Fact Sheet

# Understanding the Regulatory Pathway for 510(k) Submissions

*Leverage medical device expertise for your latest innovation to healthcare*

## Defining 510(k) submissions

In the United States, the Federal Food, Drug and Cosmetic Act (FD&C Act) regulates medical devices. The Center for Devices and Radiological Health (CDRH) is primarily accountable for pre- and post-market supervision of medical devices. Most medical devices gain marketing clearance in the United States through a premarket notification, also known as a 510(k) submission.

Key aspects include:

- A 510(k) is required for medium-risk devices that have a “predicate” (a comparator) on the market which can be used to demonstrate the safety and effectiveness of the new device
- A 510(k) submission is required for any Class II devices intended for human use unless the device is exempt by regulation
- A 510(k) submission must demonstrate that the device is substantially equivalent (SE) to one or more devices legally marketed in the U.S with the same intended use

*IQVIA MedTech can help in defining the correct classification by performing a detailed regulatory assessment for the device. Alternatively, the company can pay the FDA user fee and submit a 513(g) request for classification to the FDA for guidance.*

## Substantial equivalence for predicate devices

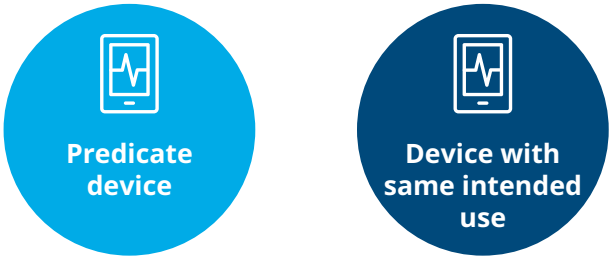
A legally marketed device in the U.S., previously cleared through the 510(K) process can be used for comparison to a new device to define "substantial equivalence" (21CFR 807.92(a)(3)). The most common method of demonstrating substantial equivalence is making a submission for FDA review and clearance via a Traditional 510(k). To determine substantial equivalence, the legally marketed device is commonly referred to as the "predicate device" and the new device as the "subject" device.

Manufacturers usually identify a single predicate device to simplify and facilitate the decision-making process. When a manufacturer does identify **multiple predicates**, the **primary predicate** refers to the one with indications for use and technological characteristics most similar to the device under review. Proof of Substantial Equivalence (SE) requires:

- Demonstration that a new device has the same intended use and the same technological characteristics as the predicate, Or
- Demonstration that the new device has the same intended use AND that differences in technological characteristics (Materials, Design, Energy source, other device features such as software or hardware) do not raise different questions regarding safety and effectiveness [performance]

**Note:** IQVIA MedTech recommends that all differences be highlighted in the comparison table and that a column be added to provide a scientific or clinical justification for why these differences do not raise new questions of safety or performance.

A determination of SE indicates that the device is at least as safe and effective as a similar, legally marketed device

