



Guide to Building a Successful 510(k) Submission



Daniel W. Lehtonen
Sr. Staff Engineer - Medical Devices

Intertek
70 Codman Hill Road
Boxborough, MA
icenter@intertek.com 1-800-WORLD-LAB www.intertek.com/510K



Introduction

Shortening time to market is important to the bottom line of medical device manufacturers worldwide. Selling medical devices in the United States requires product approval through the US Food and Drug Administration (FDA.)

On a yearly basis, the FDA sees more than 3,000 submissions through the 510(k) process alone. Devices submitted through other routes, such as the Premarket Approvals (PMA) and Investigational Device Exemptions (IDE) routes, add to their workload.

Submissions to the FDA that are poorly organized, do not follow current practices, contain inconsistencies between documents or are lacking information, will result in significant delays in the clearance process. The FDA works on a first in first out order. With multiple review cycles, up to 90 days each, device clearance can stretch to 8 months or more. A submission in which it is difficult for the FDA to find information, or the information is not clear, will slow the process. The FDA does not make interpretations--they will simply ask for revisions and clarifications.

Writing and assembling a complete and well structured 510(k) submission will certainly improve the likelihood of FDA clearance on the first round. You can help yourself by following the suggestions and guidance that FDA provides to the Medical Device Community.

Intertek, as an Accredited Person, has performed more than 400 reviews of 510(k) submissions and has analyzed the reasons that most often lead to delays in getting submissions ultimately cleared by FDA. The foremost reason for delays is missing content, which can be attributed to poor structure and incomplete content.

This white paper focuses on the structure and key elements of the 510(k) submission and explains in clear language the most common pitfalls to avoid in the development of your 510(k) submission to the FDA.



Structure and General Assembly

There is no mandatory form for 510(k) submissions. However, it is suggested that you assemble your submission following the guidance for [Format for Traditional and Abbreviated 510\(k\)s](#).¹ This will ensure that you are addressing the topics that FDA expects to see in a submission, and that you don't accidentally omit a section.

Some of the most common omissions / errors are:

- Unorganized submissions that have missing sections, lack a complete table of contents, and lack tabs for major sections
- Neglecting to include one copy of the submission with original signatures on letters and declarations
- Not utilizing the FDA form for the Indications for Use (you need to mark prescription or Over-the-Counter [OTC] use)
- Not signing or incorrectly referencing the Code of Federal Regulation (CFR) number for the Truthful and Accurate Statement
- Incomplete and inaccurate forms, particularly forms 3514 and 3654

Additionally, you should follow all device guidance documents applicable to your device. There may be device specific or topic specific (i.e. software) guidance available. FDA relies upon these guidance documents as stipulated in [Section 701\(h\) of the Federal Food Drug and Cosmetic Act](#)² though they are not legally binding.

Your goal in putting together your submission is to provide FDA a complete document, based on facts and science (not opinions and marketing), that is easy to follow and clearly explains how you came to the decision that your device is substantially equivalent to the predicate device. Remember, you are not selling your device to FDA--you are explaining and supporting equivalence.

The following list of items is from the guidance for Format for Traditional and Abbreviated 510(k)s. If a particular section does not apply to your device, you should still leave the section heading in the sequence and include an indication of "N/A" and a brief reason why.



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

If you submit your 510(k) directly to the FDA, you **must** include a form 3601. For applications sent through a 3rd Party, such as Intertek, you may omit the form.

2. CDRH Premarket Review Submission Cover Sheet

This is an **optional** form that is intended to provide the basic administrative information about the device and the firm submitting the 510(k) submission. All of the information should be included elsewhere in the submission. If you do decide to include the form, make sure that all information matches the detailed sections of the submission.

3. 510(k) Cover Letter

The cover letter is a free form document (no FDA form) that encompasses much of the same information as the CDRH Premarket Review Submission Cover Sheet. If you are submitting an electronic copy of the 510(k) submission, a cover letter is required since you will have to include text stating that the e-copy is an exact copy of the paper version of the submission.

