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. **DAY 1**
   - **Company sponsors must submit an eCopy** of completed 510(k) applications to the Agency.

2. **DAY 7**
   - 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. **DAY 15**
   - 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. **DAY 60**
   - 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. **DAY 90**
   - 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. **DAY 100**
   - 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.

## 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.
510(k) Exempt?  
- **YES** → General Controls  
- **NO**  
  - Is it the company's first FDA submission?  
  - **YES** → Is there a guidance document, special control, or voluntary consensus standard for the device?  
  - **NO** →  
    - Is the predicate the company's own device?  
    - **YES** → Is performance data needed to evaluate the device?  
    - **NO** → Special 510(k)  
    - **YES** → Traditional 510(k)  
    - **NO** → Abbreviated 510(k)  
  - **NO** →  
    - Is there a protocol to evaluate the device?  
    - **YES** → Can performance data be written in a summary or risk analysis format?  
    - **NO** →  
      - **NO** → Applicant submits appropriate submission to FDA  
      - **YES** → Applicant provides additional information to FDA  
    - **YES** → FDA issues SE determination  
    - **NO** → FDA issues NSE determination  
  - **NO** →  
    - Is performance data needed to evaluate the device?  
    - **YES** →  
      - **YES** →  
        - **YES** → FDA issues SE determination  
        - **NO** → FDA issues NSE determination  
      - **NO** → Abbreviated 510(k)  
    - **NO** → Special 510(k)  
    - **NO** → Traditional 510(k)  
  - **NO** → **Cannot determine**
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.

Tips from the Experts

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

AdvaMed Working Groups

FDA Strategy Working Group
Staff Lead: Janet Trunzo, Senior Executive Vice President, Technology and Regulatory Affairs
jtrunzo@advamed.org

510(k) Working Group
Staff Lead: Ruey Dempsey, Vice President, Technology and Regulatory Affairs
rdempsey@advamed.org

Additional guidance documents are available on the FDA website.