The Beginner's Guide to

The FDA 510(k)

Rimsys®

Contents

Introduction

Introduction

Congratulations! You have successfully developed a new medical device. Now you need to take it to market. In the United States, this often means submitting a 510(k). A 510(k) is a structured package of information about your device and its performance and safety that you submit to the Food and Drug Administration (FDA) for "clearance" before you can sell your device in the U.S. In order to receive clearance from the FDA, your 510(k) will need to demonstrate that your medical device is **substantially equivalent to another legally marketed device (called a predicate device)**. The substantial equivalence approval process is a simple equation that looks something like this:

The 510(k) is generally the most efficient route to market clearance in the U.S. because you show your device is safe and effective based on this substantial equivalence standard, instead of needing to present more extensive clinical trial data.

There are three types of 510(k): Traditional, Abbreviated, and Special. This eBook will begin with a general overview of the 510(k) process, including its purpose and benefits. Next, we will explore the Traditional 510(k) and the sections and components required in depth. Finally, we will look at the Special and Abbreviated 510(k).

Chapter 1

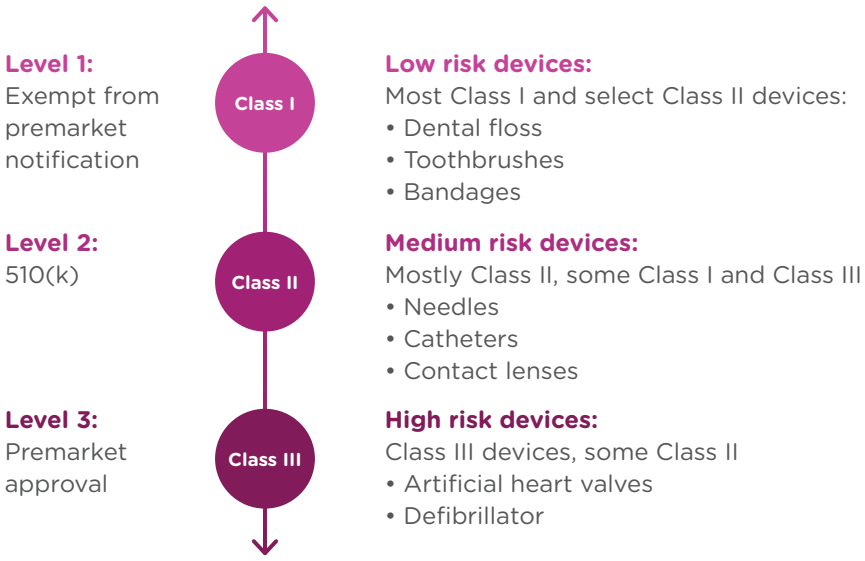
510(k) Basics

Chapter 1: 510(k) Basics

FDA: Background and Device Oversight

Before we explain what a 510(k) is let's first talk generally about the FDA and device oversight. The FDA is the U.S. governmental agency responsible for overseeing medical devices, drugs, food, and tobacco products. When it comes to medical devices, the FDA's mission is to "protect the public health by ensuring the safety, efficacy, and security of...medical devices." At the same time, the FDA also has an interest in "advancing public health by helping to speed innovations." In other words, the FDA's goal is to make sure devices are safe and effective for public use, while also ensuring that devices have a quick and efficient path to market.

In order to achieve this balance of safety and efficiency, the FDA has three different levels of oversight depending on the risk level of the device: (1) exempt from premarket submission, (2) Premarket Notification, also known as 510(k), and (3) Premarket Approval (PMA).



When is a 510(k) Required?

A 510(k) is required for medium risk devices that have a predicate on the market which can be used to demonstrate the safety and effectiveness of the new device. Meanwhile, a PMA is required for high-risk or novel devices which require a higher level of scrutiny to be confirmed safe and effective.

A 510(k) is not only required for new devices, but also for devices that have been **modified in a way that could impact safety or effectiveness**. This could include changes to the:

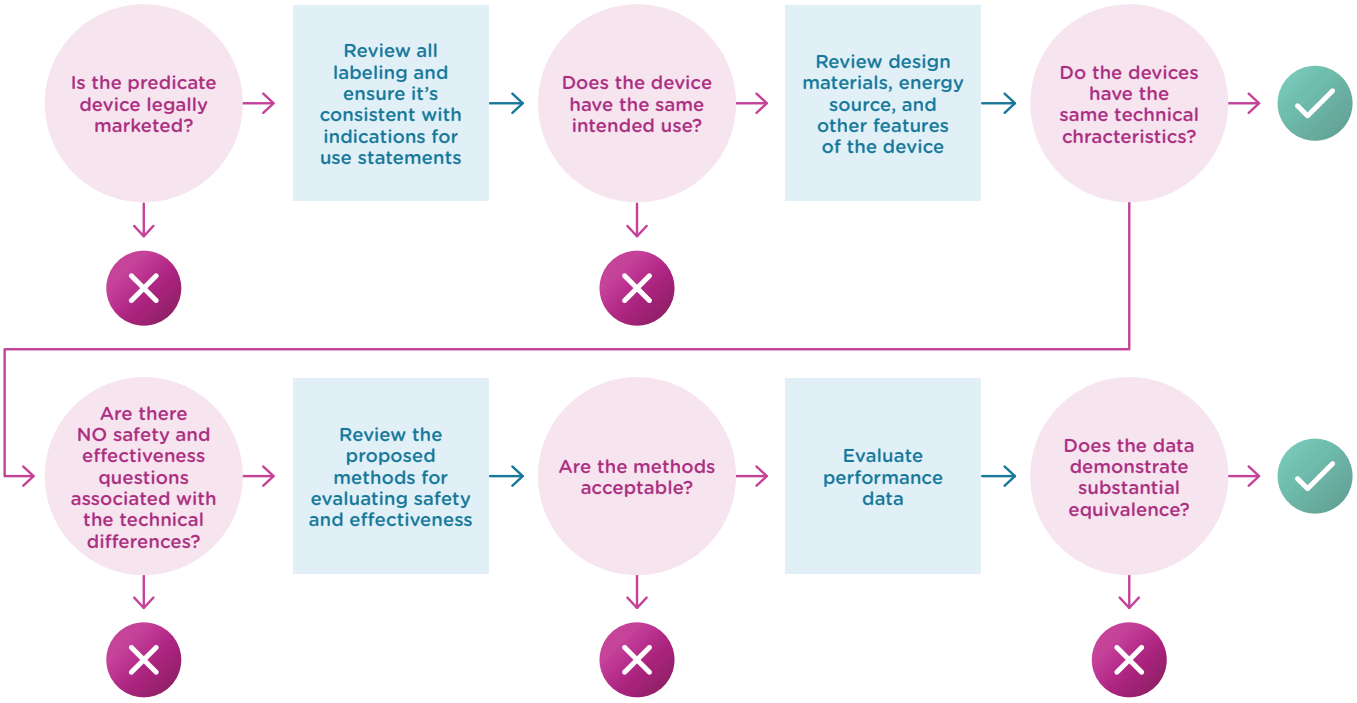
- Design
- Components
- Materials
- Chemical composition
- Energy source
- Manufacturing process
- Intended use

You must submit your 510(k) **at least 90 days before marketing** the device.

