledgement Procedure

A 510(k) applicant must submit two copies of its 510(k) to CDRH Document Control Center (DCC) to this address:

Food and Drug Administration  
Center for Devices and Radiological Health  
Document Control Center - WO66-G609  
10903 New Hampshire Avenue  
Silver Spring, Maryland 20993-0002

One of the two copies must be an eCopy.

When the DCC receives the 510(k) submission, it assigns the submission a unique control number. This number is commonly referred to as the "510(k) number," or "K number." The 510(k) number begins with the letter "K" followed by 6 digits. The first two digits designate the calendar year the application was received; the last four digits represent the submission number for the year, starting with 0001 and increasing with each new submission.

For example: the first 510(k) submission for the year 2013 would be K130001.

The DCC then conducts two verification checks:

1. The proper user fee payment was received for the submission.  
   Note: the correct user fee amount to be paid is based on when the 510(k) is received by FDA and not the date it was sent by the applicant.

2. A valid eCopy of the 510(k) submission was provided.

If the proper user fee has not been paid or a valid eCopy has not been provided, then the DCC will email or fax a Hold Letter to the 510(k) applicant, usually within 7 days of receipt of the 510(k). The applicant then has 180 calendar days from the date of the Hold Letter to fully resolve the issues with the user fee or eCopy submission. If the issues are not resolved within 180 days, then the 510(k) is deleted and the submitter will need to submit a new, complete 510(k) to pursue FDA marketing clearance.

If the proper user fee has been paid AND the valid eCopy has been provided, the DCC will mail and email/fax an Acknowledgment Letter to the contact person identified in the 510(k) submission. The Acknowledgement Letter identifies:

- the date of receipt (this is the date that FDA received the 510(k) submission, the proper user fee payment, and valid eCopy); and
- the 510(k) number assigned to the submission.

Note: The Acknowledgment Letter is NOT a marketing clearance letter. The 510(k) number identified in the Acknowledgement Letter must be referenced in all further correspondence with FDA regarding the 510(k).

Acceptance Review

After the Acknowledgement Letter is sent, the DCC routes the 510(k) to the appropriate ODE or OIR Division, based on the device classification that is listed in the 510(k) submission.
Upon receipt in the Division, the 510(k) is assigned to the appropriate Branch, and then assigned to a Lead Reviewer. The Lead Reviewer conducts the **Acceptance Review** using the appropriate **Acceptance Checklist** in FDA’s Guidance titled *Refuse to Accept Policy for 510(k)s*. In the **Acceptance Review**, the Lead Reviewer determines whether a 510(k) submission meets the minimum threshold of acceptability and should be accepted for substantive review. This should be done within 15 calendar days of receipt of the 510(k).

Once complete, the submitter will receive an electronic notification of the **Acceptance Review** result, which will:

- identify the name and contact information of the FDA Lead Reviewer assigned to the 510(k); and
- indicate the status of the 510(k).

The status will be one of the following:

- the 510(k) was accepted for substantive review; or
- the 510(k) was not accepted for review (i.e., considered refused to accept or RTA); or
- the 510(k) is under substantive review because FDA did not complete the acceptance review within 15 calendar days.

A 510(k) not accepted for review is placed on **RTA Hold**. The applicant has 180 calendar days to fully address the deficiencies cited in the **RTA Hold**. If this is not done, the 510(k) is deleted. Once deleted, the 510(k) submitter will need to submit a new, complete 510(k) to pursue FDA marketing clearance for that device.

Upon completion of **Acceptance Review**, a 510(k) not placed on **RTA Hold** proceeds to the **Substantive Review**.

**Substantive Review (including Substantive Interaction and Interactive Review)**

During **Substantive Review**, the Lead Reviewer conducts a comprehensive review of the 510(k) submission and communicates with the submitter through a **Substantive Interaction** usually within 60 calendar days of receipt of the 510(k) submission.

The **Substantive Interaction** communication can be:

- an email stating that FDA will continue to resolve any outstanding deficiencies via **Interactive Review**; or
- an **Additional Information** (AI) request which places the file on hold.

**Interactive Review**

If the Lead Reviewer chooses to continue with an **Interactive Review**, this means the Lead Reviewer has determined that any outstanding deficiencies may be adequately addressed within the timeframe set by the Medical Device User Fee Amendment of 2012 (MDUFA III) performance goal for a 510(k) (90 calendar days). The Lead Reviewer communicates with the applicant during the **Interactive Review** using tools such as:

- Emails
- Fax
- Telephone Calls
- Submission Issue Meetings

During the **Interactive Review**, the Lead Reviewer may request additional information from the applicant, who may either send the information to the Lead Reviewer directly or to the DCC. **Note**: During **Interactive Review**, any information submitted to the DCC must include a valid eCopy.

**Additional Information (AI) Request**
If the Lead Reviewer sends an **AI Request**, the submission is placed on hold. The applicant has up to 180 calendar days to respond to the **AI Request**. **Note:** **No extensions beyond 180 days will be granted.**

The applicant must submit the response, with a valid eCopy, to the DCC. The response should:

- include the applicant’s name;
- list the 510(k) number;
- identify the submission as Additional Information (AI) to the 510(k);
- list the date of FDA’s request for additional information; and
- provide the information in an organized manner.

For more information on Substantive Review and Interactive Review, please see: [FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Goals](#).

**510(k) Decision Letter**

The FDA goal to make a MDUFA Decision for a 510(k) is 90 FDA Days. FDA Days are calculated as the number of calendar days from the date the 510(k) was received, excluding the days the submission was on hold for an AI request. A MDUFA Decision is a finding of substantial equivalence (SE) or not substantial equivalence (NSE).

When a MDUFA Decision is made, FDA will issue the decision letter to the applicant by mail (and by fax if a fax number was provided).

A 510(k) with an SE decision is considered “cleared.” FDA adds the cleared 510(k) to the [510(k) database](#), which is updated weekly.

If FDA does not reach a MDUFA decision within 100 FDA days, FDA will provide a **Missed MDUFA Decision Communication** to the applicant in the form of written feedback. This feedback identifies the major outstanding review topic areas or other reasons that prevent FDA from reaching a decision and provide the applicant with an estimated date of completion.

**Timeline of Communication with 510(k) Applicants**

During 510(k) review, FDA follows the MDUFA III performance goals for review and communication of a 510(k) submission. The following diagram provides a simplified summary of event and interaction milestones during the course of a 510(k) submission.
Timeline of Communication during 510(k) Review

Day 1: FDA receives 510(k) application.

By 7 Days

FDA sends Acknowledgement Letter. OR FDA sends Hold Letter if unresolved issues with User Fee and/or eCopy.

By Day 15

FDA conducts Acceptance Review. FDA informs applicant if 510(k) is accepted for Substantive Review or placed on RTA Hold.

By Day 60

FDA conducts Substantive Review (usually by Day 60).

FDA communicates Substantive Interaction with applicant that indicates FDA will proceed with Interactive Review or ask for Additional Information.

By Day 90

FDA sends final MDUFA Decision on 510(k) (usually by Day 90).

By Day 100

If MDUFA Decision is not reached by Day 100, FDA provides Missed MDUFA Decision Communication that identifies outstanding review issues.

Important Notes:
- Days are Calendar Days.
- The timeline is based on the performance goals set by Medical Device User Fee Amendments of 2012 (MDUFA III).
- This timeline has been simplified

For more information, please see: MDUFA III Performance Goals and Procedures.
References

- MDUFA Performance Goals and Procedures Commitment Letter (PDF - 156KB)
- Guidance for Industry and Food and Drug Administration Staff - eCopy Program for Medical Device Submissions (PDF - 501KB)
- Guidance for Industry and Food and Drug Administration Staff - Refuse to Accept Policy for 510(k)s (PDF - 1.4MB)
- Guidance for Industry and Food and Drug Administration Staff - FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Goals
- Types of Communication During the Review of Medical Device Submissions - Draft Guidance for Industry and Food and Drug Administration Staff
How To Find A Predicate Device

Introduction

A Premarket Notification [510(k)] is a premarketing submission made to FDA to demonstrate that the device to be marketed is safe and effective by proving substantial equivalence (SE) to a legally marketed device (predicate device) that is not subject to Premarket Approval (PMA). Submitters must compare their 510(k) device to a similar legally marketed U.S. device(s). A device recently cleared under 510(k) is usually used as a predicate device. However, any legally U.S. marketed device may be used as a predicate. This includes: a device that has been cleared through the 510(k) process; a device that was legally marketed prior to May 28, 1976 (preamendments device); a device that was originally on the U.S. market as a Class III device (Premarket Approval) and later down classified to Class II or I; or a 510(k) exempt device.

The legally marketed device(s) to which equivalence is drawn is known as the predicate device(s). A claim of substantial equivalence does not mean the device(s) must be identical. Substantial equivalence is established with respect to: intended use, design, energy used or delivered, materials, performance, safety, effectiveness, labeling, biocompatibility, standards, and other applicable characteristics. You can claim SE to either a preamendments or postamendment device that is or was legally marketed. Legally marketed means that the predicate cannot be one that is or was in violation of the Federal Food Drug & Cosmetic (FD&C) Act. An applicant may claim SE to a device that is no longer being marketed in the U.S.

Postamendments Device

Postamendment devices are medical devices marketed after May 28, 1976. Because medical technology has changed greatly since 1976, almost all 510(k) submissions claim substantial equivalence to a postamendment device that has been recently cleared under the 510(k) process.

Preamendments Device

The term "preamendments device" refers to devices legally marketed in the U.S. by a firm before May 28, 1976 and which have not been:

- significantly changed or modified since then; and
- for which a regulation requiring a premarket approval (PMA) application has not been published by FDA.

Devices meeting the above criteria are referred to as "grandfathered" devices and do not require a 510(k). The device must have the same intended use as that marketed before May 28, 1976. If the device is labeled for a new intended use, then the device is considered a new device and a 510(k) must be submitted to FDA for marketing clearance.

In order for a firm to claim that it has a preamendments device, it must demonstrate that its device was labeled, promoted, and distributed in interstate commerce for a specific intended use and that intended use has not changed.
If you use a preamendment device as your predicate device, you may need to provide documentation that it meets the preamendment status criteria. Preamendment devices will not have a 510(k) number since preamendment devices were grandfathered from 510(k) review. Since medical science has advanced greatly since 1976, it is recommended that you use a recently cleared device under 510(k) as your predicate device.

**How to Search for a Predicate Device**

The FDA 510(k) database contains all devices cleared under the 510(k) process. The FDA databases on the web are updated on or around the 5th of every month. The classification of the device and product code is essential in searching for predicate devices. Classification of your device can be found by performing a search on the Product Code Classification Database. The classification database will provide the classification panel (e.g., orthopedic devices), common name, product code, and CFR regulation, if your device type has received final classification by FDA (e.g., 21 CFR 888.1100, arthroscope). Additional information on classification and product codes can be found in "Classify Your Medical Device."

Information which can be useful to find a predicate device includes:

- names of similar devices - traded name under which the device is marketed;
- manufacturer(s) of the similar device(s);
- marketing status, i.e., preamendments or postamendments device;
- 510(k) numbers for postamendments devices;
- classification information, i.e., product codes, classifying regulations, etc., for your device.

Once you have found the classification of your device, you should begin your search in the 510(k) database.

You may have to try several ways of searching the database. It is usually best to complete only one box in the online search form per search. The search engine searches for an exact match of text. Therefore, one descriptive word in the "device name" box is recommended.

FDA assigns a unique 3-letter product code or "procode" for each generic category of device, whether it has been formally classified by FDA or not. Only FDA generated product codes will work with the 510(k) and other FDA databases. 510(k)s for similar device types are usually linked in the 510(k) database by the same product code. While this is not always true, it is the case with enough regularity that searching for predicate devices by product code is usually the most effective (leaving the other boxes blank). Alternatively, if you know the manufacturer name(s) for a similar device, you may search the database by manufacturer name. Hyphens or spaces in names can make a difference, so try different combinations of the manufacturer's name if the search results in "no records found." Please note that the 510(k) database contains original application information only. That is, the 510(k) database maintains the name of the original applicant and the original trade name provided in the 510(k). It is not updated to reflect the current owner or distributor of the product nor any changes in trade name.

510(k) Search Engine
510(k) Submission Methods

Overview

An applicant may choose from three types of Premarket Notification 510(k) submissions for marketing clearance: Traditional, Special, and Abbreviated.

Traditional method is the original complete submission as provided in 21 CFR 807. In 1998, FDA developed "The New 510(k) Paradigm" to streamline the evaluation of Premarket Notifications. The New 510(k) Paradigm provides two optional approaches to the Traditional 510(k) method for obtaining 510(k) marketing clearance under certain instances: Special 510(k) and Abbreviated 510(k). The Special 510(k): Device Modification utilizes certain aspects of the Quality System Regulation and the Abbreviated 510(k) relies on the use of guidance documents, special controls, and recognized standards to facilitate 510(k) review.

