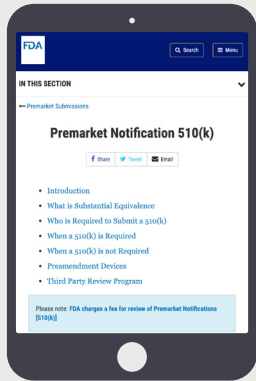


## INTRODUCTION & OVERVIEW

A **510(k) Premarket Notification** is required for low to moderate risk medical devices classified as either Class I or Class II and not exempt from 510(k). Companies are unable to market their products to health care providers, patients and other consumers until they are given 510(k) clearance by the FDA. In a 510(k) regulatory pathway, the Agency is responsible for determining whether a product is “substantially equivalent” to a predicate device in Class I or Class II, or one that legally exists on the market. Under most circumstances, suitable predicate devices are ones that have the same intended use and the same or similar technological characteristics as novel medical technologies. If the technological characteristics of the new device differ from the predicate, FDA asks whether the difference in technology raises new questions of safety or effectiveness. If so, a 510(k) is not appropriate, and a De Novo or PMA is needed. If not, the predicate may still be appropriate.



### 510(k) Application Checklist

- ☐ [Medical Device User Fee Cover Sheet](#) (Form FDA 3601)
- ☐ CDRH Premarket Review Submission Cover Sheet
- ☐ Cover Letter
- ☐ Table of Contents
- ☐ [510\(k\) Acceptance Checklist](#)
- ☐ Indications for Use Statement
- ☐ 510(k) Summary
- ☐ [Declaration of Conformity](#)
- ☐ Device Description: Narrative and Physical
- ☐ Substantial Equivalence Discussion
- ☐ Proposed Labeling
- ☐ Performance Testing

### Types of 510(k) Submissions

**Traditional 510(k)** – the most common submission type for devices with the same intended use as an existing Class I or Class II product

**Abbreviated 510(k)** – eligible for devices when there is a guidance document, special control, or consensus standard to support safety and effectiveness

**Special 510(k)** – used for certain modifications to cleared devices

### Safety and Performance Based Pathway

The [Safety and Performance Based Pathway](#) was introduced in 2019 as an expansion of the Abbreviated 510(k) pathway; once initiated, the FDA will rely on performance-based criteria to determine whether devices are substantially equivalent to their predicates.

### 510(k) Third Party Review Program

The [510\(k\) Third Party Review Program](#) allows company sponsors to submit their applications to FDA accredited third party organizations for review. Such organizations send their recommendations to FDA, which FDA uses to make a final decision.

# 510(k) SUBMISSION PROCESS

- 1 | Company sponsors must **submit an eCopy** of completed 510(k) applications to the Agency.
- 2 | Once FDA receives applications, company sponsors are issued either an **acknowledgement letter** or a **hold letter**. Typically, hold letters are issued because (1) user fees have not been paid or (2) an eCopy has not been received.
- 3 | At this stage, the Agency conducts an **Acceptance Review** based on the **Refuse to Accept (RTA) Policy for 510(k)s**, and applications are either accepted for **Substantive Review** or placed on **RTA hold**.
- 4 | During the **Substantive Review** process, FDA conducts a substantive evaluation of the data and information included in the submission, to determine whether a **substantially equivalent (SE)** decision can be reached.
- 5 | If FDA does not have sufficient information to make an **SE decision**, the Agency will determine if applications qualify for **Interactive Review**. If so, questions and answers may be exchanged between the reviewer and the company representative via telephone or e-mail, followed by a written submission. If the submission does not qualify for **Interactive Review**, it will be put on hold, and FDA will issue an Additional Information (AI) Request to the company.
- 6 | After this review, the Agency will issue a letter stating its **final decision**. If a submission cannot be cleared, FDA may suggest the company voluntarily **withdraw** the submission, in order to maintain the confidentiality of the information within.

## MDUFA Time Commitments

### DAY 1

FDA receives 510(k) application.

### DAY 7

FDA sends acknowledgement or hold letter.