What Exactly is Substantial Equivalence?

Now that we know what a 510(k) is, let's talk about the substantial equivalence standard. You'll recall from the introduction that your 510(k) must show that the new (or modified) device is **substantially equivalent to at least one other legally marketed device, called a predicate device**. Substantial equivalence looks at the intended use and the technological characteristics of the two devices. More specifically, you must show:

1. that the new device has the **same intended use** as the predicate, and
2. the differences between the two devices **do not raise questions about the safety and effectiveness** of the new device.



Now let's take a closer look at **intended use** and **technological characteristics**.

Intended Use

Intended use means the **general purpose or function of the device**. The FDA will look at your proposed labelling and your Indications of Use section of the 510(k) to determine the intended use of your device (this is covered in Chapter 2). Intended use includes:

The disease(s) or condition(s) the device is intended to address

How the device will be used (i.e. for diagnosis, prevention, or treatment)

The intended patient population

Clinical context or setting where the device will be used

Technological Characteristics

Once the FDA has determined that a predicate device exists and that the new device and the predicate device have the same intended use, it will move on to compare the technological characteristics. Technological characteristics include:

- Materials
- Design
- Energy source
- Other device features

The two devices do not have to be identical, and in fact they almost never are. The key here is to demonstrate that any differences do not have a significant impact on safety or effectiveness. Here's what to cover when you compare your device's technological characteristics with that of the predicate device:

Overall description of the device design	• Engineering drawings or diagrams to explain the device and component parts. • List of component parts and explanation of how each component contributes to the overall use and function of the device. • Physical specifications: dimensions, weight, temperature, tolerances, etc.
Materials	• Detailed chemical formulation used in all materials of constructions (especially those that come into contact with a patient). • Any additives, coatings, paint, or surface modifications. • How materials have been processed and what state they're in.
Energy Sources	• Use of batteries, electricity, etc.
Other technological features	• Software/hardware • Features • Density • Porosity • Degradation characteristics • Nature of reagents • Principle of the assay method

In deciding whether the differences in technological characteristics impact safety or effectiveness, the FDA will typically rely on descriptive information about the technological characteristics as well as non-clinical and clinical performance data.

Let's look at an example: A manufacturer submits a 510(k) for a new type of contact lens. Both the new device and the predicate device are indicated for daily wear for the treatment of astigmatism. The predicate device is only available in a clear lens, but the new device comes in a line of colors, including purple tinted lenses.

	 Predicate Device	Comparison	 New Device
Intended Use	• Single Use • Treats Astigmatism	Same	• Single Use • Treats Astigmatism
Technical Characteristics	Clear	Different, but does not raise questions of safety or effectiveness	Purple

Who is Responsible for Submitting a 510(k)?

The following four types of organizations may be responsible for submitting a 510(k):

Manufacturers	• End-of-line device manufacturers who will be placing a device on the U.S. market. • Note: Does not apply to component part manufacturers unless components will be marketed independently.
Specification Developers	• Companies that develop the specifications for a finished device which has been manufactured elsewhere
Repackers or Relabelers	• Required to submit a 510(k) if they significantly alter the labeling or condition of the device, including modification of manuals, changing the intended use, deleting or adding warnings, contraindications, sterilization status. • *Note: This is rare. The manufacturer, not the repackager or labeler, is typically responsible for the 510(k) submission.*
Importers	• Importers that introduce a new device to the U.S. market may need to submit a 510(k), if it hasn't already been submitted by the manufacturer.

Chapter 2

Contents of a Traditional 510(k)

Chapter 2: Contents of a Traditional 510(k)

Now that we've covered the basics, let's explore what actually goes into your 510(k).

A Traditional 510(k) should contain all the following components in the list below. In some cases, a particular section may not apply to your device. When that happens, it's a good idea to include the section anyway and just state "This section does not apply" or "N/A" under that heading.

1. Medical Device User Fee Cover Sheet (Form FDA 3601)
2. Center for Devices and Radiological Health (CDRH) Premarket Review Submission Cover Sheet (Form FDA 3514)
3. 510(k) Cover Letter
4. Indications for Use Statement
5. 510(k) Summary or 510(k) Statement
6. Truthful and Accurate Statement
7. Class III Summary and Certification
8. Financial Certification or Disclosure Statement
9. Declarations of Conformity and Summary Reports
10. Device Description
11. Executive Summary and Predicate Comparison
12. Substantial Equivalence Comparison
13. Proposed Labeling
14. Sterilization 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. Let's look at the requirements of each of these sections:

1. User Fee Cover Sheet

The Medical Device User Fee Cover Sheet (FDA Form 3601) is essentially a receipt showing that you have registered with the FDA and paid for your 510(k) submission. This process can be completed online here: Medical Device User Fee Cover Sheet and instructions.

2. CDRH Premarket Review Submission Cover Sheet or Equivalent

The second component of the 510(k) is the CDRH Premarket Review Submission Cover Sheet (FDA Form 3514), available here. This is a 7 page form that provides basic administrative information to help the FDA understand some basics about who you are and what your submission is for. This includes the type of 510(k) you are submitting, contact information, and basics about your device. Here's a snapshot of the cover sheet.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approved: OMB No. 0910-0120
Expiration Date: June 30, 2023
See PRA Statement on last page.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(If known)*

SECTION A — TYPE OF SUBMISSION

PMA & PDP	PMA/PDP Supplement	510(k)	CLIA	Q-Submission
☐ Original ☐ Modular Submission ☐ Amendment ☐ Report (annual or PAS) ☐ Report Amendment ☐ Other: ☐ Premarket Report (reprocessed SUD) ☐ Licensing Agreement	☐ 180 day - PAS protocol or labeling change, location change, trade name change ☐ 180 day - Design or labeling change ☐ Special CBE ☐ Panel Track ☐ 30-day Notice ☐ Real-time Review ☐ Amendment to PMA/PDP Supplement	☐ Original Submission: ☐ Traditional ☐ Special ☐ Abbreviated ☐ 3rd Party Traditional ☐ 3rd Party Special ☐ 3rd Party Abbreviated ☐ Dual Track (Dual 510(k) and CLIA Waiver by Application) ☐ Amendment ☐ Supplement	CLIA Categorization Record (CR) ☐ Original ☐ Amendment CLIA Waiver by Application (CW) ☐ Original ☐ Amendment ☐ Supplement	☐ Pre-Submission ☐ Informational Meeting ☐ Submission Issue Meeting ☐ Day 100 Meeting ☐ Agreement Meeting ☐ Determination Meeting ☐ Study Risk Determination ☐ Other *(Specify below)*