The use of either alternative does not affect FDA's ability to obtain any information authorized by the statute or regulations. Additional guidance on the new 510(k) paradigm can be found in Frequently Asked Questions on the New 510(k) Paradigm.
The 510(k) Review Fee is the same for Traditional, Special, and Abbreviated 510(k)s.

Form FDA-3674, ClinicalTrials.gov Data Bank

Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) included a provision that all 510(k) submissions are required to be accompanied with certification that all applicable clinical trial information has been submitted to the ClinicalTrials.gov data bank.
The agency has issued for comment a draft guidance, titled: "Certifications To Accompany Drug, Biological Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007". According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the not need the certification form. Anyone wishing to comment on the draft guidance is requested to submit electronic or written comments within 60 days.

If your 510(k) includes data from a clinical trial, you must determine if your study is applicable for entry into the clinical trial registry data bank at ClinicalTrials.gov. Based on this determination, check box 9.B. or 9.C., and complete the applicable sections of the form. An applicable device clinical trial is a prospective clinical study of health outcomes comparing an intervention with a device against a control in human subjects (other than a small clinical trial to determine the feasibility of a device, or a clinical trial to test prototype devices where the primary outcome measure relates to feasibility and not to health outcomes). See Title VIII - Clinical Trial Databases. Currently, FDA is reviewing the legislation and developing guidance on which clinical trials meet the definition of "applicable" trials and are required to report to ClinicalTrials.gov. Until FDA issues this guidance, 510(k) submitters are responsible for determining whether their studies meet the definition of an applicable trial and, therefore, are subject to reporting requirements.

Information on how to register your clinical trial(s) in the ClinicalTrials.gov data bank is available on the National Library of Medicine (NLM) Protocol Registration System (PRS) website.

**Traditional 510(k)**

The Traditional 510(k) may be used for any original 510(k) or for a modification to a previously cleared device under 510(k). The traditional method is the original complete submission as provided in 21 CFR 807. The Traditional 510(k) method may be used under any circumstances. See How to Prepare a Traditional 510(k) for additional information on Traditional 510(k)s.

**Special 510(k)**

The Special 510(k) is used for device modifications and utilizes the design controls aspect of the Quality System (QS) regulation (21 CFR 820.30). Special 510(k)s may be submitted for a modification to a device that has been cleared under the 510(k) process. If a new 510(k) is needed for the modification and if the modification does not affect the intended use of the device or alter the fundamental scientific technology of the device, then summary information that results from the design control process can serve as the basis for clearing the application.

Under the Quality System regulation, all Class II and III devices and certain Class I devices are required to be designed in conformance to section 820.30 Design Controls. The Special 510(k) allows the manufacturer to declare conformance to design controls without providing the data. Manufacturers of Class I devices requiring 510(k) may elect to comply with the design control provision of the QS regulation and submit a Special 510(k).

Under the Special 510(k) option, 510(k) holders who intend to modify their own legally marketed device will conduct the risk analysis and the necessary verification and validation activities to demonstrate that the design outputs of the modified device meet the design input requirements. Once the 510(k) holder has ensured the satisfactory completion of this process, a "Special 510(k): Device Modification" may be submitted. While the basic content requirements of the 510(k) (21 CFR 807.87) will remain the same, this type of submission should also reference the cleared 510(k) number and contain a "Declaration of Conformity" with design control requirements.

In order to provide an incentive for 510(k) holders to choose this option for obtaining FDA clearance for device modifications, the Office of Device Evaluation (ODE) and Office of In Vitro
Diagnostic Device Evaluation and Safety (OIVD) intend to process Special 510(k)s within 30 days of receipt by FDA’s Document Mail Center (DMC).

Some device modifications may be implemented without submission of a new 510(k). The submitter should review is a new 510(k) required for a modification to the device? to assure that a new 510(k) is required for the modification to the device.

See How to Prepare a Special 510(k) for additional information on Special 510(k)s.

**Abbreviated 510(k)**

Device manufacturers may choose to submit an Abbreviated 510(k) when:

- a guidance documents exists,
- a special control has been established, or
- FDA has recognized a relevant consensus standard.

An Abbreviated 510(k) submission must include the required elements identified in 21 CFR 807.87 [Traditional 510(k)]. However, in an Abbreviated 510(k) submission, firms elect to provide summary reports on the use of guidance documents and/or special controls or declarations of conformity to FDA recognized standards to expedite the review of a submission.

See How to Prepare an Abbreviated 510(k) for additional information on Abbreviated 510(k)s.

**References**

21 CFR 807

A New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications

Frequently Asked Questions on the New 510(k) Paradigm

Deciding When to Submit a 510(k) for a Change to an Existing Device
How to Prepare a Traditional 510(k)

Introduction

Find a Predicate Device

Locate Guidance Documents

Content and Format of a Traditional 510(k)

Alternate 510(k) Format – STED Pilot Program

Where to Submit a 510(k)

Introduction

There are three types of Premarket Notification 510(k)s that may be submitted to FDA: Traditional, Special, and Abbreviated. The Special and Abbreviated 510(k) methods were developed under "The New 510(k) Paradigm" to help streamline the 510(k) review process. The Special 510(k) and Abbreviated 510(k) methods can only be used if certain criteria are met. The Traditional 510(k) method can be used under any circumstances.

There is no Premarket Notification 510(k) "form" to complete. A 510(k) is a document containing information required under 21 CFR 807 Subpart E. All 510(k)s are based on the concept of substantial equivalence (SE) to a legally marketed (predicate) device. All 510(k)s provide a comparison between the device to be marketed and the predicate device or devices.

Predicate Device

You should identify a predicate device or devices to which you will compare your device. We strongly recommend that the 510(k) number of the predicate device be identified. Use a device(s) that is as similar to your device as possible. (You may claim equivalence to more than one predicate, if necessary). A predicate device will usually be a recently cleared device. Please refer to How to Find a Predicate Device for additional guidance.

Locate Guidance Documents

FDA has published many device specific guidance documents as well as general guidance for biocompatibility, software contained in medical device, electromagnetic compatibility, etc. These documents are available through the Guidance Documents page.

Device specific guidance documents describe in detail the information which should be included in the 510(k) to enable FDA to determine SE for that particular type of device. These guidance documents should be consulted at the device planning stage. In addition, the design control requirements (21 CFR 820.30) of the Quality System regulation should be reviewed as well since much of the information and data developed to meet design controls is the same information included in the 510(k).

Content and Format of a Traditional 510(k)

A Traditional 510(k) submission must include the required elements identified in 21 CFR 807.87 (Information required in a premarket notification submission). CDRH recommends that you follow the Traditional 510(k) format provided in the guidance document, "Format for Traditional and Abbreviated 510(k)s." The guidance document will help you create a complete 510(k). Pertinent elements of a Traditional 510(k) include:

- Medical Device User Fee Cover Sheet (Form FDA 3601). See 510(k) Review Fees for additional information on review fees.
- CDRH Premarket Review Submission Cover Sheet [PDF]
The agency has issued for comment a draft guidance, titled: "Certifications To Accompany Drug, Biological Product, and Device Applications/Submissions: Compliance with Section 402(i) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007". According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form. Anyone wishing to comment on the draft guidance is requested to submit electronic or written comments within 60 days. See Form FDA-3674, ClinicalTrials.gov Data Bank for additional information.

- Cover letter as described in the format guidance
- Table of Contents (recommended)
- Indications for Use. See Determination of Intended Use for 510(k) Devices (Update to K98-1) for additional information on indications for use.
- 510(k) Summary (21 CFR 807.92) or 510(k) Statement (21 CFR 807.93)
- Standards Data Report for 510(K)s - FDA 3654. Submit this form if your 510(k) references a national or international standard.
- Truthful and Accuracy Statement (21 CFR 807.87(k))
- Class III Certification and Summary for Class III devices (21 CFR 807.94)
- Items required under 21 CFR 807.87 (Information required in a Premarket Notification submission), including
  - the name of device, include the trade or proprietary name, if any, and the common or usual name or classification name of the device. Provide what you believe to be the classification of the device, appropriate panel (e.g. cardiovascular, dental, etc.), and product code, if known.
  - description of the device, include device specifications and reference applicable guidance documents, special controls, or standards; photographs or engineering drawings should be supplied, if applicable
  - comparison with a predicate device(s), indicating similarities and/or differences accompanied by data, as appropriate; this information may include an identification of materials, design considerations, energy expected to be used or delivered by the device, and a description of the operational principles of the device.
  - intended use of the device,
  - proposed label, labeling, and advertisements for the device and directions for use.
- Information on sterilization, biocompatibility, expiration date, etc., if applicable.

For additional information on 510(k) contents, see Content of a 510(k) and 510(k) Format Tips.

**Alternate 510(k) Format – STED Pilot Program**

As an alternative to the submission format described in "Format for Traditional and Abbreviated 510(k) s," 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). See the FDA guidance, A Pilot Program to Evaluate a Proposed Globally Harmonized Alternative for Premarket Procedures 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 “Format for Traditional and Abbreviated 510(k) s,” may help you prepare your STED submission. Appendix C shows the correlation between the sections recommended in this guidance and the STED format.

- STED Pilot Program

**Where to Submit a 510(k)**

A 510(k) should be put in a temporary, inexpensive binder. DO NOT permanently bind the application. FDA will take the submission out of whatever binding in which it was submitted, 3-hole punch the left margin, and put the 510(k) in a 3-ring "jacket" for review. Paper size should be 8.5 inches by 11 inches.
You must submit **two copies** of your 510(k) to the address below. One of your two copies must be submitted in **electronic format**. FDA does NOT return the 510(k) submission after review. You should retain a copy of your 510(k) for your records. Submissions should be sent to:

**Food and Drug Administration**
*Center for Devices and Radiological Health*
Document Mail Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

*If your device is reviewed by CBER, send your 510(k) to directly to CBER to avoid delays. The list of devices reviewed by CBER is available on [Devices Regulated by CBER](https://www.fda.gov/medical-devices).*

We recommend that you send your 510(k) to FDA by a method that will provide a signed receipt of delivery, e.g., registered mail with a return receipt or a commercial delivery service. You should receive an acknowledgment letter from FDA, including the assigned 510(k) number, within two weeks of delivery. If after 2 weeks you have not received the 510(k) acknowledgement letter, contact the Division of Small Manufacturers, International and Consumer Assistance (DSMICA) for assistance. **510(k) Submission Process** describes the review process after the submission is received by FDA.

Traditional, Special, and Abbreviated 510(k)s require the same 510(k) review fee. **Do NOT send the fee with the application.** Information on how to submit the review fee can be found at [510(k) Review Fees](https://www.fda.gov/medical-devices).

### 510(k) Format Tips

We recommend the following format tips for a 510(k) submission:

1. Because there can be several parties involved in the submission of a 510(k) e.g., manufacturer, consultant, correspondent, etc., FDA suggests that you plainly state who the 510(k) owner is for each submission. The 510(k) owner is the individual or firm that has legal authority to the 510(k). **Only one firm may own a 510(k).** Identify the person(s) FDA should contact during the review process. Notify the Document Mail Center in writing, if the contact information changes at any time during the 510(k) review. You should reference the 510(k) number in any correspondence regarding your 510(k). We cannot change the 510(k) after a final determination is made on the 510(k).
2. Please include a Table of Contents which clearly identifies each section title and corresponding page number in the 510(k). The table of contents should include a list of attachments and appendices, as appropriate. Begin each section on a new page and separate each section with tabs.
3. Provide a title and/or number for any diagrams, drawings, figures, illustrations, photos, charts, or tables that are used. Make sure citations in the text refer to them correctly.
4. Use numbered or lettered tabulation sheets to separate the sections in the 510(k). This will make it easy for the reviewer to refer or search back and forth during the review.
5. Number the pages of the 510(k), verify the page numbering when finished. Make sure the page numbering or pagination corresponds to the page numbers or section numbers in the Table of Contents. Numbering pages by section is acceptable. For example: Section 1 pages could be numbered 1-1, 1-2, 1-3. Section 2 pages will then be numbered 2-1, 2-2, 2-3, etc. Likewise, letters can be used: Section A, B, C,
etc. Numbering by section is a little faster than sequential numbering, helps reduce errors, and is easier to correct if a page is added or removed.

6. Use 8.5" x 11" (21.5 cm x 27.8 cm) 3-hole punched, white paper only; do not use colored paper.

7. Leave a 1.5" (3.8cm) margin between the left edge of the paper and the left margin of the text. This leaves enough space for FDA to bind the 510(k) in the review jacket.

8. Place the 510(k) in an inexpensive jacket or non-permanent binding. All 510(k)s are removed from the shipping binder and placed in standard jackets. The shipping binder will be discarded.

9. Sign and date the cover letter.

Maintain all FDA correspondence with your copy of the 510(k) submission, including FDA's request for additional information, if any, any additional information sent to FDA in response to FDA's request for data, and a copy of your letter of substantial equivalence (510(k) clearance letter). You may need this information to show an FDA investigator during an inspection of your establishment.