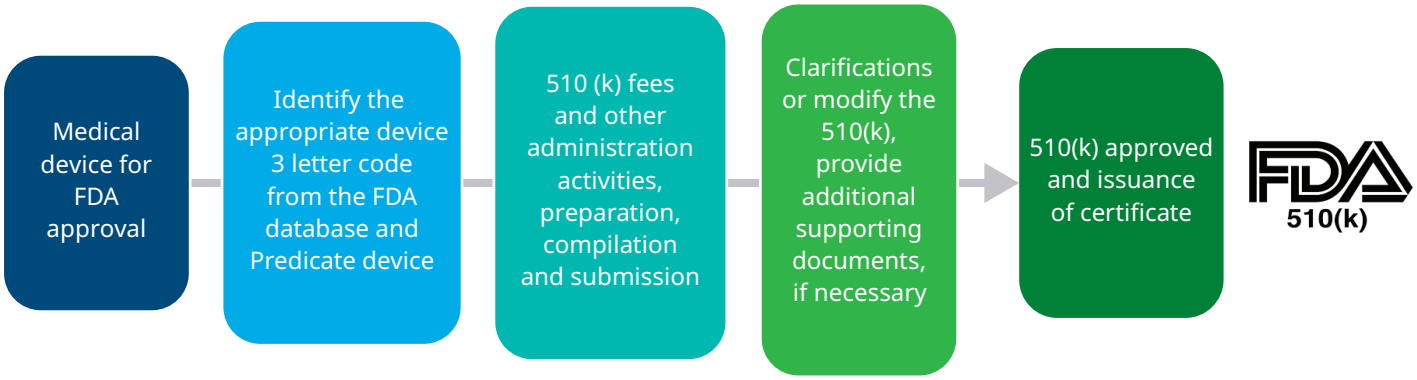



If the device is found SE by the FDA, it is cleared for commercial distribution and may be marketed. If the device is found Not Substantially Equivalent (NSE), it will require submission to the FDA of a Pre-Market Approval (PMA) application to obtain marketing approval or to be cleared via the De Novo process.

## When is 510(k) typically required?

- Manufacturer introducing a medical device to the U.S. market for the first time
- Changing indications for previously approved device
- Making significant modifications to previously cleared device, such as changes in:
  - » Design
  - » Components
  - » Materials
  - » Chemical composition
  - » Energy source
  - » Manufacturing process
  - » Intended use

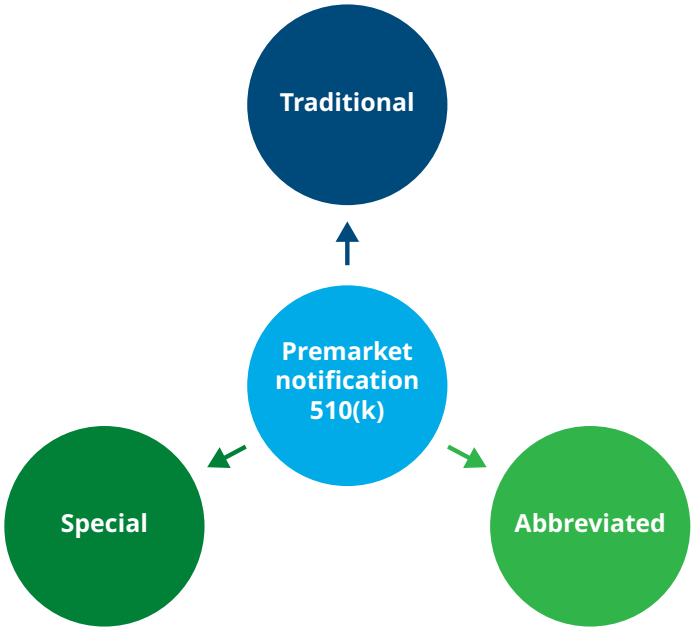
## 510(K) process—high level




## Preparation of FDA 510(k)

Preparing a 510k can be challenging. The submission has a clearly defined format and sections with specific content requirements. All required risk assessments, protocols, relevant test reports, raw data and other documents should be submitted as attachments. Even though quantity is not a marker of quality, a 510(k) submission can be hundreds of pages or more; the number of pages will vary depending on the complexity of the device.