IDE	HDE	Class II Exemption Petition	De Novo	Other Submission
☐ Original IDE: ☐ Amendment to Original IDE ☐ Supplement: ☐ Amendment to Supplement	☐ Original Submission ☐ Amendment to Original ☐ Report ☐ Report Amendment ☐ HDE Supplement:	☐ Original Submission ☐ Additional Information	☐ Original: ☐ Direct ☐ Post-NSE ☐ Amendment ☐ Supplement	☐ 513(g) ☐ Appeal ☐ Other *(Briefly describe submission below)*

3. 510(k) Cover Letter

The 510(k) cover letter should give the reviewer a basic overview of your 510(k). While the CDRH Cover Sheet covers general administrative information, your cover letter will be more descriptive of your device (but not as descriptive as your 510(k) summary). Appendix A contains a sample Cover Letter sheet. Your cover letter should include the following:

- Type of 510(k) submission (abbreviated, traditional, special, de novo, etc.)
- Common name of the device
- Company/organization submitting the 510(k)
- Primary point of contact for FDA correspondence
- Preference for confidentiality, if applicable
- Classification (class I, II, or III) of your device
- Review Panel
- Product Code
- Any FDA document numbers associated with your prior correspondence with the FDA (ie a prior 510(k))
- Basis for the submission (is this a new device, modification to a legally marketed device, new indication of use for an existing device, etc.)
- Table outlining principal factors about the design and use of the device

4. Indications for Use Statement

The Indications for Use Statement is a specific form (FDA form 3381) where you describe how your device will be used. Make sure that your indications for use statement is consistent with all of your device labeling. Your indications for use should include the following:

- Specific details of how the device will be used
- Clinical settings in which it will be used
- Target population
- Anatomical sites
- Whether it's intended for prescription and/or over-the-counter use

Below is an Indications for Use Statement for a manual wheelchair. Although this statement is brief, it effectively describes what the device is used for (to provide mobility) and who the target population is (those restricted to a sitting position)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K180852

Device Name
Manual wheelchair

Indications for Use *(Describe)*
The device is intended for medical purposes to provide mobility to persons restricted to a sitting postion

A bit of strategy and creativity is helpful in writing this section. This statement sets the boundaries for how your device can be used. If your description is too narrow, you may limit future marketing options. On the other hand, in order to gain FDA clearance, your 510(k) must demonstrate substantial equivalency to the predicate device. If the indications of use statement departs too drastically from the predicate device, or is too broad, you run the risk of not gaining market clearance.

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

A 510(k) Summary is a condensed version of all the content of your 510(k). It will be made available to the public 30 days after your 510(k) is cleared, so be mindful of the details you include! The FDA website provides guidance on the content of your 510(k) summary. We've summarized those requirements for you in Appendix C.

If you don't wish to provide a 510(k) Summary, you have the option to choose a 510(k) Statement instead which is a certification that you will provide a copy of your 510(k) submission to any person who requests it within 30 days. You may decide to provide a 510(k) Statement instead of a Summary in order to keep information from being publicly disclosed, however keep in mind that those who request information will receive a much more extensive version of your 510(k) than they would with a 510(k) Summary.

6. Truthful and Accurate Statement

This is a statement certifying that all of the information submitted in your 510(k) is truthful and accurate and that no information has been omitted. The language required for this statement can be accessed here. This section must be signed by the 510(k) holder/manufacturer.

Premarket Notification Truthful And Accurate Statement

[As Required by 21 CFR 807.87(l)]

I certify that, in my capacity as (*the position held in company*) of

(company name), I believe to the best of my knowledge, that all data

and information submitted in the premarket notification are truthful and

accurate and that no material fact has been omitted.

_____

(Signature)

7. Class III Summary and Certification

This section only applies if your 510(k) is for a Class III device. Recall from Chapter 1 that a Class III device is a device that is used to sustain or support human life, is implanted, or presents a potential unreasonable risk of illness or injury, such as a pacemaker or defibrillator. The Class III Summary and Certification serves two purposes. First, it provides a summary of the types of safety and effectiveness problems that have been associated with your particular type of device. Second, it certifies that you have thoroughly researched the safety and effectiveness of your Class III device and other similar legally marketed devices. The FDA provides standardized language for the Class III certification statement which is available here.

Note: Even if your device is not Class III, it's better to include this section anyway and just state that it "does not apply."

8. Financial Certification or Disclosure Statement

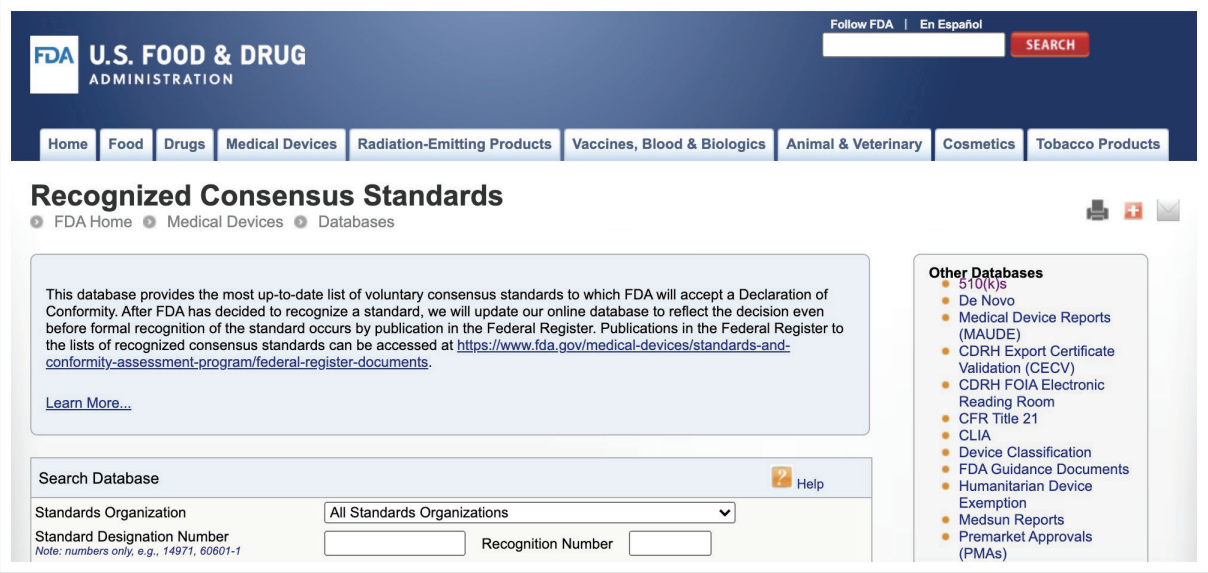
If your 510(k) includes clinical studies, you must submit a financial certification and/or a disclosure statement for each clinical investigator who participated in your study. The purpose here is to share any arrangements or financial interests that exist between the clinical investigator and the device manufacturer, and certify that those financial interests do not compromise the validity of the clinical study results. In other words, you are assuring the FDA that they can trust the clinical data for your device. The FDA provides 2 forms to complete for this section:

- Certification: Financial Interests and Arrangements of Clinical Investigators (Form FDA 3454)
- Disclosure: Financial Interests and Arrangements of Clinical Investigators (Form FDA 3455)

For more information, you can access the FDA guidance document regarding financial disclosure requirements here.