### Content of a 510(k)

- **Introduction**
- **General Information**
- **Table of Contents (recommended)**
- **510(k) Acceptance Checklist (recommended)**
- **Statement of Indications for Use**
- **510(k) Statement or Summary**
- **Truthful and Accuracy Statement**
- **Proposed Labeling**
- **Specifications**
- **Substantial Equivalence Comparison**
- **Performance**
- **Additional requirements, as appropriate**

### Introduction

The 510(k) regulation is found in 21 CFR 807 Subpart E and includes information required in a 510(k). The 510(k) is not a form. The information should be provided in an organized, tabulated document. The 510(k) should provide sufficient detail for FDA to be able to determine that the device is substantially equivalent (SE) to another similar legally marketed device(s). Some sections will contain only one page; others may contain 50 or more pages. The average 510(k) is about 35 pages; others may run to 100 or more depending on the complexity of the device. For any device, the 510(k) is formatted essentially the same way and contains the same basic information (required elements).

This section is a general guide for all 510(k)'s. Please review the appropriate information for the type of 510(k) you will submit: Traditional, Special, or Abbreviated 510(k)s.

The 510(k) submitter should prepare and submit a complete application in order to obtain marketing clearance. To facilitate FDA review of the data, analysis, and conclusions in the application, the manufacturer should check for the:

- logical presentation of the data;
- scientific soundness of the test and data analysis;
- relevance of the test program to the device and the intended use; and
- completeness of the summary report of the tests or studies.

A description of the tests and the results obtained are essential. Reasonable and sufficient details of all test procedures and results should be submitted to FDA. The following suggestions will help assure that your application is complete.
Understand the FDA decision-making process. The decision process is discussed in "Guidance on the CDRH Premarket Notification Review Program (K86-3)"

Obtain and use the right guidance. FDA provides many device specific guidance documents for the preparation of marketing applications.

Use the CDRH Premarket Review Submission Cover Sheet and the Screening Checklist for all Premarket Notification 510(k) Submissions to prepare your submission. The cover sheet is a "fill-in-the-blank" format which satisfies many of the 510(k) requirements. The checklist will assure that all required elements are provided.

Important Note: In order to address the required elements, you will need the following information to assure that your 510(k) is complete. If you do not have this information, you should obtain it prior to proceeding.

1. Classification of your device
2. Predicate device(s)
3. Final draft labeling
4. Specifications including engineering drawings, photos, etc.
5. Performance data such as bench, animal, or clinical testing (if applicable)
6. Sterilization information (if applicable)
7. Guidance document(s) specific to your device type, if it exists

It is not a requirement that you organize your 510(k) into the following labeled sections, you may make modifications in order to meet the specific needs of your device. The following is a brief discussion of the required elements.

General Information

Medical Device User Fee Cover Sheet (Form FDA 3601)

The first page of a 510(k) should be a printed copy of the Medical Device User Fee Cover Sheet (Form FDA 3601). The Medical Device User Fee Cover Sheet and instructions are available online.

CDRH Premarket Review Submission Cover Sheet

A cover letter and/or the CDRH Premarket Review Submission Cover Sheet should follow the User Fee Cover Sheet. If you choose NOT to use the CDRH Premarket Review Submission Cover Sheet, the cover letter should include all the elements contained in the coversheet. The use of the 510(k) coversheet may help expedite the processing of your 510(k).

Cover Letter

You may use a cover letter to provide the information covered on the CDRH Premarket Review Submission Cover Sheet or provide this information elsewhere in the 510(k). The information provided should include the following.

1. Submission date (month/day/year) and labeled as "510(k) Submission." The submission must be clearly identified as a 510(k) submission for accurate processing by the Document Mail Room staff. Identify the submission as a Traditional, Special, or Abbreviated 510(k).
2. Submitter name, address, phone & fax numbers. If the person who intends to market the device uses a consultant or another party to prepare the 510(k), the 510(k) submission should specify who the 510(k) owner is and who the preparer is. The 510(k) owner is the individual or firm that has legal authority to the device. Identify the person FDA should contact during the review process. A delay may occur if the FDA is not sure who to
3. Your establishment registration number. Although not a required part of the 510(k), firms (domestic and foreign) will need to register within 30 days of marketing the device or prior to importing the device. It is sufficient to state that you will register following FDA clearance. See Establishment Registration for additional information.

4. The common name of the device. The common name is the name of the device as it is commonly known e.g., syringe, hip implant.

5. The trade name (proprietary name) including the model number(s) of the device. The trade name is the name under which the device will be marketed.

6. The classification name for the device and the class in which the device has been placed. The classification name is the generic category the device has been placed. Reference the classification regulation and the three letter product code. If you determine that the device has not been classified, include a statement of that fact. For example, "To my knowledge FDA has not classified this device. The product code of xxx has been assigned to this device in the Classification Database." If known, include the appropriate classification panel such as anesthesiology, orthopedic, etc.

Accessories to classified devices take on the same classification as the "parent" device. An accessory such as software that accepts input from multiple devices usually takes on the classification of the "parent" device with the highest risk, i.e., class.

7. The reason for the 510(k). For example, it is a new device (i.e., you have never marketed the device in the U.S.) or a modification to an existing device. If the 510(k) is for a modification, describe in detail the reason for the modification. Provide the 510(k) number (if applicable) for the original device, and 510(k) number(s) for previous related submissions regardless of outcome. If you previously submitted a 510(k) that was withdrawn or found Not Substantially Equivalent, include those 510(k) numbers. If your modified device is based on a preamendments device, i.e., one marketed before May 28, 1976 which did not require a 510(k), state that no 510(k) number exists for the original device. State if the device is an accessory or finished component. A finished component is sold to the end user while an unfinished component cannot be used by the end user until further manufacturing steps occur, such as sterilization. Finished components are packaged and labeled for use and are for general sale while unfinished components are usually only sold to other device manufacturers for inclusion in another medical device.

8. Identification of the legally marketed device (predicate) to which you claim SE. If known, provide the 510(k) number for the predicate device, trade name and product code.

9. If applicable, include the registration number, name and address of each facility used to manufacture the finished device including contract sterilizers and packagers. The manufacturing process at each facility must be essentially the same and produce the same device as described in your 510(k) submission or state the differences.

10. Compliance with any special controls [section 513(b) of the Food, Drug, and Cosmetic (FD&C) Act], FDA mandatory performance standards (section 514 of the FD&C Act), standards under the Radiation Control for Health and Safety Act (RCHSA), or voluntary consensus standards. If no special controls, mandatory performance standards or radiation device standards exist for your product state, "No applicable mandatory performance standards or special controls exist for this device." If you are claiming substantial equivalence to one or more devices that meet a given standard, then your device should meet the same standard.

- Any required special controls for a device are provided in the regulation for the device under 21 CFR 800-892.

- Only one FDA mandatory performance standard exists for medical devices under section 514. Manufacturers of electrode lead wires and patient cables must conform to the standard set forth in 21 CFR 898.

- If your device emits ionizing, non-ionizing, sonic, or light radiation, performance standards may exist for the radiation emitting device under RCHSA.
Table of Contents
Prepare a draft Table of Contents and update it as you prepare your 510(k). The table of contents should list each required item with page numbers, including a list of attachments and appendices. It is usually easier to number pages by section, e.g. 1.1, 1.2 (or use dashes, 1-1), 2.2, 2.3, etc. If additional pages need to be inserted into a section, it is easier to renumber that section than having to renumber all the pages that follow the inserted material if you used sequential numbering.

510(k) Acceptance Checklist
The 510(k) Acceptance Checklist is used to determine whether the 510(k) meets a minimum threshold of acceptability and should be accepted for substantive review. It is helpful to attach the 510(k) Acceptance Checklist following the Table of Contents. It should include page numbers where each of the elements in the 510(k) can be found. This will allow the FDA to easily find each required element. Second, by writing page numbers on the checklist, the 510(k) submitter may better ensure that the 510(k) is complete. The 510(k) may not be accepted for review if any of the required elements are not provided. Acceptance Checklist for 510(k)s

Statement of Indications for Use
Prepare a Statement of Indications for Use as a separate page. We recommend that you use the Indications for Use form. The statement should include specific indications, clinical settings, define the target population, anatomical sites, etc. This statement must be consistent with your labeling, advertising and instructions for use. Once the review is complete, FDA will include the Indications for Use Statement with the Substantial Equivalence (SE) letter to the applicant and make it available to the public on the Internet.

510(k) Summary or Statement
Prepare either a 510(k) Summary or a 510(k) Statement. The Summary or Statement is required for all 510(k)s whether the device is Class I, II, or III. A 510(k) Summary is a summary of information upon which you based your claim of substantial equivalence. The 510(k) Statement is a certification that the 510(k) owner will provide safety and effectiveness information supporting the FDA finding of substantial equivalence to ANY person within 30 days of a written request.
A 510(k) Summary or 510(k) Statement must be included in your 510(k) submission in order for FDA to begin its scientific review of the 510(k) submission. The choice between the 510(k) Summary and 510(k) Statement should be made before the 510(k) is submitted. You may elect to change your choice between the summary or statement BEFORE the substantial equivalence determination is reached. However, after this determination is made, you cannot change your choice of a 510(k) Summary or 510(k) Statement.
Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

510(k) Summary
If you choose to meet the conditions for a 510(k) summary (21 CFR 807.92), it must be in sufficient detail to provide an understanding of the basis for a determination of substantial
equivalence. As required by section 807.92(a), FDA will accept summaries or amended summaries until FDA issues a determination regarding substantial equivalence.

The 510(k) summary must contain the information described below. Please make a copy of the following to use as a checklist and check off each item to make sure your summary is adequate and complete.

<table>
<thead>
<tr>
<th></th>
<th>The summary should be in a separate section of the submission. It should begin on a new page and end on a page not shared with any other part of the 510(k) submission. It is clearly identified as &quot;510(k) Summary&quot; as required by section 807.92(c).</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>The summary contains on the first page, preferably on your letterhead paper, the 510(k) owner's name, address, phone and fax numbers, name of contact person, and date the summary was prepared [807.92(a)(1)].</td>
</tr>
<tr>
<td></td>
<td>The summary includes the name of the device, including the trade or proprietary name, if applicable, the common or usual name, and the classification name, if known [807.92(a)(2)].</td>
</tr>
</tbody>
</table>
|   | Example:  
|   | Trade name - DRAG@N LATEX EXAMINATION GLOVES  
|   | Common name - exam gloves  
|   | Classification name - patient examination glove (21 CFR 880.6250, Product Code FMC) |
|   | The summary identifies the legally marketed device to which your firm is claiming equivalence [807.92(a)(3)]. |
|   | The summary includes a description of the device such as might be found in the labeling or promotional material for the device, including an explanation of how the device functions, the scientific concepts that form the basis for the device, and the significant physical and performance characteristics of the device, such as device design, material used, and physical properties; [807.92(a)(4)]. |
|   | The summary provides the intended use of the device including a general description of the diseases or conditions that the device will diagnose, treat, prevent, cure, or mitigate, including a description, where appropriate, of the patient population for which the device is intended. If the indication statements are different from those of the predicate device, the 510(k) summary shall contain an explanation as to why the differences are not critical to the intended therapeutic, diagnostic, prosthetic, or surgical use of the device, and why the differences do not affect the safety and effectiveness of the device when used as labeled [807.92(a)(5)]. |
|   | The 510(k) summary contains a summary of the technological characteristics of your device compared to the predicate device. If the device has the same technological characteristics (i.e., design, material, chemical composition, energy source) as the predicate device, a summary of the technological characteristics of the new device in comparison to those of the predicate device should be included. If your device has different technological characteristics from the predicate device, provide a summary of how the technological characteristics of your device compare to the predicate device. [807.92(a)(6)] |
|   | If the determination of substantial equivalence is also based on an assessment of non-clinical performance data, the summary includes a brief discussion of the nonclinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalence and how their results support a determination of substantial equivalence [807.92(b)(1)]. |
|   | If the determination of substantial equivalence is also based on an assessment of clinical performance data, the summary includes a brief discussion of clinical tests |
submitted, referenced, or relied on in the premarket notification submission for a
determination of substantial equivalence and how their results support a
determination of substantial equivalence. This discussion shall include, where
applicable, a description of the subjects upon whom the device was tested, a
discussion of the safety or effectiveness data obtained from the testing, with
specific reference to adverse effects and complications, and any other information
from the clinical testing relevant to a determination of substantial equivalence
[807.92(b)(2)]. Please note: Clinical data is not needed for most devices cleared by
the 510(k) process.

The summary includes the conclusions drawn from the nonclinical and clinical tests
(discussed above) that demonstrate that the device is as safe, as effective, and
performs as well as or better than the predicate device . 807.92(b)(3)

The summary includes any other information reasonably deemed necessary by
FDA. Such requests will be made directly to the applicant by FDA or the
requirements will be published in guidance documents. Additional information
requested by FDA during review of the 510(k) may include additional safety and
effectiveness information which may necessitate an update of your summary if
requested by FDA. 807.92(d)

Please make sure you have included all of the information listed above and verify
that the following criteria have been met.

" The summary includes only information that is also covered in the body of
the 510(k).
" The summary does not contain any puffery or unsubstantiated labeling
claims.
" The summary does not contain any raw data, i.e., contains only summary
data.
" The summary does not contain any trade secret or confidential
commercial information.
" The summary does not contain any patient identification information.