### DAY 15

FDA conducts Acceptance Review and informs companies if their applications have been accepted for Substantive Review or placed on RTA hold.

### DAY 60

FDA conducts Substantive Review—review staff determines if applications can be completed via Interactive Review or placed on hold while the company submits additional information.

### DAY 90

FDA sends decision to company sponsors via email.

### DAY 100

If FDA does not reach a decision after 100 days, review staff will provide company sponsors with written feedback and explain why a decision has not been reached.

*Time line shown for Traditional and Abbreviated 510(k)s, which have 90-day review time. Special 510(k)s have a 30-day review time.*

## 510(k) Decisions

### 510(k) Exempt

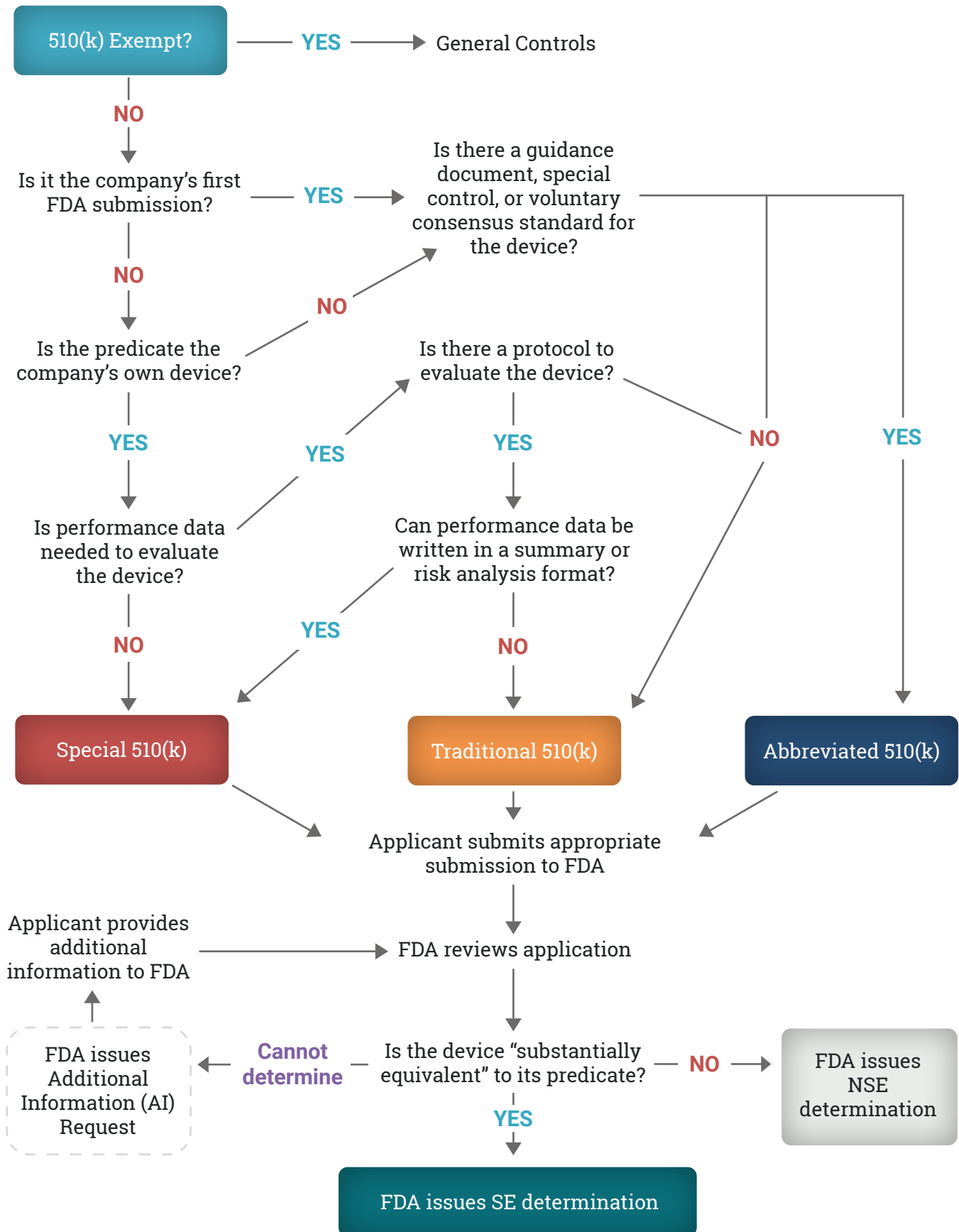
Manufacturers can bring their devices to market without assurance of safety and effectiveness, but such products are still required to comply with all applicable device regulations, including the Quality System Regulation (QSR).

