

US Guidance on Formatting 510(k)s

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There is no official form for submitting a United States premarket notification or 510(k) submission. A recent Food and Drug Administration guidance document describes the manner in which this type of premarket submission should be formatted. This article discusses this document and some important aspects of the 510(k) process.

When to submit a 510(k)

Companies wishing to market medical devices in the United States (US) must determine whether or not the Food and Drug Administration (FDA) has classified their devices and, if so, into which Class the device falls. In the US, medical devices are classified into Classes I, II or III, whereby Class I is the lowest risk category and Class III the highest. Anyone wishing to market a device in Classes I or II and some Class III devices must submit a premarket notification or 510(k) to FDA at least 90 days before marketing the device. However, most Class I devices and some Class II devices are exempt from 510(k) regulations, therefore, a check should be made at the beginning of the submission process to determine whether or not the device to be marketed in the US is exempt. Readers should consult the Center for Devices and Radiological Health's (CDRH) website (www.fda.gov/cdrh) for procedures to follow if the device is not classified.

If the device is not exempt, the premarket regulations briefly discussed later should be reviewed. This is a critical step because the regulatory basis of the 510(k) process needs to be understood before developing the 510(k) submission. A 510(k) submission must demonstrate that the device to be marketed is substantially equivalent to a legally marketed device, that is, it does not raise any new issues of safety and effectiveness. The legally marketed device used for comparison is called a "predicate device." Therefore, applicants must compare their device with one

or more predicate devices and provide adequate comparative, descriptive and, when necessary, performance data to support claims of substantial equivalence. A comprehensive description of the steps for completing the premarket submission process can be found in Device Advice at the website: www.fda.gov/cdrh/devadvice

Premarket notification regulations

The requirements for the premarket submission process are specified in the US Code of Federal Regulations (CFR) in 21 CFR 807, Establishment Registration and Device Listing for Manufacturers and Initial Importers of Devices, Subpart E, Premarket Notification Procedures. These regulations specify requirements relating to

- when a premarket notification submission is required
- exemption from premarket notification
- information required in a premarket notification submission
- format of a premarket notification submission
- content and format of a 510(k) summary
- content and format of a 510(k) statement
- format of Class III certification
- confidentiality of information
- misbranding by reference to premarket notification.

Sources of help

Although the regulations list the information that is required in a 510(k) submission and provide some



Image: Digital Vision



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→ details on the format, additional information is needed to develop a satisfactory 510(k) for most devices. Therefore, FDA has produced a number of guidance documents, not only for 510(k) applicants, but also for FDA staff to help ensure uniformity in the review process. These guidance documents can be found on the CDRH's website where general as well as many device-specific guidance documents are available.

Readers searching for guidance documents for a specific medical device or category of devices such as sterile devices or devices containing software can search FDA's Guidance Documents database at www.fda.gov/cdrh/guidance.html. Another source of information is the A-Z Index on the CDRH homepage, which lists more than 30 guidance documents on the premarket notification process under the letter "P." The guidance document on formatting 510(k)s is one of these.

Types of 510(k) submissions

There are three types of 510(k)s that can be submitted to FDA:

- Traditional 510(k). This must include the elements specified in 21 CFR 807.87, Information required in a premarket notification submission.
- Abbreviated 510(k). This must also include the elements identified in 21 CFR 807.87; however, this type of 510(k) was introduced to streamline the submission process when conformity to FDA-recognised standards is declared or FDA device-specific guidance is followed.
- Special 510(k). This includes the elements identified

in 21 CFR 807.87. It was also introduced to streamline the submission process; however, in this case, for use when a modification has been made to a device that has already been cleared under the 510(k) process. This type of 510(k) is not covered by the guidance document on formatting traditional and abbreviated 510(k)s, which is described below, and is not discussed further in this article.

Guidance on formatting 510(k)s

In August 2005, FDA issued a guidance document for industry and FDA staff: "Format for Traditional and Abbreviated 510(k)s" to provide guidance on how to format a submission for these two types of 510(k)s.