FDA will place the summary on the Internet 30 days following the substantial equivalent decision.

510(k) Statement

If you choose to submit a 510(k) Statement, the regulation requires the specific statement as
provided in 21 CFR 807.93. The statement should be clearly identified as "510(k) Statement" and
must be signed by the certifier, not a consultant to the 510(k) submitter.

For a new submission, leave the space for the 510(k) number blank. You will receive your 510(k)
number in your 510(k) acknowledgment letter. The 510(k) document control number begins with
the letter K followed by 6 digits.

If you elect to prepare a signed 510(k) Statement, anyone may request a copy of the 510(k)[with
patient identifiers, trade secret and confidential information deleted] from the applicant of record.
These written requests must be filled within 30 days. 510(k) owner's may not charge requesters
for compiling and disseminating this data. Noncompliance with the 510(k) statement will be
deemed a prohibited act under section 301(p) of the FD&C Act and FDA may choose to use its
enforcement powers to obtain compliance.
Truthful and Accurate Statement

All 510(k) submitters 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. The statement may be included in the 510(k) Cover Letter or may be on a separate page identified in the table of contents. If the CDRH Premarket Review Submission Cover Sheet is used, the statement should attached as a separate page. Truthful and Accurate Statement

Proposed Labeling

Prepare a labeling section to include copies of all proposed labels, labeling, package inserts, service manuals, instructions for use, advertising and/or promotional materials. The directions for use should include a specific intended use statement and any warnings, contraindications, or limitations. The material does not have to be glossy, finished labeling or promotional material, draft is sufficient. However, the labeling you submit should be final draft. Copies of labeling for the predicate device(s) is recommended. Labeling guidance is provided below:

Labeling
Blue Book Memorandum #G91-1: Device Labeling Guidance

Specifications

This section should include both a narrative description of the device and a physical or technical description.

The narrative description of the "new" device should include the indications for use, principles of operation, power source, composition and other information necessary to understand the device. If the 510(k) is for an accessory or component sold to an end-user, describe a typical device with which the accessory or component will be used. List all variations of the "new" device which you intend to market.

The physical description of the "new" device may include labeled diagrams, photographs or pictures, engineering drawings, schematics, etc. These may include all internal and external, assembled and unassembled, interchangeable, etc., parts of the device and should address their name and function. In addition, the description should include the length, width, height, diameter, weight, etc., of the device and identify any parts which are intended for single use.

Device specific guidance documents, if available, usually provide extensive information on the level of detail which should be included in the specifications list.

Substantial Equivalence Comparison

The device specifications are the basis for the comparison of features between the new and the legally marketed device to which compared (predicate device). Substantial equivalence is to be established with respect, but not limited to, intended use, design, energy used/delivered, materials, performance, safety, effectiveness, labeling and other applicable characteristics, such as sterility. You should include a comparison table AND discussion of the similarities and differences of your device compared to one or more predicate devices to which you are claiming equivalency.

The equivalence information should be provided in a clear and comprehensive format. A chart, table or other side-by-side comparison is a systematic way to compare the devices. Side-by-side comparisons, wherever possible, are desirable. For some devices a simple table of comparison which lists characteristics will be sufficient to establish equivalence. Often, information is necessary to resolve questions of safety or effectiveness, especially where differences in technologies exists between the predicate and the new device. It must be shown that technological differences do not adversely affect safety and effectiveness. Supporting information can be obtained from bench testing, animal studies or clinical studies (information gathered from medical literature) or clinical trials.

State whether the legally marketed device for comparison is a preamendments device, or a device which has been granted marketing clearance by FDA following the submission of a 510(k).
Provide the 510(k) document control number (i.e., K followed by 6 digits) for the device to which you are claiming equivalency, if known.

The comparison table should identify relevant similarities and differences in areas such as:

- intended use;
- indications for use;
- target population;
- anatomical sites;
- where used (hospital, home, ambulance, etc);
- energy used and/or delivered;
- human factors;
- design;
- performance;
- standards met

- materials
- biocompatibility
- compatibility with the environment and other devices
- sterility
- electrical safety
- mechanical safety
- chemical safety
- thermal safety
- radiation safety

The discussion of the similarities and differences should elaborate on the similarities identified in the table of comparisons and justify the differences with supporting rationale and/or data. It is recommended to submit labeling for the device to which you are claiming equivalency.

**Performance**

Most 510(k)s will include some type of performance data. The extent of performance data will depend on the complexity of the device and its intended use and indications. Performance data should be provided to help demonstrate SE of your device to one or more legally marketed devices (predicate device). The data may include test results from engineering, bench, design verification, human factors, and animal testing, and clinical studies and clinical trials. Tests should be conducted on all sizes and models of the device in a manner as similar as possible to how the device will be used. The results of testing and methodology / parameters used for testing should be included. Information on the extent of performance testing as well as the extent of specification documentation can be found in the product specific guidance documents, if one has been prepared for your device by FDA. Search the Guidance Document page to determine if guidance documents are available for your type of device.

**Additional requirements**

Additional information may be required under certain conditions; such as if your device contains software or a color additive, is labeled sterile, or emits electronic radiation. See "Special Considerations" under Device Advice Premarket Notification 510(k) for additional guidance.
How To Prepare A Special 510(k)

- **Overview**
- **Background**
- **Criteria for a Special 510(k)**
- **Conformance Assessment**
- **Content/Format of a Special 510(k)**
- **Where to Submit a 510(k)**
- **Frequently Asked Questions**
- **References**

**Overview**

There are three types of Premarket Notification 510(k)s that may be submitted to FDA: Traditional, Special, and Abbreviated. The Special and Abbreviated 510(k) methods were developed under the "New 510(k) Paradigm" to help streamline the 510(k) review process.

Product modifications that could significantly affect safety and effectiveness are subject to 510(k) submission requirements under 21 CFR 807 as well as design control requirements under the Quality System (QS) regulation. Under the QS regulation, all Class II and III devices and certain Class I devices are required to be designed in conformance to 21 CFR 820.30 Design Controls.

The "Special 510(k): Device Modification" utilizes the design control requirement of the Quality System Regulation (21 CFR 820) and may be submitted for a modification to a device that has been cleared under the 510(k) process. The Special 510(k) allows the manufacturer to declare conformance to design controls without providing the data. While the basic content requirements of the 510(k) (21 CFR 807.87) remain the same, this type of submission should also reference the cleared 510(k) number and contain a "Declaration of Conformity" with design control requirements. Manufacturers of Class I devices requiring 510(k) may elect to comply with the design control provision of the QS regulation and submit Special 510(k)s.

Manufacturers of preamendments devices may also submit Special 510(k)s. When the legally marketed (unmodified) device is a preamendments device, the submitter should clearly state that the device is a preamendments device, is legally marketed, and has not been the subject of Premarket Notification 510(k) clearance. (Refer to "Documentation Required for Preamendments Status" for the procedures for demonstrating preamendments status. Submitters should maintain this information in their files.)

**Background**

Effective June 1, 1997, manufacturers of Class II, Class III, and certain Class I devices are required to follow design control procedures when originally developing devices and for subsequent modifications. In accordance with the Quality System Regulation, manufacturers must have a systematic set of requirements and activities for the management of design and development, including documentation of design inputs, risk analysis, design output, test procedures, verification and validation procedures, and documentation of formal design reviews. In this process, the manufacturer must ensure that design input requirements are appropriate so the device will meet its intended use and the needs of the user population. The manufacturer must also establish and maintain procedures for defining and documenting design output in terms that allow an adequate evaluation of conformance to design input requirements. Thus, manufacturers may need to refine their device design requirements as verification and validation results are obtained. The design specifications that result from this process are the design outputs, which form the basis for the device master record (DMR). [See 21 CFR 820.3(i)] The DMR is subject to inspection by FDA personnel.
Since design control requirements are now in effect and require the manufacturer to conduct verification and validation studies of a type that traditionally may have been included in 510(k) submissions in the past, FDA believes that it may be appropriate to forgo a detailed review of the underlying data normally required in the 510(k) program. For this reason, FDA is allowing an alternative to the traditional method of demonstrating substantial equivalence for certain device modifications. For these well-defined modifications, FDA believes that the rigorous design control procedure requirements produce highly reliable results that can form, in addition to the other 510(k) content requirements, a basis for the substantial equivalence determination. Under the Quality Systems Regulation, data that is generated as a result of the design control procedures must be maintained by the manufacturer and be available for FDA inspection.

In order to provide an incentive for manufacturers to choose this option for obtaining FDA clearance for device modifications, the Office of Device Evaluation (ODE) and the Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD) intend to process Special 510(k)s within 30 days of receipt by the Document Mail Center (DMC). The Special 510(k) option allows FDA to review modifications that do not affect the device's intended use or alter the device's fundamental scientific technology within this shorter time frame. FDA does not believe that modifications that affect the intended use or alter the fundamental scientific technology of the device are appropriate for review under this type of submission, but rather should continue to be subject to the traditional 510(k) procedures [i.e., "Traditional 510(k)"] or may be subject to an Abbreviated 510(k)].

Criteria for a Special 510(k)

Under the New 510(k) Paradigm, a manufacturer should refer to 21 CFR 807.81(a)(3) and the FDA guidance document entitled, *Deciding When to Submit a 510(k) for a Change to an Existing Device,* to decide if a device modification may be implemented without submission of a new 510(k). If a new 510(k) is needed for the modification and if the modification does not affect the intended use of the device or alter the fundamental scientific technology of the device, then summary information that results from the design control process can serve as the basis for clearing the application along with the required elements of a 510(k) found in 21 CFR 807.87.

To optimize the chance that a Special 510(k) will be accepted and promptly cleared, 510(k) submitters should evaluate each modification against the considerations described below to insure that the particular change does not: (1) affect the intended use or (2) alter the fundamental scientific technology of the device.

**Intended Use**

Modifications to the indications for use of the device or any labeling change that affects the intended use of the device will not be accepted as a Special 510(k). Therefore, FDA recommends that submitters of Special 510(k)s highlight, or otherwise prominently identify, all changes in the proposed labeling that may result from modifications to their legally marketed device. In addition, it should be clearly stated in the Special 510(k) that the intended use of the modified device, as described in its labeling, has not changed as a result of the modification(s). Please note that a labeling change from prescription use to over the counter use, or vice versa, is considered a change in intended use and, therefore, is not eligible for the Special 510(k) method.

**Fundamental Scientific Technology**

Special 510(k)s also will not be accepted for modifications that have the potential to alter the fundamental scientific technology of the device. These types of changes generally include modifications to the device's operating principle(s) or mechanism of action, such as automation of a manual device or incorporation of a sensing or feedback circuit. Specific examples that illustrate these types of changes that alter the fundamental scientific technology and thus should not be submitted as Special 510(k)s include:

1. A change in a surgical instrument that uses a sharpened metal blade to one that cuts with a laser;
2. A change in an in vitro diagnostic (IVD) device that uses immunoassay technology to one that uses nucleic acid hybridization or amplification technology;
3. Incorporation of a sensing mechanism in a device to allow the device to function "on demand" rather than continuously.

In addition, FDA is concerned with changes in materials in certain devices. While FDA acknowledges that many such changes can be processed as Special 510(k)s, there are certain types of changes in materials that may raise safety or effectiveness issues that continue to warrant a more intensive evaluation. This includes a change in material(s) in an implant, or other device that contacts body tissues or fluids, to a material type that has not been used in other legally marketed devices within the same classification regulation for the same intended use (i.e., "legally marketed predicate device"). For example, a change in a material in a finger joint prosthesis from a known metal alloy to a ceramic that has not been used in a legally marketed predicate, should not be submitted as a Special 510(k). Similarly, a change in a device's active ingredient or agent to one that has not been used in other legally marketed predicate devices should not be submitted for review as a Special 510(k). For example, if a manufacturer of a contact lens disinfecting solution wanted to change from hydrogen peroxide to an antiseptic that had not been previously used in a legally marketed predicate, such a change would not be appropriate for review as a Special 510(k). Both of the above types of modifications involve major changes in the principle component of the device and thus would be considered a change to the fundamental scientific technology of the device and should be submitted for review as either Abbreviated or Traditional 510(k)s.

A change, however, in formulation in a material or a change to a type of material that has been used in other legally marketed devices within the same classification regulation for the same intended use could be reviewed as a Special 510(k). This should be true for both non-contacting devices as well as implants and devices that contact body tissues or fluids. Thus, a manufacturer of a hip implant could change from one alloy to one that has been used in another legally marketed predicate through the submission of a Special 510(k). Similarly, a contact lens manufacturer could submit a Special 510(k) for a change in their polymer to another material that has been used in a legally marketed predicate. Finally, changes in an inactive or secondary ingredient/agent should be appropriate for review as Special 510(k)s as this should not be considered a major change to the fundamental scientific technology of the device. For example, a manufacturer of a urologic catheter could submit a Special 510(k) to add an antimicrobial coating to the device if the coating has been used on another legally marketed predicate of the same material.

