US

510(k) Premarket Notification

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510(k) Premarket Submission

What is a 510k Premarket Notification?

A 510(K) is a premarket submission made to FDA to demonstrate that the device to be marketed is at least as safe and effective and substantially equivalent, to a legally marketed device . All Class II and certain Class III medical device/IVD's require a 510k Premarket Notification to be 'cleared' by the FDA before they can be sold in the US.

Substantial equivalence means that the new device is at least as safe and effective as the predicate. The legally marketed device(s) to which equivalence is drawn is commonly known as the "predicate."

A claim of substantial equivalence does not mean the new and predicate devices must be identical. They can have different technological characteristics compared to each other, but these differences should not raise any safety and effectiveness concerns.

What are the different types of 510(k)?

According to FDA, there are **three** types of 510(k) submissions:

- **Traditional 510(k)**

  A Traditional 510(k) is the original complete submission of a medical device as provided in 21 CFR 807.

  It is used for any original submission or for a substantial modification to a previously cleared 510(k).

- **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).

- **Abbreviated 510(k)**

  Device manufacturers may choose to submit an Abbreviated 510(k) when a guidance document exists, a special control has been established or when FDA has recognized a relevant consensus standard.

  For an Abbreviated 510(k) submission, summary reports on the use of guidance documents and/or special controls or declarations of conformity to FDA recognized standards are provided to expedite the review of a submission.

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510(k) Review Process

What is the 510(k) Review Process?

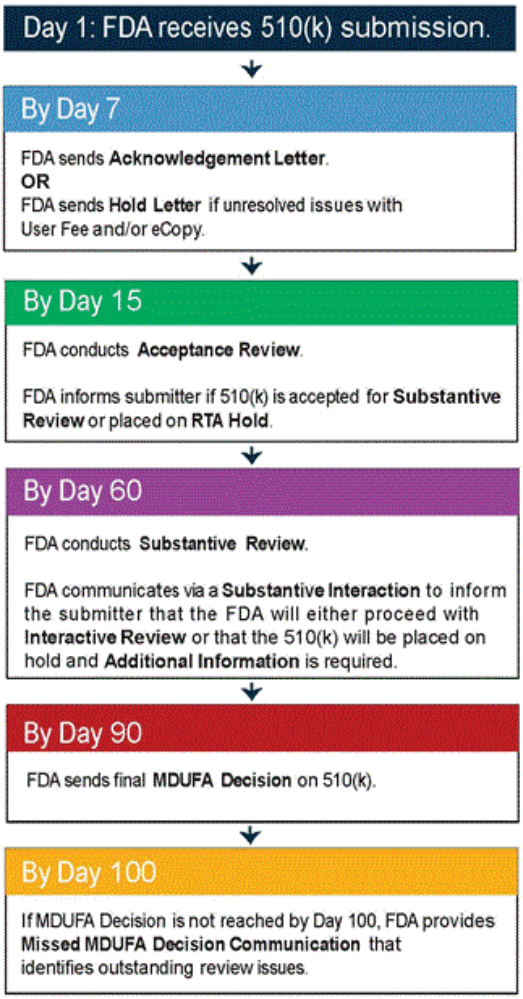
FDA Decisions for 510(k) submissions include findings of substantially equivalent (SE) or not substantially equivalent (NSE).

According to MDUFA, FDA has to make a decision on Traditional 510(k) in 90 days and on special 510(k)s in 30 days. There are no requirements for Abbreviated 510(k) submissions. (Figure 1)

If FDA does not reach a MDUFA decision within 100 FDA days (i.e., 10 days after the MDUFA goal), FDA will issue a Missed MDUFA Communication, which is written feedback to the submitter with reasons that are preventing FDA from reaching a final decision, and an estimated date of completion.

When a decision is made, FDA will issue the decision letter to the submitter by email to the email address provided in the 510(k) cover letter. A 510(k) that receives an SE decision is considered "cleared."

Figure 1: The timeline for FDA communication during the 510(k) process



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Traditional 510(k) Content

What is the content of a Traditional 510(k)?