9. Declarations of Conformity and Summary Report

A declaration of conformity is a certification that you have followed a specific set of rules, called a consensus standard, in designing your product and/or testing it for safety and effectiveness. A consensus standard is a set of rules or principles that have been agreed upon and approved by a recognized body, such as the International Organization for Standardization ("ISO"). ISO 13458 is an example of a common consensus standard: it addresses quality management for medical devices.

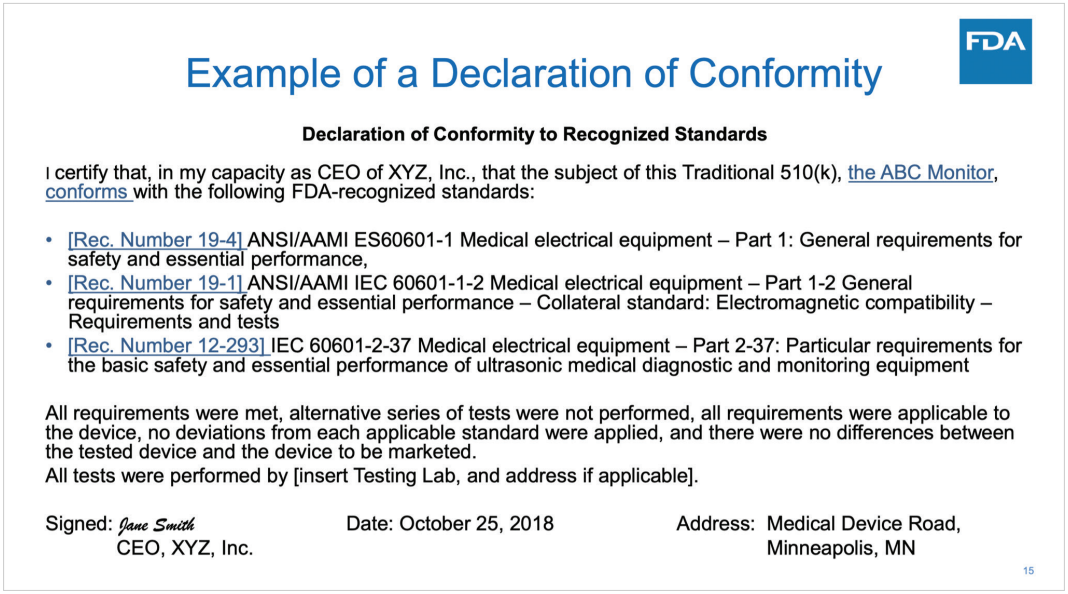


Conformity with a consensus standard is voluntary, but it helps to assure the FDA that your design is optimal and your safety and effectiveness data is reliable. It can also reduce the amount of supporting data you need to submit to the FDA in order to prove substantial equivalence or safety and effectiveness. These assurances ultimately streamline your device's path to market by increasing FDA confidence in protecting the public health, which is a benefit to everyone! The FDA keeps a publicly accessible database of recognized consensus standards.

The Declarations of Conformity section is especially important if you are submitting an Abbreviated 510(k). With that type of submission you are telling the FDA that your device is safe and effective because it conforms with a consensus standard (or multiple standards) that are recognized by the FDA as safe and effective. For more information on how to use voluntary consensus standards in your 510(k), you can consult this FDA guidance document.

The requirements of a Declaration of Conformity ("DOC") as outlined in ISO/IEC 17050-1 are:

- Name and address of the applicant/sponsor responsible for the DOC
- Product/device identification, including product codes, device marketing name, model number and any other unique product identification data specific to the DOC in question
- Statement of conformity
- A list of standards for which the DOC applies including, for each standard, the options selected, if any
- The FDA recognition number for each standard
- The date and place of issuance of the DOC
- Signature, printed name, and function of the sponsor responsible for the DOC
- Any limitation on the validity of the DOC (e.g., how long the declaration is valid, what was tested, or concessions made about the testing outcomes)



Example of a Declaration of Conformity

Declaration of Conformity to Recognized Standards

I certify that, in my capacity as CEO of XYZ, Inc., that the subject of this Traditional 510(k), the ABC Monitor, conforms with the following FDA-recognized standards:

- [Rec. Number 19-4] ANSI/AAMI ES60601-1 Medical electrical equipment – Part 1: General requirements for safety and essential performance,
- [Rec. Number 19-1] ANSI/AAMI IEC 60601-1-2 Medical electrical equipment – Part 1-2 General requirements for safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests
- [Rec. Number 12-293] IEC 60601-2-37 Medical electrical equipment – Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment

All requirements were met, alternative series of tests were not performed, all requirements were applicable to the device, no deviations from each applicable standard were applied, and there were no differences between the tested device and the device to be marketed.
All tests were performed by [insert Testing Lab, and address if applicable].

Signed: *Jane Smith*
CEO, XYZ, Inc.

Date: October 25, 2018

Address: Medical Device Road,
Minneapolis, MN

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10. Device Description

This section is where you provide the most detailed description of your device. The FDA isn't looking for brevity here - you can plan to send over most of your design history file. Your device description should contain 2 parts: a narrative description of your device and the physical or technical specifications of the device.

The **narrative description** must include the following:

- Product or trade name
- General description - including the intended purpose (must be consistent with labelling)
- UDI - if available
- Indications for use - including intended patient population, medical condition it addresses, whether it's used for diagnosis, treatment, preventative care, etc.
- Principles of operation: including how the device will be used or implanted, anatomical location, how the device interacts with other devices and the patient, etc.
- Risk class and applicable classification rule
- Description of components, accessories, and any other devices or materials that will be used in combination with the device
- Power source
- Composition
- Any other information necessary to understand the device. *Note – If the 510(k) is for an accessory or component sold directly to a consumer or end-user, describe the device with which the part will be used.*

The **physical specifications** of the device should include:

- Description of various configurations
- General description of key functional elements: including diagrams, photographs, and engineering drawings
- Raw materials used, and any that make direct or indirect contact with the human body
- Specific technical specifications, including: length, width, heigh, diameter, and weight of the device
- Previous generations of the device
- Any parts which are intended for single use
- Any other information related to a special controls guidance document for the particular device.

11. Executive Summary and Predicate Comparison

The Executive Summary is an expansion of the 510(k) Summary covered in Section 5. The main difference is that the Executive Summary IS NOT publicly released, unlike the 510(k) Summary. This means that the Executive Summary can (and probably should) include much more detail and/or sensitive information than your 510(k) Summary—which should be more succinct. A key component of the Executive Summary is a table comparing your device with the predicate device.

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

In addition to the comparison table, the Executive Summary also includes a **description of your medical device** (including the indications for use and type of technology used), test report summary (including type of testing, methods, and conclusions drawn), and **conclusions of substantial equivalence** based on your performance testing.