Chapter I of the guidance document identifies the overall outline of the 510(k) format. Chapter II describes each section of the 510(k) and identifies sources of information that FDA believes is useful for that section. Chapter III provides a summary listing of the individual sections and links to related sources. Most of the sections listed by the guidance will be familiar to those who have developed 510(k) submissions based on previous FDA guidance and checklists (see Table I). However, the contents of the cover sheet have been updated and the information requested in the cover letter has been expanded. In addition, FDA requests that the submission contain the sections listed in Table I. If a particular section is not applicable, FDA requests that the section be retained with the statement of "This section does not apply" or "N/A" under the title.

An especially useful feature of the guidance document is that it provides Internet links to information related to the preparation of each section. FDA indicates that even though the guidance documents or other resources referred to in the links may be revised over time, the links will not change.

Executive Summary

This is a new section to include in a 510(k) submission that is designed to provide an overall understanding of the device. It is based on a section described in the Global Harmonisation Task Force (GHTF) document: "Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices," also known as the "draft STED document." In fact, as an alternative to the submission format described in the 510(k) formatting guidance document, a 510(k) submission for certain devices may be made in the globally harmonised format that is described in the draft STED document. Additional information on the FDA pilot programme, which permits this approach, can be obtained from the CDRH website: www.fda.gov/cdrh/ode/guidance/1347.html

FDA recommends that the Executive Summary includes a concise description of the device, including the indications for use and technology; a device comparison table; and a concise summary of any performance testing in the submission. The guidance document states that the device comparison table should outline the differences

Table I: Suggested 510(k) sections for traditional or abbreviated 510(k)s.

1.	Medical Device User Fee Cover Sheet (Form FDA 3601)
2.	CDRH Premarket Review Submission Cover Sheet
3.	510(k) Cover Letter
4.	Indications for Use Statement
5.	510(k) Summary or 510(k) Statement
6.	Truthful and Accuracy Statement
7.	Class III Summary and Certification
8.	Financial Certification or Disclosure Statement
9.	Declarations of Conformity and Summary Reports
10.	Executive Summary
11.	Device Description
12.	Substantial Equivalence Discussion
13.	Proposed Labelling
14.	Sterilisation and Shelf Life
15.	Biocompatibility
16.	Software
17.	Electromagnetic Compatibility and Electrical Safety
18.	Performance Testing – Bench
19.	Performance Testing – Animal
20.	Performance Testing – Clinical
21.	Other

and similarities between the device to be marketed and the predicate device(s). It also recommends that a discussion is provided on how this comparison supports substantial equivalence. Not surprisingly, there may be some degree of duplication between the information provided in this section and that provided in the section: Substantial Equivalence Discussion. However, where possible, the information included in the Executive Summary should be more concise than that provided in the Substantial Equivalence Discussion section. The Executive Summary should include a summary for each performance testing section and sufficient detail to allow a broad understanding of the type of testing performed, the methods used and the conclusions drawn from the results.

Varying or missing elements

As mentioned previously, a significant amount of information on the 510(k) submission process is provided on the CDRH Device Advice website. Indeed, in some cases it provides additional information to that found in the formatting guidance. In addition, the formatting guidance provides links to various parts of the Device Advice website.

In limited instances, it will be necessary to decide whether to follow the guidance on the website or that provided in the formatting guidance document. For example, the section, Content of a 510(k) on the Device Advice site (available at www.fda.gov/cdrh/devadvice/314312.html#link_7) includes information that goes beyond the details in the formatting guidance document. That is, the Introduction of this section includes, for example, general information on the average number of pages of a typical 510(k), helpful suggestions for facilitating the review process, suggestions for ensuring that the 510(k) submission is complete, and a list of the type of information that should be available before proceeding with the 510(k). In another instance, the formatting guidance document includes a link to this section of Device Advice to obtain additional information regarding the content of the 510(k) Summary and 510(k) Statement.

It is interesting to note that the formatting guidance document does not discuss the inclusion of a Table of Contents. However, the Device Advice section, Content of a 510(k) section, recommends its inclusion. There are differences of opinion among some regulatory professionals on this issue and, if included, the way in which the Table of Contents should be formatted. This may seem like a minor point, but any approach that facilitates FDA's review of a 510(k) submission is desirable. If a Table of Contents is included, it should be appropriately correlated with the sections listed in the formatting guidance documents. **mdt**

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