Device modifications that should be appropriate for review as Special 510(k)s also include those changes identified below:

- Energy type
- Environmental specifications
- Performance specifications
- Ergonomics of the patient-user interface
- Dimensional specifications
- Software or firmware
- Packaging or expiration dating
- Sterilization

It should be noted that in cases where FDA has issued guidance, established special controls, or recognized standards that address issues such as device testing or performance, manufacturers should consider this in their implementation of design control requirements. For example, if a manufacturer is modifying a contact lens, then the manufacturer's design control inputs should include the special controls that FDA has established for this device. Further, if a manufacturer modifies an in vitro diagnostic, the manufacturer's design inputs should include any recognized clinical standards such as those developed by NCCLS (formerly known as National Committee of Clinical Laboratory Standards) or a reasonable alternative. Thus, submitters of Special 510(k)s...
need to be aware of any relevant guidance documents, special controls, or recognized standards that apply to their device and that should be addressed by their design control processes.

Clinical Considerations

FDA recognizes that clinical evaluation may be involved in the validation of the design of a modified device. Please note that all clinical investigations must conform to the applicable regulations, including 21 CFR Parts 812, 50 and 56. Collection of clinical data to support a Special 510(k) may require submission of an Investigational Device Exemptions (IDE) application to FDA. The fact that a significant risk device investigation was conducted to support any of the activities listed above, however, does not necessarily preclude the submission of a Special 510(k).

Manufacturers who intend to conduct clinical investigations of a modified device as part of design validation are encouraged to contact the appropriate ODE review division before preparing a Special 510(k). When a clinical investigation is necessary to answer safety and effectiveness questions relating to a particular modification, FDA believes that the modification is likely to have gone beyond that which is suitable for review as a Special 510(k). In contrast, where design validation involves clinical evaluation intended to ensure that the modified device meets user requirements as opposed to patient safety and effectiveness or to demonstrate continued conformance with a special control or recognized standard, FDA believes that the Special 510(k) may be the appropriate submission.

If FDA determines that a Special is not eligible for review as submitted, the FDA reviewer will notify the firm of this decision and offer the option of having the document converted to a Traditional 510(k) or withdrawing it for future submission. If the 510(k) is converted, the original receipt date remains as the start of the review period. Manufacturers should be aware that, in most cases, additional information will be necessary for converted documents.

Conformance Assessment

In the Special 510(k) process, a manufacturer who is intending to modify his/her own legally marketed device will conduct the risk analysis and the necessary verification and validation activities to demonstrate that the design outputs of the modified device meet the design input requirements. Once the manufacturer has ensured the satisfactory completion of this process, a "Special 510(k): Device Modification" may be submitted.

Under the Quality System Regulation, manufacturers are responsible for performing internal audits to assess their conformance with design controls. A manufacturer could, however, use a third party to provide a supporting assessment of the conformance. (This use of a third party should not be confused with FDA’s Third Party Review Program where recognized third parties review entire 510(k) submissions.) In this case, the third party will perform a conformance assessment for the device manufacturer and provide the manufacturer with a statement to this effect. The marketing application should then include a declaration of conformity signed by the manufacturer, while the statement from the third party should be maintained in the Device Master Record (DMR). As always, responsibility for conformance with design control requirements rests with the manufacturer. Under the Quality Systems Regulation, data that is generated as a result of the design control procedures must be maintained by the manufacturer and be available for FDA inspection.

Content/Format of a Special 510(k)

A Special 510(k) should be well organized and formatted in sections, with page numbering, and include the required elements:

- Medical Device User Fee Cover Sheet (Form FDA 3601). See 510(k) Review Fees for additional information on review fees.
- CDRH Premarket Review Submission Cover Sheet (FDA Form 3514) [PDF]
- Certification of Compliance with ClinicalTrials.gov Data Bank, FDA-3674*
*Beginning December 26, 2007, all 510(k) submissions must include a completed copy of form FDA-3674. See Form FDA-3674, ClinicalTrials.gov Data Bank for additional information.

- Cover Letter, clearly identifying the application as a "Special 510(k)." Include 510(k) holder name, address, and facility registration number, if available.
- Table of Contents (recommended)
- 510(k) Screening Checklist (recommended)
- Statement of Indications for Use
- Standards Data Report for 510(K)s - FDA 3654 [PDF] Submit this form if your 510(k) references a national or international standard.
- Truthful and Accuracy Statement
- Class III Certification and Summary (if applicable)
- The name of the legally marketed (unmodified) device and the 510(k) number under which it was cleared. Include the trade or proprietary name, if any, and the common or usual name or classification name of the device. Provide the classification of the device, appropriate panel (e.g. cardiovascular, dental, etc.), and product code, if known.

In cases where the referenced 510(k) was submitted under a different name than that of the submitter of the Special 510(k), FDA recommends that a statement to this effect be included in the Special 510(k) and that the submitter maintain adequate information demonstrating his legal right to distribute the device.

When the legally marketed (unmodified) device is a preamendments device, the submitter should clearly state that the device is a preamendments device, is legally marketed, and has not been the subject of premarket notification clearance. (Refer to "Documentation Required for Preamendments Status" for the procedures for demonstrating preamendments status.) Submitters should maintain this information in their files.

- Items required under §807.87 (Information required in a Premarket Notification submission), including
  - description of the modified device; where applicable, photographs or engineering drawings should be supplied,
  - comparison to the cleared device indicating similarities and/or differences accompanied by data, as appropriate; this information may include an identification of materials, design considerations, energy expected to be used or delivered by the device, and a description of the operational principles of the device.
  - intended use of the device,
  - proposed label, labeling, and advertisements for the device and directions for use. It is recommended that submitters of Special 510(k)s highlight, or otherwise prominently identify, all changes in the proposed labeling that may result from modifications to their legally marketed device. In addition, it should be clearly stated in the Special 510(k) that the intended use of the modified device, as described in its labeling, has not changed as a result of the modification(s). Please note that a labeling change from prescription use to over the counter use, or vice versa, is considered a change in intended use and, therefore, is not eligible for the Special 510(k) method.
- A concise summary of the design control activities. FDA may consider the information generated from these activities to be "appropriate supporting data" within the meaning of §807.87(g). This summary should include the following:
  - An identification of the Risk Analysis method(s) used to assess the impact of the modification on the device and its components as well as the results of the analysis;
  - Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and the acceptance criteria applied; and
A declaration of conformity with design controls. (See Attachment 2 of 510(k) Paradigm) Please note that if a recent Quality System inspection has resulted in the issuance of a violative inspection report, the manufacturer should be prepared to describe those corrective actions taken, if needed, that form the basis for the declaration of conformity.

The declaration of conformity should include:

4. A statement that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met; and

5. A statement that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review. If a recent Quality System inspection has resulted in the issuance of a violative inspection report, the manufacturer should be prepared to describe those corrective actions taken, if needed, that form the basis for the declaration of conformity.

The above two statements should be signed by the designated individual(s) responsible for those particular activities.

- Information on sterilization, biocompatibility, expiration date, etc., if applicable.

Tabs may be used to separate each section but in any case each section should begin on a new page. The order in which required elements are presented is less important than completeness. In other words, it is not strictly required that labeling be presented as part of the device specifications, or in a separate section. For additional information, see Content of a 510(k) and Format of a 510(k).

An example of a Special 510(k) can be found in Frequently Asked Questions on the New 510(K) Paradigm.

Where to Submit a 510(k)

A 510(k) should be put in a temporary, inexpensive binder. DO NOT permanently bind the application. FDA will take the submission out of whatever binding in which it was submitted, 3-hole punch the left margin, and put the 510(k) in a 3-ring "jacket" for review. Paper size should be 8.5 inches by 11 inches.

You must submit two copies of your 510(k) to the address below. One of your two copies must be submitted in electronic format. FDA does NOT return the 510(k) submission after review. You should retain a copy of your 510(k) for your records. Submissions should be sent to:

U.S. Food and Drug Administration*
Center for Devices and Radiological Health
Document Mail Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

* If your device is reviewed by CBER, send your 510(k) to directly to CBER to avoid delays. The list of devices reviewed by CBER is available on Devices Regulated by CBER.

We recommend that you send your 510(k) to FDA by a method that will provide a signed receipt of delivery, e.g., registered mail with a return receipt or a commercial delivery service. You should receive an acknowledgment letter from FDA, including the assigned 510(k) number, within two weeks of delivery. If after 2 weeks you have not received the 510(k) acknowledgement letter, contact the Division of Small Manufacturers, International and Consumer Assistance (DSMICA) for assistance. 510(k) Submission Process describes the review process after the submission is received by FDA.

Traditional, Special, and Abbreviated 510(k)s require the same 510(k) review fee. Do NOT send the fee with the application. Information on how to submit the review fee can be found at 510(k) Review Fees.
**Frequently Asked Questions**

1. Can FDA rely on a declaration of conformity for a substantial equivalence determination in a Special 510(k) if the manufacturer states that they will conform rather than they are in conformance?

   A manufacturer may not state that it will conform to design controls at some future date, but rather conformance must have already been determined at the time the application is submitted.

2. What advantage, if any, is there for a firm to use a third party to assess conformance with design controls? If a firm does use a third party for the assessment, should this information be included in the 510(k) submission?

   Many device manufacturers employ third parties in assessing conformance with design controls as a matter of routine practice. Although it is ultimately the submitter's responsibility for assuring conformance when electing to submit a declaration of conformity in a premarket submission, third party involvement may provide the manufacturer with added confidence when submitting a declaration and provide the FDA with additional assurance of conformance. Involvement by an independent, technically competent third party can only benefit the overall process.

   FDA recommends that 510(k) submitters follow Attachment 2 in The New 510(k) Paradigm when preparing declarations of conformity to design controls. If a manufacturer uses a third party to perform a conformance assessment of design control requirements, the third party information should be maintained in the firm's device master record (DMR).

3. What happens if the FDA determines that a Special 510(k) can not be reviewed as such? Is the submission rejected? Is the review clock reset?

   If the FDA determines that a Special 510(k) is not eligible for review as submitted, the reviewer will notify the firm of this decision and offer the option of having the document converted to a Traditional 510(k) or withdrawing it for future submission. If the 510(k) is converted, the original receipt date remains as the start of the review period. Manufacturers should be aware that, in most cases, additional information will be necessary for converted documents.

4. For Special 510(k)s, Attachment 2 of The New 510(k) Paradigm guidance document states that the manufacturer's declaration of conformity should include a statement that "all verification and validation activities were performed. . . . " Since some of these activities are not usually performed until just prior to marketing, what activities should be performed prior to submission of the Special 510(k)?

   This statement in the declaration of conformity is intended to capture the manufacturer's compliance with those verification and validation activities that are related to the design modification(s). Therefore, prior to submission of a Special 510(k), FDA would expect that the verification and validation activities, as identified by the risk analysis to ensure that the modified device is as safe and effective as the predicate device, would be completed and would demonstrate that the predetermined acceptance criteria had been met. In accordance with the Quality System Regulation, however, all process validation must be completed and appropriately documented before commercialization of the device.

5. If a firm obtains clearance for a Special 510(k), will the firm necessarily be inspected to verify conformance with design controls?

   No. The Office of Compliance is developing an audit program to help determine if firms that submitted Special 510(k)s were in fact in conformance with design control requirements. This does not mean, however, that all firms that submit Special 510(k)s will be audited. Under the pilot program, a limited number of cleared submissions will be identified for
verification of conformance with design controls by inspection. If a firm is to be inspected, FDA will notify the firm ahead of time and follow established GMP inspection procedures. However, please note that routine GMP inspections for Class II and III devices are required by the statute. Thus, submitters of 510(k)s for such devices are subject to inspection whether the premarket notification is submitted for review as an Abbreviated, a Special, or a Traditional 510(k).

6. For Special 510(k)s that were submitted but later determined to be ineligible for review as such, what were the most common reasons for this determination?

The most frequently observed problem with Special 510(k)s has been related to the design control information that was submitted in support of the device modification. Several submissions did not include a complete declaration of conformity to design controls. Other submissions included a statement indicating that the firm would comply with the design control requirements rather than a statement that the firm is in conformance. In a few 510(k)s, it was determined that the firm did not perform a complete risk analysis for the device modification.

Finally, one of the other problems observed with the Special 510(k)s that have been submitted for review has been related to the device modification that is the subject of the submission. As discussed in the Guidance, changes to the intended use and fundamental scientific technology should be submitted as Abbreviated or Traditional 510(k)s rather than as Special 510(k)s. Several of the Special 510(k)s that were submitted included a change to either the intended use or to the fundamental scientific technology.

References

- [A New 510(k) Paradigm](#) - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications
- [Frequently Asked Questions on the New 510(k) Paradigm](#)
- [Do It By Design - An Introduction to Human Factors in Medical Devices](#)
- [Design Control for Manufacturers](#)
How to Prepare an Abbreviated 510(k)

Overview

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Overview

There are three types of Premarket Notification 510(k)s that may be submitted to FDA: Traditional, Special, and Abbreviated. The Special and Abbreviated 510(k) methods were developed under the "New 510(k) Paradigm" to help streamline the 510(k) review process.