A Traditional 510(k) submission must include the required elements provided in 21 CFR 807.87 and in the FDA guidance document, "Format for Traditional and Abbreviated 510(k)s."

510(k)	Content
Traditional	Medical Device User Fee Cover Sheet (Form 3601)
	CDRH Premarket Review Submission Cover Sheet (Form 3514)
	Certificate of Compliance with clinicaltrials.govDataBank
	Cover letter/ Table of Contents
	Indications for Use Statement
	510(k) Statement or Summary
	Standards Data Report FDA Form 3654
	Truthful and Accuracy Statement
	Class III Certification and Summary if Class III
	Financial Certification or Disclosure FDA Form 3454
	Declarations of Conformity or Summary Reports
	Executive Summary
	Device Description
	Substantial Equivalence Discussion
	Proposed Labeling
	Sterilization Information
	Drawings/ Photos Biocompatibility
	Software information
	Electromagnetic Compatibility and Safety
	Performance Testing-bench, animal and clinical (if applicable)

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Abbreviated 510(k) Content

What is the content of an Abbreviated 510(k) submission?

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. Under certain conditions, test data may not be required to be submitted. The content of an Abbreviated 510(k) is provided below:

510(k)	Content
Abbreviated	Class III Certification and Summary if Class III medical device
	Summary report of how the guidance document or special controls were used to address risks
	Declaration of Conformity to a Recognized Standard (if one is used)
	Provide data not covered by guidance documents, special controls or standards
	Provide information on sterilization, biocompatibility Medical Device User Fee Cover sheet (Form 3601)
	CDRH Premarket review submission cover sheet (Form 3514)
	Certificate of compliance with clinicaltrials.gov DataBank
	Cover letter/Table of Contents
	Indications for Use statement
	510(k) Statement or Summary
	Standards Data Report FDA 3654 Form
	Truthful and Accuracy Statement

Definitions

Guidance Documents - FDA has developed numerous device-specific guidance documents with public participation. 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.

Special Controls - Special controls, such as performance standards, are a means of providing reasonable assurance of the safety and effectiveness a Class II device. 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. 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. An Abbreviated 510(k) that relies on a recognized standard must include a Declaration of Conformity to the Recognized Standard.

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Special 510(k) Content

What is the content of a Special 510(k)?

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.

In the Special 510(k) process, a manufacturer who is intending to modify his/her own legally marketed device must 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.

The content of a special 510(k) is provided here below:

510(k)	Content
Special	510(k) Summary or Statement
	Standards Data Report for 510(k)s Form 3654
	Truthful and Accuracy Statement
	Class III Certification and Summary if Class III
	Description of the device and changes
	Comparison to cleared device
	Summary of the design controls
	Risk analysis
	Declaration of Conformity to Design controls*
	*should include all verification and validation activities performed and also a statement that the company is in conformance with design control/procedure requirements and the records are available for review.

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To Learn More..

Need help with Establishment Registration and Medical Device Listing?

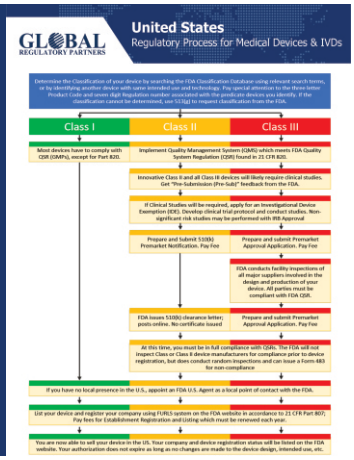
Global Regulatory Partners helps medical devices companies register their establishment and list their medical devices with FDA. To learn more about the process, check out our white paper on this subject or Contact Us today!

Need help with medical device & IVD registration in the US?

Global Regulatory Partners helps medical devices companies register their products with the FDA and access U.S. market by providing the following services:

- Medical Device Classification
- Pre-Submission meetings with the FDA
- Medical Device Registration
- FDA 21 CFR Part 820 - Quality Management System

For detailed information, check out our white paper on Medical Device Registration Process in US today!



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