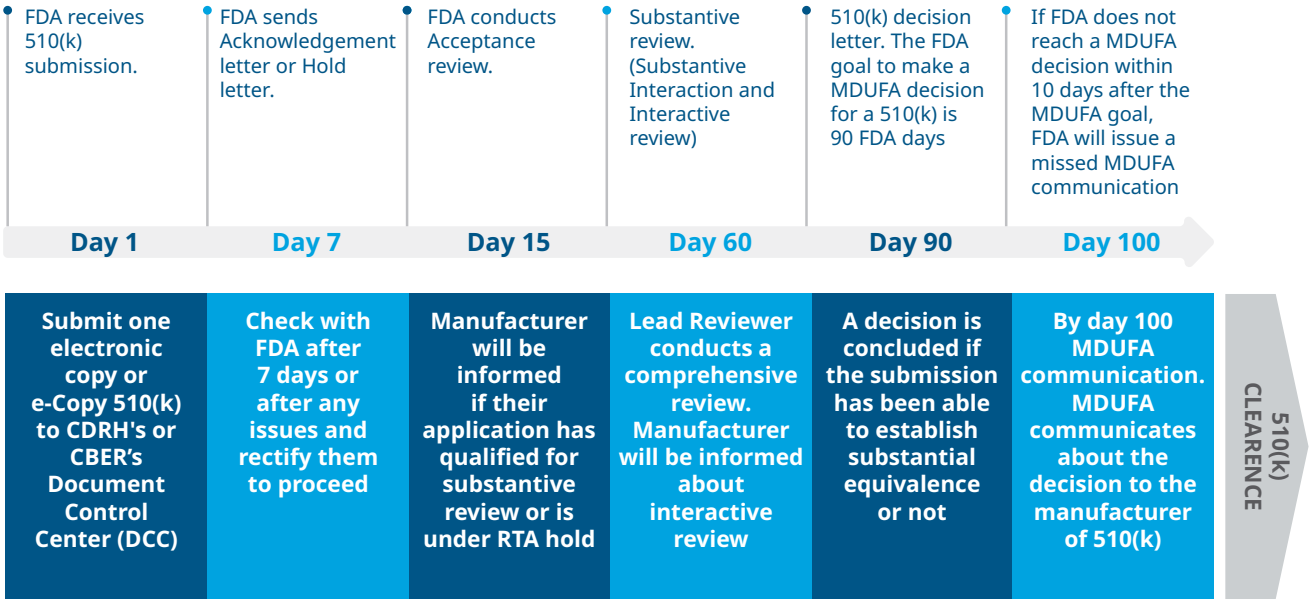
However, if your device is novel without a similar device for comparison then it would follow the FDA De Novo process. The De Novo process provides a pathway to market for novel devices with a low to medium risk profile.




## Different types of 510(k)

- **Traditional**: Submission to FDA according to 21 CFR Part 807, Manufacturer established substantial equivalence with an available predicate device
- **Abbreviated**: manufacturer may opt when their submission is based on FDA guidance documents and demonstration of compliance with special controls for the device or voluntary FDA consensus standards
- **Special**: Manufacturer whose device is already in the U.S. market require a change or intent to modify Labelling, Design, manufacturing process while ensuring that safety and performance are acceptable

# 510(k) Application Timeline




## How IQVIA MedTech can help you?

IQVIA MedTech offers professional services from strategic regulatory advice and marketing applications to regulatory maintenance and end-to-end IVD & Medical Devices product lifecycle support. Adapting to the new EU IVD Regulation is not easy, our expert team can thoroughly assess your products, review existing Quality Management System (QMS) data, technical documents, product data, labelling, and performance and stability data to identify gaps, and help you to remediate and streamline your timely FDA submissions. We support organizations that need assistance with regulatory strategy, maintenance, lifecycle support, and establishing your QMS.

- Performing a Regulatory Strategy Analysis to ensure the IVD device classification and product codes are correct and ensure your device is eligible for the 510(k) process
- Searching the FDA's 510(k) databases for possible predicate devices cleared under the 510(k) process
- Identifying a primary predicate device which is most similar to your IVD device with respect to intended use, risk profile and technological characteristics
- Ensuring your analytical and clinical studies follow the applicable FDA-recognized standards and regulations for IVDs
- Reviewing your product labeling to ensure FDA's IVD labeling requirements are followed
- Submitting a pre-submission request that may be necessary for novel technologies to help familiarize the FDA with your product in advance of the submission
- Planning, attending, and providing follow-up support for FDA pre-submission meetings
- Preparing the eCopy publication and liaise with the FDA through the 510(k) Submission Process

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