4. Indications for Use Statement

Not using the current Indication for Use Forms ([ODE](#)³ or [OIVD](#)⁴) will lead to a delay. Having inconsistent Indications Statements in the submission will also lead to delays. Make sure that you review all locations in which the statement appears to ensure that they are **identical**, not similar.

Additionally, you should not try to incorporate new indications that are not supported by the predicate or differences that are not fully explained as to how the intended therapeutic or diagnostic effect is impacted. Mixing and matching of predicates can lead to issues if the indications from one device and the technology from another device are combined. This often leads to new types of safety and effectiveness questions and substantially equivalent determination.

When picking your predicate device, you should carefully review the intended use of the device and the cleared indications for use, not the labelling, and write your indications accordingly. Even minor differences in language and words can impact the indications statement.

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

All submissions must contain either a 510(k) summary or 510(k) statement, but not both. The content of the documents must follow the CFR requirements as appropriate. For 510(k) summaries, do not base your content on that of the predicate devices. Historically, the content of the summaries has been rather light, but FDA is now looking very carefully at summaries to make sure that the content meets the CFR requirements.

If you choose to provide a 510(k) statement, the text must be verbatim from the CFR.

6. Truthful and Accuracy Statement

All 510(k) submissions must include a Truthful and Accurate Statement in accordance with **21 CFR 807.87(k)**. There are numerous guidance documents that have an incorrect reference to section (j). There is no need to cite the CFR reference. The recommended format for the statement can be found at:

[Truthful and Accurate Statement Format](#)⁵

7. Class III Summary and Certification

A Class III Summary and Certification is very uncommon. There are currently only 44 device types that have gone through the 510(k) process and are Class III devices. None of the devices are eligible for 3rd Party Review.

If you do have a Class III device, the suggested format and content can be found at:

[Premarket Notification Class III Certification and Summary](#)⁶

8. Financial Certification or Disclosure Statement

If your submission includes clinical studies, FDA form [3674](#)⁷ will need to be included, and potentially, Form [3454](#)⁸ and [3455](#)⁹.

These forms are relatively uncommon in the 3rd Party Review Program as submissions for Class II devices that rely upon clinical data for substantiation are excluded from the program. If you need to include clinical data, you will have to submit directly to FDA.

9. Declarations of Conformity and Summary Reports

Standards are becoming more important in 510(k) submissions. The FDA continues to recognize new standards and current versions of existing standards. Recognized standards provide a more consistent review result. Since FDA has recognized the standards, they are comfortable with the methods and pass/fail criteria. However, it is important to explain how and why you are using a particular standard in the submission - that is what is being addressed (i.e. safety, effectiveness, performance, etc.) Additionally, you need to review of the FDA's Extent of Recognition of the standard. The extent of recognition will tell you if any specific information needs to be provided. For instance, IEC 60601-1-2 has several points that need to be addressed outside of submitting a declaration or test report. Some standards require the test results be provided, whereas others may just allow a statement of conformance. Most importantly, you must complete the FDA form [3654](#)¹⁰ as this will answer most of FDA's questions regarding the use of the standard.

10. Executive Summary

The content of this section is intended to provide a summary demonstrating how you came to the conclusion that your device is equivalent to the predicate device. This section should essentially pull the key aspects of the submission together and provide the reader with a single section to gain an understanding of the device, its intended use, the features that support equivalence, and a summary of the testing performed to demonstrate equivalence and performance.

Basically, this section should be a science and fact based reasons for why your device is equivalent. Do not include sales or marketing statements.

It is suggested that you look at the FDA Review Memo template and instructions when writing this section. You can find these documents at:

[510\(k\) Review Template](#)¹¹

[510\(k\) Review Template Instructions](#)¹²

11. Device Description

The description should provide the technical specifications for the device, all models that are being offered (including clear explanation of the differences between them), and accessories or components that are included with the device. You should support this section with information that allows for a complete understanding of the device and its performance. Supporting information may include photos, engineering drawings, electrical schematics, etc.