12. Substantial Equivalence Discussion

Congratulations on making it this far! We've made it to the critical part of your 510(k) where you demonstrate substantial equivalence. As we discussed earlier, substantial equivalence is the process of showing that the new (or modified) device has **the same intended use and similar technical characteristics to at least one other legally marketed predicate device**. Through this comparison to a device that has already been deemed safe and effective by the FDA, you show that your device is also safe and effective.

You will begin this section by identifying the predicate device and stating its trade name, model number, 510(k) submitter/holder, and 510(k) number, if available. Then you will need to show substantial equivalence to the predicate device in the following areas:

- Indications for use
- Technology
- Design
- Energy source
- Materials
- Performance specifications, including testing
- Safety
- Effectiveness
- Labeling
- Any other applicable characteristics, such as sterility

It's important to note that substantial equivalence does not mean identical. Differences can and likely will exist. The key is to demonstrate to the FDA that those differences do not adversely affect safety and effectiveness. Information to support your safety and effectiveness claims can come from bench testing, animal studies, clinical studies, or clinical trials.

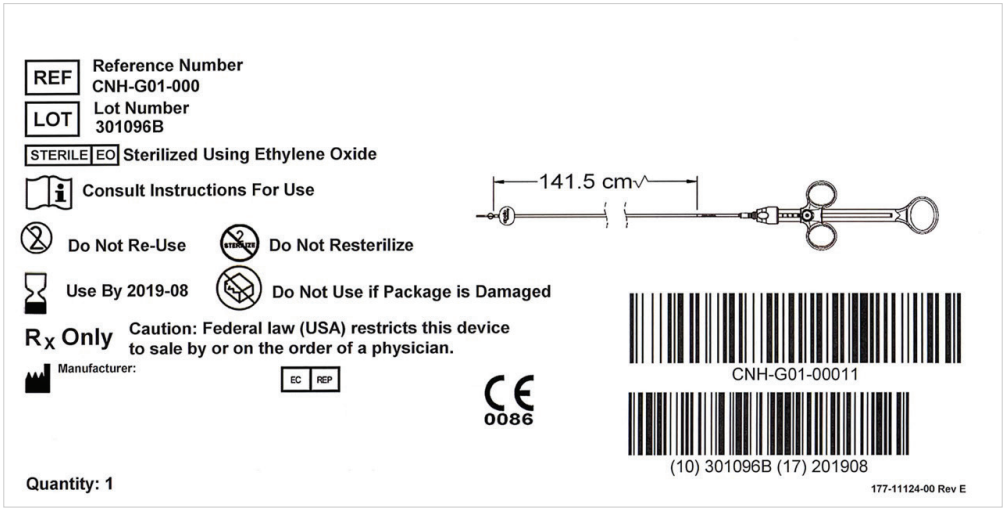
Your substantial equivalence information should be organized in a table that outlines the similarities and differences between the new device and the predicate device. Let's look at an example of a substantial equivalence comparison table:

Element of Comparison	New Device	Predicate Device
510(k) Number		
Regulation Number		
Regulation Name		
Regulatory Class		
Product Code		
Intended Use		
Indications for Use		
Technological Characteristics		
Power Source		
Standards Compliance		
Sterility		
Biocompatibility		

13. Proposed Labeling

The FDA wants to make sure that what you tell the public about your device is clear, accurate, and not misleading in any way. You will need to submit all proposed labeling to the FDA for review in your 510(k), including:

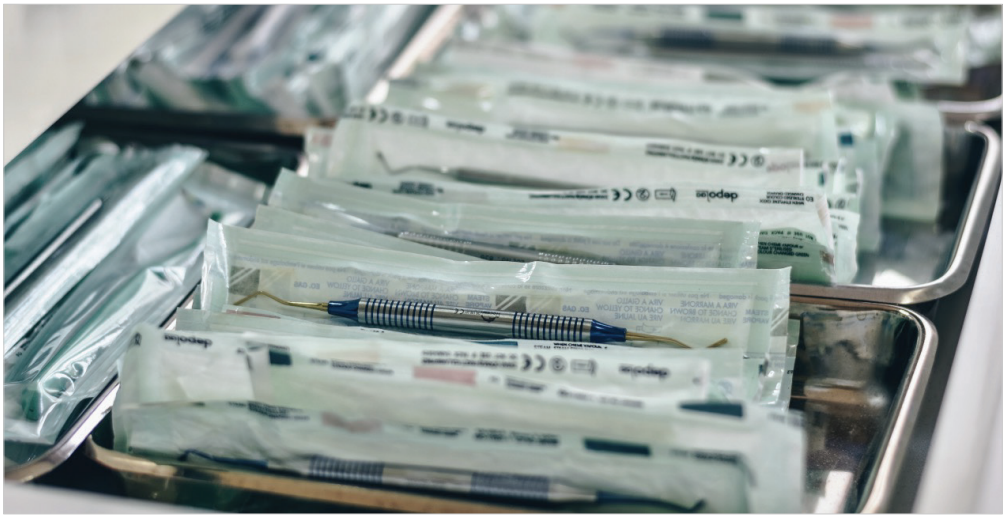
- Package inserts
- Service manuals
- Instructions for use
- Advertising
- Website content
- Promotional materials



The FDA will review all proposed labelling that you submit to ensure that it is consistent with your intended use statement and accurately conveys warnings, contraindications, or limitations.

14. Sterilization and Shelf Life

The FDA will also review your claims regarding sterility and shelf life to make sure that they are supported by data and consistent with ensuring patient health and safety. If you intend to market your device as sterile, you will need to explain the sterilization method used. Similarly, the FDA will want to review your claimed shelf life to ensure its validity.



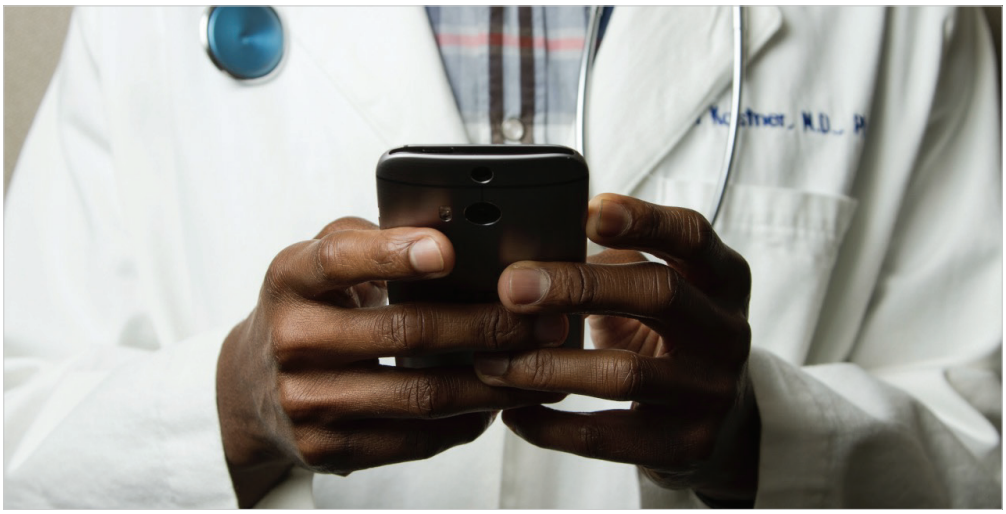
Consensus standards can come in handy here; the FDA has published a guidance document approving certain types of sterilization methods as safe and effective.