The Abbreviated 510(k) relies on the use of guidance documents, special controls, and recognized standards. An Abbreviated 510(k) submission must include the required elements identified in 21 CFR 807.87 (Information required in a premarket notification submission). Under certain conditions, you may not need to submit test data in an abbreviated 510(k).

Device manufacturers may choose to submit an Abbreviated 510(k) when:

1. a guidance documents exists,
2. a special control has been established, or
3. FDA has recognized a relevant consensus standard.

In an Abbreviated 510(k) submission, manufacturers elect to provide summary reports on the use of guidance documents and/or special controls, or declarations of conformity to recognized standards, to expedite the review of a submission.

Guidance Documents

FDA has developed numerous device-specific guidance documents with public participation. The main focus of these guidance documents is the identification of the information recognized as appropriate for marketing authorization for the device. You can search the guidance document page for an appropriate guidance document.

An Abbreviated 510(k) that relies on a guidance document should include a summary report that describes adherence to the relevant guidance document and how the guidance document was used during device development and testing. The summary report should include information regarding the manufacturer's efforts to conform with the guidance document and should outline any deviations.

Special Controls

Special controls are a means of providing reasonable assurance of the safety and effectiveness a Class II device. Special controls are defined in section 513(a)(1)(B) of the federal Food, Drug & Cosmetic Act (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.

The device classification regulations list special controls for the device, if any. The device classification regulations are available in the product classification database.

An Abbreviated 510(k) that relies on a special control(s) should include a summary report that describes adherence to the special control and how the special control(s) was used during device
development and testing, including how the special control(s) was used to address a specific risk or issue. The summary report should include information regarding the manufacturer's efforts to conform with the special control(s) and should outline any deviations.

**FDA Recognized Standards**

In addition to device-specific guidance documents and special controls, CDRH is committed to recognizing individual consensus standards. FDA is authorized to recognize all or part of national and international standards through publication of a notice in the Federal Register. Recognized standards could be cited in guidance documents or individual policy statements, or established as special controls that address specific risks associated with a type of device.

An Abbreviated 510(k) that relies on a recognized standard must include a Declaration of Conformity to the Recognized Standard. Under certain conditions, conformance test data are not required to be submitted in the 510(k).

FDA has recognized approximately 400 standards to which 510(k) submitters can declare conformity. A current list of FDA recognized standards and guidance on the recognition and use of consensus standards can be found on CDRH's Standards website.

If FDA determines that an Abbreviated 510(k) is not eligible for review as submitted, the reviewer will notify the firm of this decision and offer the option of having the document converted to a Traditional 510(k) or withdrawing it for future submission. Please note if you withdraw your 510(k) and resubmit, a new user will apply. If the 510(k) is converted, the original receipt date remains as the start of the review period. Manufacturers should be aware that, in most cases, additional information will be necessary for converted documents.

**Conformance Assessment**

In the Abbreviated 510(k) process, a manufacturer must assess conformance of the device with a recognized standard. Once the manufacturer has ensured the satisfactory completion of this process, the Abbreviated 510(k) may be submitted.

The manufacturer has the option of using a third party to assess conformance with the recognized standard. (This use of a third party should NOT be confused with the Agency's Third Party Review Program where recognized third parties review entire 510(k) submissions.) Under this scenario, the third party will perform a conformance assessment to the standard for the device manufacturer and should provide the manufacturer with a statement to this effect.

The Abbreviated 510(k) should include a declaration of conformity signed by the manufacturer, while the statement from the third party should be maintained in the Device Master Record (DMR) pursuant to the Quality System Regulation (21 CFR 820). Responsibility for conformance with the recognized standard, however, rests with the manufacturer, not the third party.

**Declaration of Conformity to a Recognized Standard**

In preparing a declaration of conformity to recognized standards, manufacturers should refer to the guidance document, "Recognition and Use of Consensus Standards." Declarations of conformity to recognized standards should include the following:

- An identification of the applicable recognized consensus standards that were met;
- A specification, for each consensus standard, that all requirements were met, except for inapplicable requirements or deviations noted below;
- An identification, for each consensus standard, of any way(s) in which the standard may have been adapted for submission to the device under review, e.g., an identification of an alternative series of tests that were performed;
- An identification, for each consensus standard, of any requirements that were not applicable to the device;
- A specification of any deviations from each applicable standard that were applied (e.g., deviations from international standards which are necessary to meet U.S. infrastructure conventions such as the National Electrical Code (ANSI/NFPA 70);
- A specification of the differences that may exist, if any, between the tested device and the device to be marketed and a justification of the test results in these areas of difference; and
The name and address of any test laboratory or certification body involved in determining the conformance of the device with the applicable consensus standards and a reference to any accreditations of those organizations.

**Content/Format of an Abbreviated 510(k)**

CDRH recommends that you follow the Abbreviated 510(k) format provided in the guidance document, "Format for Traditional and Abbreviated 510(k)s." The guidance document will help you create a complete 510(k). Pertinent elements of an Abbreviated 510(k) are reiterated below and are described in the guidance.

- Medical Device User Fee Cover Sheet ([Form FDA 3601](https://www.fda.gov/downloads/AboutFDA/AbouttheFDACenterforFoodandMedicalPolicies/CDRHUserFee/ucm388277.pdf)). See [510(k) Review Fees](https://www.fda.gov/medicaldevices/aboutfda/centersoffices/cber/510kreviewfees/) for additional information on review fees.
- CDRH Premarket Review Submission Cover Sheet [PDF](https://www.fda.gov/downloads/medicaldevices/aboutfda/centersoffices/cber/510kreviewfees/ucm101875.pdf)
- Certification of Compliance with ClinicalTrials.gov Data Bank, [FDA-3674](https://www.fda.gov/downloads/medicaldevices/aboutfda/centersoffices/cber/510kreviewfees/ucm101875.pdf)*
  - *Beginning December 26, 2007, all 510(k) submissions must include a completed copy of form FDA-3674. See [Form FDA-3674, ClinicalTrials.gov Data Bank](https://www.fda.gov/downloads/medicaldevices/aboutfda/centersoffices/cber/510kreviewfees/ucm101875.pdf) for additional information.
- Cover letter as described in the format guidance
- Table of Contents (recommended)
- **Indications for Use.** See [Determination of Intended Use for 510(k) Devices (Update to K98-1)](https://www.fda.gov/downloads/medicaldevices/aboutfda/centersoffices/cber/510kreviewfees/ucm934469.pdf) for additional information on indications for use.
- Standards Data Report for 510(K)s - [FDA 3654](https://www.fda.gov/downloads/medicaldevices/aboutfda/centersoffices/cber/510kreviewfees/ucm101875.pdf) [PDF] Submit this form if your 510(k) references a national or international standard.
  - the name of device, include the trade or proprietary name, if any, and the common or usual name or classification name of the device. Provide what you believe to be the classification of the device, appropriate panel (e.g. cardiovascular, dental, etc.), and product code, if known.
  - description of the device, include device specifications and reference applicable guidance documents, special controls, or standards; photographs or engineering drawings should be supplied, if applicable
  - comparison with a predicate device(s), indicating similarities and/or differences accompanied by data, as appropriate; this information may include an identification of materials, design considerations, energy expected to be used or delivered by the device, and a description of the operational principles of the device.
  - indications for use of the device,
  - proposed label, labeling, and advertisements for the device and directions for use.
- For a submission that relies on a **guidance document** and/or **special control(s)**, provide a summary report that describes how the guidance and/or special control(s) were used to address the risks associated with the particular device type. (If a manufacturer elects to use an alternative approach to address a particular risk, sufficient detail should be provided to justify that approach.);
- For a submission that relies on a **recognized standard**, provide a [Declaration of Conformity to a Recognized Standard](https://www.fda.gov/downloads/medicaldevices/aboutfda/centersoffices/cber/510kreviewfees/ucm101875.pdf);
- Provide data/information to address issues not covered by guidance documents, special controls, and/or recognized standards; and
- Provide information on sterilization, biocompatibility, expiration date, etc., if applicable.
For additional information on 510(k) submissions, see Content of a 510(k) and 510(k) Format Tips.

Alternate 510(k) Format – STED Pilot Program

As an alternative to the submission format described in “Format for Traditional and Abbreviated 510(k)s,” 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). See the FDA guidance, A Pilot Program to Evaluate a Proposed Globally Harmonized Alternative for Premarket Procedures 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 “Format for Traditional and Abbreviated 510(k)s,” may help you prepare your STED submission. Appendix C shows the correlation between the sections recommended in this guidance and the STED format.

- STED Pilot Program

Where to Submit a 510(k)

You should place your 510(k) in a temporary, inexpensive binder. DO NOT permanently bind the submission. FDA will take the submission out of whatever binding in which it was submitted, 3-hole punch the left margin, and put the 510(k) in a 3-ring "jacket" for review. Paper size should be 8.5 inches by 11 inches.

You must submit two copies of your 510(k) to the address below. One of your two copies must be submitted in electronic format. FDA does NOT return the 510(k) submission after review. You should retain a copy of your 510(k) for your records. Submissions should be sent to:

Food and Drug Administration *
Center for Devices and Radiological Health
Document Mail Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

* If your device is reviewed by CBER, send your 510(k) to directly to CBER to avoid delays. The list of devices reviewed by CBER is available on Devices Regulated by CBER.

We recommend that you send your 510(k) to FDA by a method which will provide a signed receipt of delivery, e.g., registered mail with a return receipt or a commercial delivery service. Submitters should receive an acknowledgment letter from FDA, including the assigned 510(k) number, within two weeks of delivery. If the 510(k) acknowledgement letter is not received after 2 weeks contact the Division of Small Manufacturers, International and Consumer Assistance (DSMICA) for assistance. 510(k) Submission Process describes the review process after the submission is received by FDA.

Traditional, Special, and Abbreviated 510(k)s require the same 510(k) review fee. Do NOT send the fee with the submission. Information on how to submit the fee can be found at 510(k) Review Fees.

Frequently Asked Questions

1. Can FDA rely on a declaration of conformity for a substantial equivalence determination in an Abbreviated 510(k) if the manufacturer states that they will conform rather than they are in conformance?

A declaration of conformity to a recognized standard must certify that the device is in conformance. Therefore, in order for the FDA to rely upon a declaration of conformity to a standard in making a substantial equivalence (SE) determination in an Abbreviated 510(k), the declaration must indicate that the submitter is in conformance. That is, a manufacturer may not state that they will conform at some future date, but rather conformance must have already been determined at the time the submission is submitted.
2. What happens if an Abbreviated 510(k) includes a statement indicating that the device will conform but is not yet in conformance with a standard?

As stated above, for issues material to the substantial equivalence determination, FDA would not be able to rely upon such a statement. A declaration of conformity certifying that the device is in conformity to the standard would be needed.

The only exception to the above would be for cases where substantial equivalence had previously been demonstrated for devices of this type without conformance to the standard. For example, if a manufacturer states that a device will conform to IEC-60601-1-2 Electromagnetic Compatibility and substantial equivalence for the predicate device had been determined without conformance to the standard, then the submission could be reviewed as an Abbreviated 510(k). If, as stated above, conformance to this standard is integral to the SE determination, then conformance would need to be established before the 510(k) is submitted.

3. What advantage, if any, is there for a firm to use a third party to assess conformance with recognized standards? If a firm does use a third party for the assessment, should this information be included in the 510(k) submission?

Many device manufacturers employ third parties in assessing conformance with standards as a matter of routine practice. Although it is ultimately the submitter's responsibility for assuring conformance when electing to submit a declaration of conformity in a premarket submission, third party involvement may provide the manufacturer with added confidence when submitting a declaration and provide the FDA with additional assurance of conformance. Involvement by an independent, technically competent third party can only benefit the overall process.

An Abbreviated 510(k) with a Declaration of Conformity to a Recognized Standard should include the name and address of any test laboratory or certification body involved in the conformance assessment as well as a reference to the accreditation of the third party as stated in Attachment 4 of the New 510(k) Paradigm. FDA recommends that 510(k) submitters follow Attachment 4, when preparing declarations of conformity to standards. That is, declarations of conformity to standards should include the name, address, and accreditation of all third parties involved in the conformance assessment. If a manufacturer uses a third party to perform a conformance assessment of standards, this information should be maintained in the firm's device master record (DMR).

4. What happens if the FDA determines that an Abbreviated 510(k) can not be reviewed as such? Is the submission rejected? Is the review clock reset?

If the FDA determines that an Abbreviated 510(k) is not eligible for review as submitted, the reviewer will notify the firm of this decision and offer the option of having the document converted to a Traditional 510(k) or withdrawing it for future submission. If the 510(k) is converted, the original receipt date remains as the start of the review period. Manufacturers should be aware that, in most cases, additional information will be necessary for converted documents.

5. Is the 30 day review clock for Special 510(k)s also applicable to Abbreviated 510(k)s?

No. While the FDA expects that declarations of conformity to standards will reduce the review time for Abbreviated 510(k)s compared to Traditional 510(k)s, FDA has not established a 30 day review clock for Abbreviated 510(k)s.