Do not make the reader guess what the device is, what it looks like or how it will perform its intended functions. If there are particular safety features associated with the device, make sure you describe them and explain why and how they will function. The performance testing of the device should also include testing that shows proper and repeatable functionality.

12. Substantial Equivalence Discussion

One of the most important sections is your Substantial Equivalence (SE) Discussion. This section is going to provide the details on why and how your device is equivalent. Make sure you are comparing the important technical features and aspects of the device, not just secondary or minor comparisons.

You will need to include both similarities and differences in your discussion. It is important to provide fact based explanations as to how the differences do not impact the safety or effectiveness of the device - this can be both negative and positive (too much of a good thing). Use of terms such as "similar" in the discussion will always lead to questions. Be specific and forthcoming. The more information you can provide the better.

13. Proposed Labeling

You will need to include at least draft labeling for your device and you should acquire and include the labeling for your identified predicate device. Since you are telling the FDA that your device is equivalent, your comparison should contain a review and comparison of your labeling to the predicate.

14. Sterilization and Shelf Life

Be sure to include all pertinent details for the sterilization of your device. This would apply to devices that are sold sterile and to those that are intended to be reprocessed. The FDA has created a summary page that details the information that you should consider in your submission. Inserting and completing the table will be beneficial. You can find the specific information at:

[Sterile Devices in Premarket Notification \[510\(k\)\] Submissions](#)¹³

15. Biocompatibility

A common mistake made by firms is performing their testing on individual components of the device or including comments to the effect of "USP Class VI" material. Though these avenues can be important in a device design process, they are inappropriate for supporting biocompatibility on an overall device. You should reference both the ISO 10993 series of standards and the FDA Blue Book

Memo G95-1 for guidance in selecting the tests appropriate to your device. Testing needs to be performed on a final finished and, if applicable, sterilized device. Engineering prototypes are typically not well suited for biocompatibility testing.

Additionally, many of the biocompatibility standards do not have a specific pass / fail criteria. The results of the test are reported and you determine whether the result is appropriate for your device and its use.

16. Software

There are numerous guidance documents that you should reference in putting together the software section of the submission. The starting point is typically the [Guidance for the Content of Premarket Submission for Software Contained in Medical Devices](#)¹⁴. The two important points regarding software is that for the most part, based on current understanding;

- a. There is no such thing as software with a **minor** level of concern since a software malfunction could lead to a delay in delivery of medical care and
- b. There is **no difference** in the information that you need to have on file based on the identified level of concern.

If you think that a moderate level is appropriate and FDA reviews and determines that major is more appropriate, it should be only a matter of copying the additional documents and providing them.

17. Electromagnetic Compatibility and Electrical Safety

Active device are commonly assessed to the IEC 60601 series of standards. Currently, FDA has recognized many of the collateral and part 2 standards associated with the 1988 version of IEC 60601-1. It is in process of recognizing the standards associated with the 2005 version of the standard. In June of 2013, you will need to be using the newer version.

In the interim, making use of the standards can help support documenting the electrical safety of your device. This can be particularly important if the predicate is identified as meeting the standards. If this is the case, you will need to demonstrate an equivalent level of safety and complying with the same standards is a straightforward means to accomplish this.

18. Performance Testing – Bench

Bench testing is often used to show that the device meets its stated specifications and performs in an equivalent manner to the predicate. When

relying on bench testing, merely including a summary report of data is typically not sufficient. As previously noted, the FDA will not make interpretations about the data - you need to include as part of the submission a complete explanation. You need to explain why you chose a specific test method, what your endpoints are, and what your pass / fail criteria is, and why it is appropriate. This is especially important if there is more than one method available. You will need to document how you did the testing - the setup, the data collection and the results. You must analyze the data and draw conclusions from it. Your summary of testing should include a brief explanation of the test, the devices used in the test (all models, some models, prototype, pre-production, etc.) and whether there were any deviations from the established method or protocol.