15. Biocompatibility

If your device will have direct or indirect contact with human tissue, you must include biocompatibility testing to show that the materials are safe and won't cause an adverse biological response when it comes into contact with the body. You can find the guidance for biocompatibility testing and discussion here.

16. Software

If your device includes or uses software, you will need to provide specific documentation about it. Start by identifying the device's **Level of Concern**, which is an estimate of the severity of injury that the device could inflict as a result of device failures, design flaws, or simply by virtue of employing the device for its intended use. The level of concern can be minor, moderate, or major.



Next, provide documentation that shows you have accurately identified the potential hazards and how you plan to manage those risks appropriately. This guidance document explains how to determine your device's level of concern and specifies the documentation you must then provide.

Lastly, be sure to include the cybersecurity controls you plan to implement to ensure privacy and protection of information.

17. Electromagnetic Compatibility and Electric Safety

If your device requires electricity to operate, you will have to provide information about its electromagnetic compatibility and electric safety. In particular, you must show whether there is any potential for interference to or interference from other electronic products, and provide information to prove that the device appropriately accommodates for that interference and is electrically safe. For more information, you can refer to the FDA Guidance: "Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically-Powered Medical Devices."

18. Performance Testing – Bench

This is the first of three sections where you show performance data to support your claim of substantial equivalence. The first section is dedicated to bench performance testing, which is **design verification and validation** testing. Bench performance testing can include:

- Mechanical and biological engineering performance: such as fatigue, wear, tensile strength, compression, and burst pressure
- Tests using human tissue or animal tissue
- Human or animal cadaver testing

Your test report summary should include:

- **Tests performed:** including any guidance documents or consensus standards followed
- **Test objectives:** the goal that the test accomplishes
- **Test methods**: including sample size, devices tested, and consensus standards utilized
- Definition of **acceptance criteria** (criteria that determines whether your device passes or fails the test), if applicable
- **Summary of data**:
  - Quantitative results: including mean, standard deviation, minimum and maximum, etc.
  - Qualitative results: observations
- **Discussions and Conclusions**: how does your data provide evidence of substantial equivalence and/or safety and effectiveness

In preparing your performance test results, remember that the FDA loves tables! Here's an example of how you might use a table to organize your summary results:

Test Performed	Test title, document number, location in file
Device Description/ Sample Size	Test/control article identification, sample size
Test Method/ Applicable Standards	Test method used, preconditioning, consensus standards used
Acceptance Criteria	Include clinical/scientific/engineering justification
Unexpected Results / Significant Deviations	Report any unexpected results or significant deviations with an explanation of how they do not affect the overall conclusion
Results	Pass/Fail **or** Min, Max, Average, **or** Qualitative results

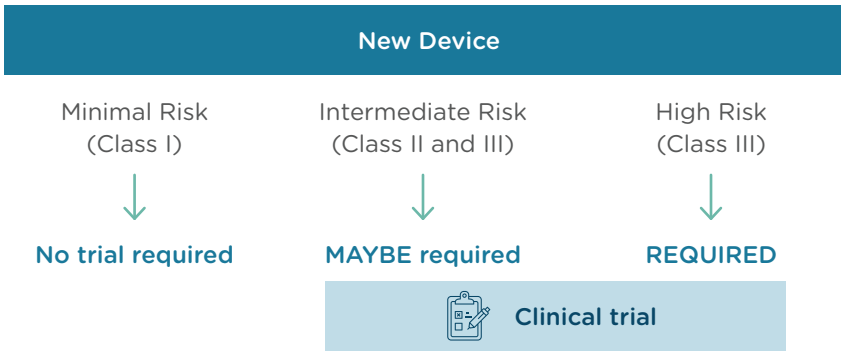
Note: DO NOT include any raw data in this section. If you feel you need to include it, add it as an appendix.

19. Performance Testing – Animal

You are not required to do any testing on animals, and the FDA will always consider alternatives to animal studies where appropriate. Any data included here should be presented following the same guidelines as bench testing.

20. Performance Testing – Clinical

Clinical testing means testing on human subjects. Clinical testing is typically not required in the 510(k) process, but the FDA may require it in situations where the device is considered high-risk. These requirements will be outlined in the guidance document for your device group.



If clinical testing is necessary, you must include a Certificate of Compliance with the requirements of the ClinicialTrials.gov Data Bank (FDA Form 3674) to verify that you are following all applicable regulations.

Quality and safety regulations are outlined in the **Good Clinical Practice (GCP)** guidelines, which are available here.

Chapter 3

510 (k) Submission and Timelines

Chapter 3: 510 (k) Submission and Timelines

510(k) Checklist

Hooray! You have finished preparing your 510(k) and are now wondering what comes next. Before you submit your 510(k) you should thoroughly check to make sure it is complete. Luckily, the FDA has prepared helpful checklists for you to use. There is a separate checklist for the Traditional, Abbreviated, and Special 510(k), available here. As you go through the checklist, write down the page number that corresponds with each required section in the checklist, and include this in your 510(k) submission. It acts as a Table of Contents and also assures the FDA that you have reviewed your 510(k) for completeness.

510(k) Review Process and Timeline

The FDA will conduct two reviews of your 510k: (1) an acceptance review, and (2) a substantive review. The acceptance review will be done within 15 days from receipt of your submission and confirmation that the user fee has been paid.

Within those 15 days the FDA will either accept the 510(k) submission for substantive review, or will refuse to accept (RTA) the submission. If the submission is refused, the FDA will send a RTA letter along with a list of sections that are required for the submission to be accepted.

Once the submission is accepted, the substantive review begins. This is the stage where the FDA fully reviews all of the information you've provided, and determines substantial equivalence. The substantive review is typically completed within 60 days of the 510(k) being accepted.

After that, the FDA will complete your 510(k) review and issue a decision within 90 days of the 510(k) being accepted.

Day 1

The FDA receives 510(k) application

Within 7 days

FDA sends an Acknowledgement Letter or a Hold Letter of there are issues with user fees and/or eCopy

By day 15

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

By day 60

The FDA conducts a Substantive Review. The FDA communicates Substantive Interaction with the applicant that indicates whether the FDA will proceed with an Interactive Review or ask for Additional Information.

By day 90

FDA sends final MDUFA Decision on 510(k)

By day 100

If a MDUFA Decision is not reached by day 100, the FDA provides a Missed MDUFA Decision Communication that identifies any outstanding review issues.