6. Could a submitter be held liable if a declaration of conformity to a standard is based on information that turns out to be false? What if the information was provided to the
submitter by a third party? What are the consequences of submitting a false declaration of conformity?

Yes. Submitting a false declaration of conformity to a standard is specifically identified as a prohibited act in section 301(x) of the Act. If it is determined that the information underlying the declaration of conformity is false or misleading in any material respect, the submitter of the declaration could be held liable. This is true whether the information was generated by the submitter or by a third party (e.g., a testing facility). Therefore, it is important that a person declaring conformity to a standard carefully review the information forming the basis for the declaration before it is submitted to the FDA.

However, the FDA does wish to distinguish a "false" or "misleading" declaration of conformity from a declaration of conformity in which FDA disagrees with the adequacy of the supporting data. The FDA acknowledges that a manufacturer may make a good faith effort to conform with a standard and yet FDA may disagree with the basis upon which the declaration was made. Under such circumstances, the FDA will make every effort to resolve the issue with the submitter.

7. During the review of a 510(k), does FDA anticipate that it will routinely ask for the data or information supporting a declaration of conformity to a standard?

FDA may request, at any time, data or information relied upon for the declaration of conformity. FDA does not, however, expect that this would routinely occur, but rather only on a case-by-case basis if a serious concern arises during the review of the submission. The concurrence of senior management would be needed before such a request would be made. [Section 514 of the Act]

8. How long should the records supporting a declaration of conformity to a standard be maintained?

Persons declaring conformity to a standard must maintain data and information demonstrating conformity of the device to the standard for two years after the date of the substantial equivalency determination or for a period equal to the expected design life of the device, whichever is longer. [Section 514 of the Act]

References
- Format for Traditional and Abbreviated 510(k)s
- The New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications
- Frequently Asked Questions on the New 510(k) Paradigm
- Recognition and Use of Consensus Standards
- Frequently Asked Questions on Recognition of Consensus Standards
- FDA Recognized Consensus Standards Database
Special Considerations

- **510(k)s for Biologic Products**
- **Biocompatibility**
- **Class III Certification and Summary**
- **Combination Products**
- **Design Controls**
- **Electronic Copies**
- **Evaluation of Automatic Class III Designation (De Novo Process)**
- **Expedited Review**
- **In Vitro Diagnostic Devices**
- **Kits**
- **Radiation Emitting Products**
- **Software**
- **Standards**
- **Sterilants and High Level Disinfectants**
- **Sterility**

### 510(k)s for Biologic Products

The Center for Biologics, Evaluation, and Research (CBER) has expertise in blood, blood products, cellular therapies, and other biologics as well as the integral association of certain medical devices with these products. To utilize this expertise, CBER reviews marketing and investigational device submissions (Premarket Notification 510(k), Premarket Approval, and Investigational Device Exemption) for medical devices associated with blood collection and processing procedures as well as those associated with cellular therapies and vaccines. Although these products are reviewed by CBER, the medical device laws and regulations still apply.

- **Devices reviewed by CBER**
- **Premarket submissions for devices reviewed by CBER**

Center for Biologics Evaluation and Research  
Office of Communication, Training and Manufacturers Assistance (HFM-43)  
1401 Rockville Pike, Room 200N  
Rockville, MD 20852-1448 U.S.A.  
Telephone Number: 301-827-2000 or 800-835-4709  
Fax Number: 301-827-3843  
Email: matt@cber.fda.gov

### Biocompatibility

Biological evaluation of medical devices is performed to determine the potential toxicity resulting from contact of the component materials of the device with the body. The device materials should not, either directly or through the release of their material constituents: (i) produce adverse local or systemic effects; (ii) be carcinogenic; or, (iii) produce adverse reproductive and developmental effects. Therefore, evaluation of any new device intended for human use requires data from systematic testing to ensure that the benefits provided by the final product will exceed any potential risks produced by device materials.

FDA recognizes the standard ISO 10993 (International Standards Organization) for biological evaluation of medical devices. This standard provides guidance for selecting the tests to evaluate...
the biological response to medical devices. When selecting the appropriate tests for biological evaluation of a medical device, the chemical characteristics of device materials and the nature, degree, frequency and duration of its exposure to the body must be considered.

The specific clinical application and the materials used in the manufacture of the new device determines which tests are appropriate. Some devices are made of materials that have been well characterized chemically and physically in the published literature and have a long history of safe use. Therefore, it may not be necessary to conduct all the tests suggested in the FDA's testing guidance matrix.

Additional information on how to use the ISO 10993 standard can be found in the following guidance document:

- Required Biocompatibility Training and Toxicology Profiles for Evaluation of Medical Devices, Blue Book Memo, G95-1

In a 510(k) submission for devices which come into direct contact with the patient or user, an exact identification and composition of all materials that contact the patient should be provided and a statement regarding any material differences from the legally marketed device(s) should be explicitly stated. If the materials are identical to the legally marketed device(s) and are identically processed and sterilized, then this should be stated. If the materials and manufacturing processes and intended use are not identical, or this information is not available for a predicate device, biocompatibility testing should be performed.

Therefore, manufacturers will need to provide biocompatibility test results for any new materials when the new device is compared to a legally marketed device made of different materials. The results should be in a separate, identified biocompatibility section, be well organized, and be complete.

**Class III Certification and Summary**

A preamendment device is one that was legally in commercial distribution before May 28, 1976, the date the Medical Device Amendments were signed into law. After the Medical Device Amendments became law, FDA was required to classify all preamendment type devices. All known devices were classified into Class I, Class II, or Class III. It was intended that all preamendment Class III devices would eventually require Premarket Approval (PMA) for marketing approval. Preamendment Class III devices require a PMA only after FDA publishes a final regulation calling for PMA. After FDA publishes the requirement for PMA, the classification regulation in the Code of Federal Regulations (CFR) will state the effective date that a PMA is required.

If FDA has not required a PMA for the type of device, a Class III device that enters the market after May 28, 1976 must have a cleared Premarket Notification 510(k) prior to marketing. Class III devices for which we have not called for PMAs and require a 510(k) are identified in the CFR as Class III and include the statement "Date premarket approval application (PMA) or notice of completion of product development protocol (PDP) is required. No effective date has been established of the requirement for premarket approval." Examples include intra-aortic balloon and control system (21 CFR 870.3535), ventricular bypass (assist) device (21 CFR 870.3545), and topical oxygen chamber for extremities (21 CFR 878.5650).

510(k)s for Class III devices must contain a Class III Certification and Summary. The certification states that you have conducted a search for information about your device type. The Class III Summary is a summary of the types of safety and effectiveness problems associated with the type of device being compared and a citation to the information upon which the summary is based. The summary must be comprehensive and describe the problems to which the type of device is susceptible and the causes of such problems. The certification should be signed by the 510(k) submitter, NOT a consultant to the 510(k) submitter, and be clearly identified as "Class III Certification and Summary." The summary of problem data, bibliography or other citations upon which the summary is based should be immediately follow the certification statement. The Class III Certification and Summary should be identified in the table of contents of the 510(k).
Combination Products

A combination product is a product comprised of two or more regulated components (drug/device or biologic/device) that are combined as a single entity or is a product labeled for use with a specified drug, device, or biologic where both are required to achieve the intended use, indication, or effect.

To ease the regulatory burden of industry, FDA has established Inter-center agreements which establishes the lead FDA Center for review and oversight of certain categories of products. Inter-center agreements with CDRH are referenced below.

Inter-center Agreement Between the Center for Biologics Evaluation and Research and the Center for Devices and Radiological Health.

Inter-center Agreement Between the Center for Drug Evaluation and Research and the Center for Devices and Radiological Health.

Some combination products involve cutting edge, novel technologies that raise not only unique scientific and technical questions, but also regulatory challenges related to where and how they should be regulated in order to ensure adequate and consistent regulatory oversight. The Office of Combination Products assigns review responsibility for combination products. The Office is also responsible for designating the component of FDA with primary jurisdiction for the premarket review and regulation of any product requiring a jurisdictional designation.

Additional information regarding combination products can be found at the following website:

- Office of Combination Products

Design Controls (§ 820.30)

All manufacturers (including specification developers) of Class II and III devices and select Class I devices (listed below) are required to follow design controls (§820.30) during the development of their device. The design control requirements are basic controls needed to ensure that the device being designed will perform as intended when produced for commercial distribution.

Class I Devices Subject to Design Controls

<table>
<thead>
<tr>
<th>Section</th>
<th>Device</th>
</tr>
</thead>
<tbody>
<tr>
<td>868.6810</td>
<td>Catheter, Tracheobronchial Suction.</td>
</tr>
<tr>
<td>878.4460</td>
<td>Glove, Surgeon's.</td>
</tr>
<tr>
<td>880.6760</td>
<td>Restraint, Protective.</td>
</tr>
<tr>
<td>892.5740</td>
<td>Source, Radionuclide Teletherapy.</td>
</tr>
</tbody>
</table>

The manufacturer (including specification developer) must establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met [820.30(a)]. Design controls include establishing and maintaining plans that describe the design and development activities and also define responsibility for implementation [820.30(b)]. The plans must identify and describe the interfaces with different groups or activities that provide, or
result in input to the design and development process [820.30(b)]. The design process also includes:

- conducting a risk analysis [820.30(g)];
- identifying design input or requirements for the device [820.30(c)];
- developing the design output or specifications for the device [820.30(d)];
- verifying that the design output meets the design input [820.30(f)];
- holding design reviews at appropriate points during the design process to identify significant problems with the design or the design process [820.30(e)];
- validating that the design meets defined user needs and intended uses [820.30(g)];
- validating any software used in the device [820.30(g)];
- transferring the device design to production specifications [820.30(h)];
- controlling changes to the design during the design process and changes in the design of products on the market [820.30(i)]; and
- documenting design control activities in the design history file [820.30(j)].

The manufacturer must have procedures in place and must maintain documentation in the design history file to demonstrate compliance with the design control requirements of §820.30 and completion of the activities identified in the design plan. The design history file must be made available for FDA inspection. FDA will evaluate the adequacy of manufacturers' compliance with design control requirements during routine quality systems inspections for all classes of devices subject to design control.

The following documents provide additional guidance on the design control requirements under the Quality System regulation.

- Design Control Guidance for Manufacturers
- Do It by Design

See Good Manufacturing Practices (GMP)/Quality Systems (QS) for additional guidance on 21 CFR 820, Quality System.

**Electronic Copies**

You may submit one copy of a 510(k) submission in electronic form. An electronic copy is an exact duplicate of a paper submission, created and submitted on a CD or DVD, and must accompany the paper submission. Please indicate in your cover letter that you are submitting an electronic copy that is an exact duplicate of the paper copies submitted.

The electronic copy should be sent in an Acrobat Portable Document Format (PDF) because the 510(k) review staff will use Adobe’s Acrobat to view the submission. This will assure that what a reviewer sees on the screen is the same as what would have been seen on paper.

An electronic application does not change the order in which submissions are reviewed. No preferential treatment will be given to manufacturers who submit an electronic application. An electronic copy will provide additional navigational tools for the review staff who will be working with your document. Additional copies of some reports may be requested in order to help facilitate the review.

- Electronic Copies for Pre-Market Submissions

**Evaluation of Automatic Class III Designation (De Novo Process)**

Prior to the FDA Modernization Act of 1997 (FDAMA), all devices on the market as of May 28, 1976 were classified according to their risk. Any new type of device that was found not substantially equivalent for a reason other than performance data required a Premarket Approval (PMA) application. A device could be moved out of Class III only through a reclassification process. The De Novo process provides a possible route to market low risk device types. This process does not apply to devices that have been classified by regulation into class III, i.e., preamendment class III devices or class III devices for which a premarket approval application or a reclassification petition is appropriate.
FDAMA amended Section 513(f)(2) to provide a new mechanism for classifying new Class III devices for which there is no predicate device. The De Novo process is intended to apply to low risk products that have been classified as class III because they were found not substantially equivalent (NSE) to any identifiable predicate device. It allows the recipient of an NSE (not substantially equivalent) letter to request a risk-based classification determination to be made for the device.

An applicant of a 510(k) who receives a Not Substantially Equivalent (NSE) determination placing the device into a Class III category can request a de novo classification of the product into Class I or II. The request must be in writing and sent within 30 days from the receipt of the NSE determination. In addition, the request should include a description of the device, labeling for the device, reasons for the recommended classification (into Class I or II), and information to support the recommendation. The de novo process has a 60 day review period. If FDA classifies the device into Class I or II, the applicant will then receive an approval order to market the device. This device type can then be used as a predicate device for other firms to submit a 510(k). However, if FDA determines that the device will remain in the Class III category, the device cannot be marketed until the applicant has obtained an approved PMA.

Additional guidance on the De Novo process is provided in the guidance document below.

- Evaluation of Automatic Class III Designation

**Expedited Review**

Expedited review of devices subject to 510(k) will generally be considered when a device offers a potential for clinically meaningful benefit as compared to the existing alternatives (preventative, diagnostic, or therapeutic) or when the new medical device promises to provide a revolutionary advance (not incremental advantage) over currently available alternative modalities.