19. Performance Testing – Animal

The content in the Animal Testing section, if used, would be very similar to the Bench Testing discussion. All of the same information would be required and, in addition, identification of the animal used and why it is representative for human comparison. If you are conducting significant animal testing, it is recommended that you discuss the device and testing with FDA prior to submitting the 510(k). This can often be accomplished through a Pre-IDE meeting, as this allows FDA to allot time to look at the documents and discuss the content with you.

20. Performance Testing – Clinical

Most submissions do not require clinical data to establish equivalence. This is primarily based on the differences between the subject device and the predicate or the nature of the device itself. The more significant the differences between the devices, the higher the likelihood that the submission will need to include clinical data. Again, it is very beneficial to discuss the need for clinical data with the FDA prior to submitting. The time and costs associated with clinical testing warrant such action. Additionally, you may need to go through the IDE process should the device be considered significant risk.

21. Other

This section is reserved for any additional information that you feel that FDA would need to agree with your determination that your device is substantially equivalent to the identified predicate device.



Conclusion

The areas identified in this paper represent some of the most common 510(k) submission issues that cause the FDA to return submissions for revisions and clarifications. Resubmitting a submission causes delays in the clearance process which result in delays in getting your product to market. A complete and well structured 510(k) submission will give you a higher probability of FDA clearance on the first pass.

Third party review programs, such as Intertek's Five, Ten or Fifteen Day Reviews, also provide a higher probability of success for clearance on the first pass and shorten your time to market. The FDA is required to respond to Intertek's submission within 30 days, compared to the 90 days the FDA can take to respond to a direct submission. Intertek can help you get your product to market faster - as much as 50 days faster!

About Intertek

Intertek provides quality and safety solutions to a wide range of industries, through a network of 25,000 people in 1000 laboratories and offices in 100 countries around the world.

For more information about how Intertek's Five, Ten or Fifteen Day 3rd party 510(k) review can help you increase your chances of approval on your first submission and shorten your time to market visit our web site at www.intertek.com/510k or call 800-WORLDLAB (Outside the US call 978-635-8690).

This publication is copyright Intertek and may not be reproduced or transmitted in any form in whole or in part without the prior written permission of Intertek. While due care has been taken during the preparation of this document, Intertek cannot be held responsible for the accuracy of the information herein or for any consequence arising from it. Clients are encouraged to seek Intertek's current advice on their specific needs before acting upon any of the content.



Links

¹ Guidance for Format of Traditional and Abbreviated 510(k) Submissions

<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084396.pdf>

² Section 701 of the Federal Food Drug and Cosmetic Act

<http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCA/FCActChapterVIIGeneralAuthority/ucm109349.htm>

³ ODE Indications for Use

<http://www.fda.gov/ScienceResearch/SpecialTopics/CriticalPathInitiative/ArticlesandPresentations/ucm080275.htm>

⁴ OIVD Indications for Use

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/IVDRegulatoryAssistance/ucm142725.htm>

⁵ Truthful and Accurate Statement

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/Pre-marketSubmissions/PremarketNotification510k/ucm142707.htm>

⁶ Premarket Notification Class III Certification and Summary

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/Pre-marketSubmissions/PremarketNotification510k/ucm142662.htm>

⁷ FDA Form 3674

<http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM048364.pdf>

⁸ FDA Form 3454

<http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM048304.pdf>

⁹ FDA Form 3455

<http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM048310.pdf>

¹⁰ FDA Form 3654

<http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM081667.pdf>

¹¹ 510(k) Review Template

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/Pre-marketSubmissions/PremarketNotification510k/ucm071420.htm>

¹² 510(k) Review Template Instructions

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/Pre-marketSubmissions/PremarketNotification510k/ucm071484.htm>

¹³ Sterile Devices in Premarket Notification [510(k)] Submissions

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/Pre-marketSubmissions/PremarketNotification510k/ucm134828.htm>

¹⁴ Guidance for the Content of Premarket Submission for Software Contained in Medical Devices

<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089593.pdf>