Chapter 4

Other Types of 510(k)

Chapter 4: Other Types of 510(k)

In addition to the Traditional 510(k) that we've detailed in Chapter 2, there are other (less intensive) versions that can be used in certain circumstances.

Abbreviated 510(k)

An Abbreviated 510(k) is an optional submission method where you rely on guidance documents, special controls, and/or consensus standards to show substantial equivalence. In doing so, you streamline the amount of data needed to prove substantial equivalence or safety and effectiveness. In this approach your reliance on guidance documents, special controls, and/or consensus standards ensures that your design and testing is optimal and that your device is safe and effective.

An Abbreviated 510(k) includes **all of the same sections as a Traditional 510(k)**, but you do not have to provide as much data about your product. You must include a summary report describing the guidance, special controls, and/or consensus standard(s) your device complies with; this is included in Section 9 with the Declarations of Conformity. The Summary Report must also describe your device's design, risk management information, and test methods used to address performance characteristics.

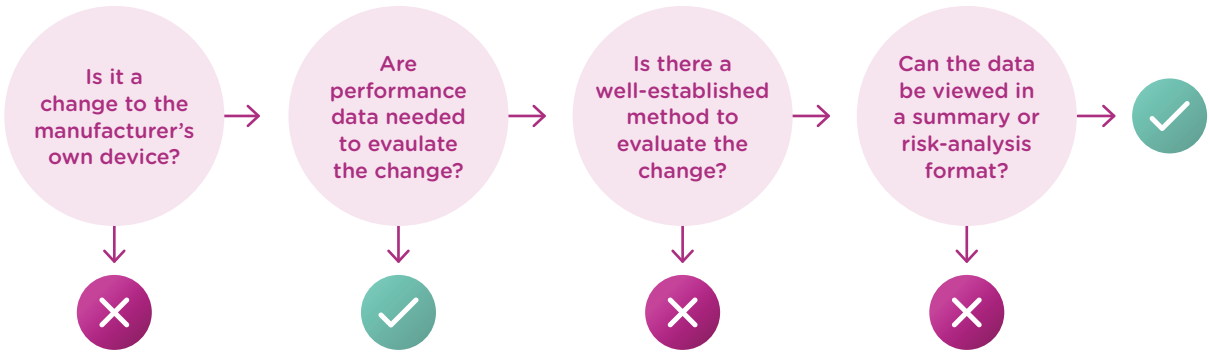
If the FDA does not believe that your device meets criteria for an Abbreviated 510(k) submission, it will reclassify it as a Traditional 510(k) and notify you of the change.

Special 510(k)

A Special 510(k) is another voluntary 510(k) submission method you can use when you have made a modification to your own legally marketed device. The FDA reviews Special 510(k) submissions within 30 days of receipt, instead of the traditional 90 days for Traditional and Abbreviated 510(k)s. In order to qualify for the Special 510(k) process, the modification has to meet the following requirements:

1. The proposed changes are to the manufacturer's own predicate device
2. Performance data is unnecessary OR if performance data is necessary, there are well-established methods available to evaluate the change
3. All performance data necessary to support substantial equivalence can be reviewed in a summary or risk analysis format.

Here's a flowchart to help demonstrate when a Special 510(k) is appropriate:



Change APPROPRIATE for review in a Special 510(k)

Change INAPPROPRIATE for review in a Special 510(k)

Let's break these requirements down further and look at some examples.

1. Is it a change to the manufacturer's own device?
   This requirement is pretty self-explanatory. If you are not the manufacturer of the predicate device, you cannot use a Special 510(k).
2. Is performance data needed to evaluate the change being made?
3. Let's look at an example of this: Say you are the producer of metal bone screws that were previously sold as unsterilized. You are now seeking clearance to sell the same bone screws pre-sterilized with a novel sterilization method that has not been used before. The FDA will need to look at performance data to ensure that your novel sterilization method is safe and effective. In this case, a Special 510(k) is not appropriate and you will need to submit a Traditional 510(k).
4. If performance data is required, is there a well-established method to evaluate the change?
5. Let's look at the same example again, but this time the screws will be sterilized using gamma irradiation. The FDA recognizes this as a well-established sterilization method. Because of this, the safety and effectiveness of the device can be verified without additional performance data. You just need to show that you conform with the consensus standards for gamma irradiation sterilization. Here, you can now use a Special 510(k) for your modification.
6. Can the data be reviewed in a summary or risk analysis format?

The last factor is that you must be able to summarize your data in a summary or risk-analysis format in order to use a Special 510(k). In other words, if you need to provide the FDA with underlying data, such as images, raw graphs, or line-item data in order to show substantial equivalence, you will need to submit a Traditional 510(k).

Let's return to our bone screw example: your device is being modified to be sold pre-sterilized through gamma irradiation sterilization. A Special 510(k) is appropriate here, because the safety and effectiveness of this change can be reviewed through a risk-analysis format like this:

Device Change	Risk	Verification/ Validation Method(s)	Acceptance Criteria	Summary of Results
Gamma iradiation sterilization	Patient infection	Sterilization validation was completed using an established method (gamma irradiation) in conformity with ISO 11137-1 without deviation. The sterilization validation approach was Verification Dose Maximum (VD_{max}) for a Sterility Assurance Level (SAL) of 10-6 in accordance with AAMI TIR33.[82] Package integrity testing was also conducted using methods consistent with the predicate device (seal integrity, dye penetration, and visual inspection).	Devices shall maintain package integrity and have SAL of 10^{-6}.	Package integrity testing results all passed (n=30 each). Bioburden studies passed. Sterilization validation established SAL of 10^{-6}.

Summary

Summary

Nice work! You are hopefully now an expert on the 510(k) and the regulatory steps required to bring a new device to market in the U.S. To recap: 510(k) is the premarket notification required for FDA clearance before you can market a new or modified device that is medium-risk. It provides information for the FDA to confirm that your device is safe and effective for its intended use. In order to receive clearance, your 510(k) must demonstrate that your medical device is substantially equivalent to another legally marketed predicate device. Substantial equivalence looks primarily at the intended use and technological characteristics of the new device and predicate device.

There are three types of 510(k)s: Traditional, Abbreviated, and Special. A Traditional 510(k) is the most thorough and proves substantial equivalence through performance data. An Abbreviated 510(k) relies on guidance documents, special controls, and/or consensus standards to show substantial equivalence, and therefore streamlines the amount of performance data needed. Lastly, a Special 510(k) is an expedited submission process specific for modifications made to a manufacturer's own legally marketed device.

Traditional and Abbreviated 510(k)s require 90 days for review, although that timeline may expand if the FDA requires more information prior to giving clearance. Meanwhile, the FDA requires 30 days to review a Special 510(k).

Appendix

Appendix A: Sample 510(k) Cover Letter

Company letterhead

U.S Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center - WO66-0609
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

RE: Traditional 510(k) Pre-Market Notification
Company name
Device trade name

To whom it may concern:

The enclosed 510(k) Pre-Market Notification requests clearance for the (Device trade name). General information for the subject device is provided in the table below.