### Substantially Equivalent (SE)

Devices are given 510(k) clearance, meaning that company sponsors can send them to market.

### Not Substantially Equivalent (NSE)

Devices are not given 510(k) clearance, either due to a lack of predicate device or insufficient information to prove that the “new” device is substantially equivalent to its predicate. If company sponsors receive an NSE decision, they can contact their Lead Reviewer with technical questions, or submit a Pre-Submission application for additional guidance. If unresolved, the company can file a formal appeal.



# FDA GUIDANCE DOCUMENTS\*

## General:

[The 510\(k\) Program: Evaluating Substantial Equivalence in Premarket Notifications](#)

[General/Specific Intended Use](#)

[FDA and Industry Actions on Premarket Notification \(510\(k\)\) Submissions: Effect on FDA Review Clock and Goals](#)

[User Fees and Refunds for Premarket Notification Submissions \(510\(k\)s\)](#)

## Application Process:

[Safety and Performance Based Pathway](#)

[Format for Traditional and Abbreviated 510\(k\)s](#)

[Deciding When to Submit a 510\(k\) for a Change to an Existing Device](#)

[Deciding When to Submit a 510\(k\) for a Software Change to an Existing Device](#)

## Specific Device Types:

[Benefit-Risk Factors to Consider When Determining Substantial Equivalence in Premarket Notifications \(510\(k\)\) with Different Technological Characteristics](#)

[Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices](#)

[Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices](#)

[Content of Premarket Submissions for Management of Cybersecurity in Medical Devices](#)

[Recommended Content and Format of Non-clinical Bench Performance Testing Information in Premarket Submissions](#)

[Submission and Review of Sterility Information in Premarket Notification \(510\(k\)\) Submissions for Devices Labeled as Sterile](#)

\*Additional guidance documents are available on the FDA website.

## Additional FDA Resources

[FDA Presentation: Safety and Performance Based Pathway \(November 7, 2019\)](#)

[Product Code Classification Database](#)

[How to Find and Effectively Use Predicate Devices](#)

[FDA Has Taken Steps to Strengthen The 510\(k\) Program](#)

## Tips from the Experts

1. **Request a face-to-face Pre-Submission meeting with the Agency**, as needed, to build a relationship with the CDRH review team and obtain information on requirements for contents of the submission.
2. **Provide a video demonstration of the device**, or a prototype if it is small enough, so that FDA can understand what it is and how it operates.
3. **Research a product's predicate before submitting a 510(k) application**, making sure they have the same intended use and the same or similar technological characteristics that do not raise new questions of safety or effectiveness compared to the predicate.
4. **A product's Indications for Use Statement and 510(k) Summary are the most important elements of a 510(k) application**, so make sure to spend a significant amount of time on writing them.
5. In discussing substantial equivalence, bear in mind that **the submission is an advocacy document and must persuade FDA of the appropriateness of an SE decision**.
6. **Review all applicable FDA guidance documents** (including product specific guidance) as well as the 510(k) Acceptance checklist before submitting a final 510(k) application.
7. **Make sure all application contents are organized and flow logically**. Include a completed checklist with page numbers.
8. **Have someone unfamiliar with the device read the submission** to determine whether a person not involved in its development can understand what it is and how it works.
9. **Proofread the final document at least twice before submitting to FDA**. Fix typographical errors, and assure page numbers and any references are correct and match the submission.

## AdvaMed Working Groups

FDA Strategy Working Group

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