FDA considers a device appropriate for expedited review if the device:

1. is intended to treat or diagnose a life-threatening or irreversibly debilitating disease or condition, and
2. addresses an unmet medical need, as demonstrated by one of the following:
   a. The device represents a breakthrough technology that provides a clinically meaningful advantage over existing technology; or
   b. No approved alternative treatment or means of diagnosis exists; or
   c. The device offers significant, clinically meaningful advantages over existing approved alternative treatments; or
   d. The availability of the device is in the best interest of patients.

Granting expedited review status means that a marketing application that is determined to be appropriate for expedited review is placed at the beginning of the appropriate review queue and receives additional review resources, as needed.

Additional information on the criteria and procedure for expedited review are provided in the following guidance document.

- Expedited Review of Premarket Submissions for Devices

**In Vitro Diagnostic (IVD) Devices**

**Definition**

In vitro diagnostics are medical devices that analyze human body fluids, such as blood or urine, to provide information for the diagnosis, prevention, or treatment of a disease. The device classification for these devices can be found under 21 CFR 862, 21 CFR 864, and 21 CFR 866.

**510(k) Submissions**
You may submit a traditional, special, or abbreviated 510(k) for in vitro diagnostic devices. You are encouraged to use CeSub eSubmitter software to create a 510(k) for an in vitro diagnostic device that is reviewed in Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD). The software will support single and “bundled” applications for all traditional, abbreviated, and special 510(k)s including:

- Antimicrobial Susceptibility Testing (AST) devices
- All other in vitro device types
- CLIA waiver and categorization applications

The software may also be used to submit 510(k) Supplements (responses to requests by FDA for additional information to a 510(k) while it is under review). The software will help you submit a complete 510(k) and is available to the public for free.

- Turbo 510(k) Electronic Submissions URL may be dead.

**Labeling**

In vitro diagnostic products have special labeling requirements and distribution restrictions under 21 CFR 809. In Vitro Diagnostic Products for Human Use. Additional guidance can be found under "Device Advice Labeling Requirements for In Vitro Diagnostic Devices."

**Clinical Laboratory Improvement Amendments (CLIA) of 1988**

In addition to FDA regulation under the Food, Drug, and Cosmetic Act, in vitro diagnostic devices are also subject to the Clinical Laboratory Improvement Amendments (CLIA) of 1988. This law established quality standards for laboratory testing and an accreditation program for clinical laboratories.

The requirements that apply vary according to the technical complexity in the testing process and risk of harm in reporting erroneous results. The regulations established three categories of testing on the basis of the complexity of the testing methodology: waived tests, tests of moderate complexity, and tests of high complexity. Laboratories performing moderate- or high-complexity testing or both must meet requirements for proficiency testing, patient test management, quality control, quality assurance, and personnel. These specific requirements do not apply to tests in the waived category.

In January 2000 the categorization of commercially marketed in vitro diagnostic tests under CLIA was transferred from the Center for Disease Control and Prevention (CDC) to FDA. CDRH's Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD) determines the appropriate complexity categories for clinical laboratory devices as they evaluate premarket submissions. Waived products, devices exempt from premarket notification, and devices under premarket review by other FDA Centers are also processed by OIVD. Responsibilities currently assigned to CDC, including review of test systems, assays, or examinations not commercially marketed as IVD products, will remain with CDC.

Below is a list of CLIA Program Information Resources:

**FDA**

- complexity categorizations
- assignment of CLIA categories
- waivers

**Center for Medicare and Medicaid Services**

- guidelines for laboratories
- laboratory certification

**Center for Disease Control**

- Clinical Laboratory Improvement Advisory Committee (CLIAC)
- cytology proficiency testing

**Additional IVD Guidance**

Additional information regarding in vitro diagnostics devices is available from the Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD).
Kits
Convenience Kits
Two or more separate types of finished devices packaged together for the convenience of the user is considered to be a kit. Kits (or trays) are often utilized in the surgical arena. The classification of the kit is based on the highest classification of the devices that are provided in the kit. Submissions for convenience kits should identify all devices provided in the kit. Certain convenience kits that meet the criteria in the Convenience Kit Interim Regulatory Guidance are under enforcement discretion and do not require a 510(k).

Guidance documents pertaining to convenience kits are provided below.
- Convenience Kits Interim Regulatory Guidance
- Sterilized Convenience Kits for Clinical and Surgical Use

510(k) Kit Certification
If the device is to be marketed as a kit, identify all devices in the kit and document the marketing status of each device in the kit as shown in the Kit Certification. If a 510(k) submission is required, please include the kit certification in your 510(k). If a 510(k) is not required, we recommend you maintain this information in your files.
- Kit Certification for 510(k)s

Drugs in Kits
If the device kit contains components which are subject to regulation as drugs, a substantially equivalent determination of the included devices by CDRH does not apply to the drugs in the kit. For information on applicable FDA requirements for marketing the drugs in a kit, you should contact the Center for Drug Evaluation and Research.

Gloves in Kits
A medical device kit may include medical gloves. Kit manufacturers and assemblers should assure that gloves in their kits are cleared for marketing and that the gloves can meet the appropriate FDA and ASTM standards (such as ASTM D3577, ASTM D3578, ASTM D5250, ASTM D6319) or an equivalent test method after the kit is sterilized.

We recommend that you enclose natural rubber latex gloves in their own packaging within the kit to avoid possible protein contamination of other devices. You must label the kit appropriately for any device or packaging containing natural rubber (21 CFR 801.437).

Additional guidance and other requirements for medical gloves are available in Guidance for Medical Gloves.

Sutures in Kits
Kit manufacturers and assemblers should assure that sutures in their kits are cleared for marketing. If the kit contains sutures, you should provide evidence that the sterilant does not contact the sutures during sterilization of the kit. Some kit assemblers package the sutures separately from the main tray. After processing and sterilizing the main tray, the package of sutures is piggybacked onto the main tray. Based on the evidence, FDA can conclude if the sutures are or are not further processed. However, including sutures as a component in your kit requires you to comply with the following conditions:
- The labeling, packaging, and method of sterilization of the sutures you have listed cannot be changed without prior notification, review, and approval by FDA; and
- the supplier(s) of the sutures included in your kit cannot be changed without prior notification, review, and clearance by FDA.
Radiation Emitting Products

If your medical device also emits electronic product radiation, additional requirements apply under the Electronic Product Radiation Control Provisions of the Food, Drug and Cosmetic Act. Electronic product radiation means:

- any ionizing or non-ionizing electromagnetic or particulate radiation, or
- any sonic, infrasonic, or ultrasonic wave,
- which is emitted from an electronic product as the result of the operation of an electronic circuit in such product.

Examples of products that emit electronic radiation include lasers, ultraviolet lamps, microwave ovens, ultrasound therapy devices and medical diagnostic x-ray equipment.

Regulatory requirements for these products are in place to protect the public from hazardous or unnecessary radiation exposure emitted by these products. Requirements may include submission of reports to FDA, compliance with applicable radiation safety performance standards, retention of certain records, and reporting of accidental radiation occurrences or product defects to FDA. Additional information on requirements for radiation emitting products is available on the Radiological Health Program website.

Software

If the device contains software or is controlled by a computer, the submission should contain documentation of software development and validation appropriate to the level of risk of the software. The submission should include any information, prompts, and cautions displayed by the system. The software documentation should support all performance and safety claims.

The following guidance documents provide guidance on the recommended software documentation for a premarket submission and on software validation.

- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices
- Guidance for Off-the-Shelf Software Use in Medical Devices
- Cybersecurity for Networked Medical Devices Containing Off-the-Shelf (OTS) Software
- General Principles of Software Validation

Standards

Conformance with recognized consensus standards can provide a reasonable assurance of safety and/or effectiveness for many aspects of medical devices. Information submitted on conformance with such standards will have a direct bearing on safety and effectiveness determinations made during the review of premarket submissions. If any premarket submission contains a declaration of conformity to the recognized consensus standards, this will, in some cases, eliminate the need to review the actual test data for those aspects of the device addressed by the standards.

Conformance with recognized consensus standards in and of itself, however, may not always be a sufficient basis for regulatory decisions. For example, a specific device may raise a safety or effectiveness issue not addressed by any recognized consensus standard, or a specific FDA regulation may require additional information beyond what conformity to the recognized consensus standards provides. Under such circumstances, conformity with recognized standards will not satisfy all requirements for marketing the product in the United States.

FDA recognizes certain consensus standards. If the device complies to an FDA recognized standard, the applicant may provide a declaration of conformity to the standard and use the Abbreviated 510(k) submission method. Conformance to FDA recognized standards are voluntary and may be used to demonstrate performance or safety of a device.
Information on FDAs standard program including a database of FDA recognized standards can be found on the following website.

- CDRH Standards Program

**Sterilants and High Level Disinfectants**

The document below provides a list of 510(k) cleared devices that can be used as a predicate device for a 510(k) submission.

- FDA Cleared Sterilants and High Level Disinfectants with General Claims for Processing Reusable Medical and Dental Devices

**Sterility**

For devices that are labeled sterile, the 510(k) should include the following:

- the sterilization method (e.g., dry heat, moist heat, ethylene oxide (EO), radiation);
- the method used to validate the sterilization cycle, but not the validation data itself;
- a description of the packaging to maintain the device's sterility (Do not include packaging integrity test data in the 510(k) submission.);
- the sterility assurance level (SAL), e.g., 10^-6 for all devices, except 10^-3 for devices only contacting intact skin, for the device that the manufacturer intends to meet;
- the maximum levels of residues of EO and ethylene chlorohydrin that remain on the device when ETO is used to sterilize the device (Note: The ethylene glycol residual level is no longer requested because the recognized standard, "ANSI/AAMI/ISO 10993-7:1995 Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide sterilization residuals," does not include measurement of ethylene glycol residuals);
- for devices that are labeled "pyrogen free," a description of the method used to make that determination, e.g., limulus amebocyte lysate (LAL). Devices contacting blood or cerebrospinal fluids should be pyrogen free.; and
- the radiation dose, if radiation sterilization will be used.

If only parts of the device are labeled sterile or non-pyrogenic, the labeling should clearly identify which parts are sterile and non-pyrogenic.

The labeling for devices intended to be sterilized by the user must identify one validated method of sterilization. The instructions should be detailed and specific enough for the user to follow and obtain the required sterility assurance level. The instructions should also adequately describe any precautions to be followed such as:

- special cleaning methods required;
- any changes in the physical characteristics of the device that may result from reprocessing and re-sterilization, especially those which may affect the safety, effectiveness, or performance; and
- any limit on the number of times re-sterilization and reuse can be done without adversely affecting the safety, effectiveness, or performance of the device.

The manufacture may use an FDA-recognized validation method or an equivalent method to validate the sterilization cycle. You can find consensus standards that FDA has recognized for sterilization by searching the CDRH standards database.

- CDRH Standards Database

Additional information on sterilization can be found in the following documents:

*Updated 510(k) Sterility Review Guidance K90-1; Final Guidance for Industry and FDA*
Container and Closure System Integrity Testing in Lieu of Sterility Testing as a Component of the Stability Protocol for Sterile Products

Labeling Reusable Medical Devices For Reprocessing In Health Care Facilities: FDA Reviewer Guidance
THE PROCESS – GETTING TO MARKET WITH A MEDICAL DEVICE IN THE USA.

Is the product a Medical device

A Drug? A biologic? Combination?

Look for other regulations.

NO

Classify your device

The US FDA has already cleared to market another similar device

Identify a predicate device.
- Device class
- Regulatory controls
- Exemptions? Limitations?
- FDA Regulation Number
- FDA Product Code

The Device is unique and no similar device has yet been cleared to market

510g Request and/or determine level of risk: 510g FDA Classifies Class

510(k) NSE Request “risk-based” (de novo) classification

Class I

Exempt

Class II

Refuse to Accept

DCG FDA Release to Market 7/05/2013

Delphi Consulting Gr

Class III

File a Premarket Approval (PMA) with FDA User Fee
First one free to small business

Clinical Studies

Device approved to market by FDA

Establishment Registration (form FDA-2891) & Medical Device Listing (form FDA-2892)

Basic Regulatory Requirements
- Quality System (QS) regulation and SOPs
- Labeling requirements
- Medical Device Reporting (MDR)
- Recall of Medical Devices
- Corrections and Removals
- Other 21 CFR Part 820 requirements.

YES
The below [optional], electronic copy of this booklet is in PDF file format.

Delphi Consulting Group (DCG) provides U.S. Food and Drug Administration release to market for medical device companies. DCG was formed in 1987.

DCG maximizes the Internet to provide fast response, reduce travel and provide reasonable costs. With the simplest of tools, such as Skype, Skype video, and / or other teleconference systems and with share computer screens software the cost of travel can be reduced to zero.

For assistance with new or modified 513g, 510(k), PMA or PreSub submissions and other Medical Device Regulatory needs contact Delphi Consulting Group (DCG) at:

www.delphiconsulting.com
harvey.knauss@gmail.com
info@delphiconsulting.com
832-675-9281 voice
832-532-8021 Skype with or without video