General information	
Trade name	
Common name	
Predicate 510(k)	
Product code	
Classification	
Review panel	
Manufacturer	
Registration number	

This pre-market notification is organized following the recommendations contained in the CDRH guidance titled *Format for Traditional and Abbreviated 510(k)s* (September 13, 2019). As recommended in the FDA guidance, a table summarizing the device design and use is provided on the following page.

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

Contact information	
Primary contact	**Secondary contact**
Name Title Phone Email	Name Title Phone Email

This 510(k) submission, and the information it contains, is considered confidential; Company respectfully requests that the FDA give it the maximum protection provided by law.

In accordance with Section 510(k) of the of the Federal Food, Drug, and Cosmetic Act and in conformance with 21 CFR 801, one (1) complete original paper submission and one (1) electronic copy on CD-ROM, which is a complete and exact copy of the paper submission, are provided. Please contact me if you require any further information.

Sincerely,

Name
Title
Company
Address
City, State, ZIP

Appendix B: Content of 510(k) Summary

Format	• The summary must be a separate section of the 510(k) submission. • Begins on a new page and ends on a page not shared with any other part of the 510(k) submission. • Clearly identified as "510(k) Summary" as required by section 807.92(c).
Contact Info	• 510(k) applicant's name, address, phone and fax numbers, name of contact person, and date the summary was prepared [807.92(a)(1)]. • Contact info must appear on first page of the summary. • Preferably printed on letterhead paper.

Device Name	• Name of the device:
	  • including the trade or proprietary name, if applicable
	  • common or usual name, and
	  • classification name, if known [807.92(a)(2)].

Predicate Device Info	• The legally marketed device which the 510(k) uses to claim equivalence [807.92(a)(3)].

Device Description	• Description of the device, similar to what might be found on the labeling or promotional material.
	• Must include an explanation of:
	  • how the device functions
	  • scientific concepts that form the basis for the device, and
	  • significant physical and performance characteristics of the device, such as device design, material used, and physical properties; [807.92(a)(4)].

Intended Use of the Device	• Intended use of the device including a general description of the diseases or conditions that the device will diagnose, treat, prevent, cure, or mitigate. • A description, where appropriate, of the target patient population. • If the indication statements are different from those of the predicate device, 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)].
Technological Characteristics	• Technological characteristics (i.e., design, material, chemical composition, energy source) of the device compared to the predicate device. • A summary of how the technological characteristics of the new device compare to the technological characteristics of the predicate device [807.92(a)(6)].
Clinical and Nonclinical Performance Data and Conclusions	• Any clinical and non-clinical performance data, including the tests used and an explanation of how their results support a determination of substantial equivalence. [807.92(b)]. • The description of clinical performance data should include, where applicable, the subjects upon whom the device was tested, a discussion of the safety or effectiveness data, 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)*
Assurances of Safety and Effectiveness	• Conclusions drawn from the nonclinical and clinical tests 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).

Additional Information	• 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.
	• Ensure that:
	  • The summary does not include information that is not also covered in the body of the 510(k).
	  • The summary does not contain any puffery or unsubstantiated labeling claims.
	  • The summary only contains summary data, not raw data.
	  • The summary does not contain any trade secret or confidential commercial information.
	  • The summary does not contain any patient identification information.

Glossary

Glossary

510(k): Section 510(k) of the Food, Drug and Cosmetic Act requires device manufacturers who must register, to notify FDA of their intent to market a medical device at least 90 days in advance. This is known as Premarket Notification - also called PMN or 510(k).

Traditional 510(k): Most commonly used of the 510(k) types.

Abbreviated 510(k): An optional 510(k) pathway that uses guidance documents, special controls, and/or voluntary consensus standards to facilitate FDA's review of the 510(k) submission.

Special 510(k): An optional pathway for certain well-defined device modifications where a manufacturer modifies its own legally marketed device, and design control procedures produce reliable results that can form, in addition to other 510(k) content requirements, the basis for substantial equivalence (SE).

FDA: The United States Food and Drug Administration (FDA or USFDA) is a federal agency of the Department of Health and Human Services. The FDA is responsible for protecting and promoting public health through the control and supervision of food safety, tobacco products, dietary supplements, prescription and over-the-counter pharmaceutical drugs (medications), vaccines, biopharmaceuticals, blood transfusions, medical devices, electromagnetic radiation emitting devices (ERED), cosmetics, animal foods & feed[4] and veterinary products.

Premarket Notification (PMN): Another name for 510(k).

Premarket Approval (PMA): Premarket approval (PMA) is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices.

Class I Devices: Low-risk devices. Examples include bandages, handheld surgical instruments, and nonelectric wheelchairs.

Class II Devices: Devices that have a moderate to high risk to the patient and/or user. Most medical devices are considered Class II devices.

Class III Devices: Devices that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury.

Predicate Device: A predicate device is a medical device that is legally marketed in the U.S and used as a point of comparison for new medical devices seeking approval through FDA's 510(k) premarket clearance pathway.

Substantial Equivalence: Has the same intended use and technological characteristics as a predicate device OR has the same intended use and different technological characteristics but the differences do not raise different questions of safety and effectiveness as the predicate device.

Intended Use: What the device is meant to do over its lifetime, as conveyed on the device labelling.

Indications of use: The circumstances or conditions in which the device would be used. For example, the device may be designed to diagnose, treat, prevent, cure, or mitigate. Indications of Use also includes a description of the target patient population.

Technological Characteristics: The materials, design, energy source, and additional features of a medical device.

510(k) Summary: A summary of information upon which you based your claim of substantial equivalence.

510(k) Statement: 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.

Biocompatibility: How materials interact with the human body.

Bench Performance Testing: Testing related to the mechanical and design characteristics of a device used to support a claim of substantial equivalence. Includes, but is not limited to: mechanical and biological engineering performance (such as fatigue, wear, tensile strength, compression, burst pressure); bench tests using ex vivo, in vitro, and in situ animal or human tissue; and animal carcass or human cadaveric testing.

Animal Performance Testing: Testing conducted on non-human animals to assess safety or effectiveness used to support a claim of substantial equivalence.

Clinical Performance Testing: Testing conducted on people used to support a claim of substantial equivalence.

About Rimsys

Rimsys is bringing regulatory order to the medtech industry. The Rimsys Regulatory Information Management (RIM) platform digitizes and automates regulatory activities, freeing teams from inefficient administrative work, and helping them confidently establish and secure global regulatory compliance. Unlike complex spreadsheets, or expensive consultants, Rimsys centralizes all regulatory information, automates submission processes, and monitors relevant expirations, standards, and global regulations. Overburdened regulatory affairs teams struggle to keep pace with the increasingly complex global landscape. Rimsys streamlines all regulatory activities in an integrated platform, helping MedTech companies get to market more quickly and reduce risk of non-compliance, product recalls, and unexpected expirations.

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