



**U.S. FOOD & DRUG  
ADMINISTRATION**

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

November 2018

## Table of Contents

INTRODUCTION.....	3
1. The FDA has increased its premarket expectations for 510(k) submissions.....	4
2. The FDA implemented a Refuse-To-Accept policy to improve the quality of 510(k) submissions.	5
3. The FDA has improved consistency and thoroughness of 510(k) review.....	6
4. The FDA has taken steps to eliminate the use of 510(k) for Class III devices .....	7
5. The FDA has eliminated the use of MORE THAN 1000 510(k)s as legal predicates .....	8

## INTRODUCTION

---

---

The Pre-market Notification (510(k)) Program is the most common pre-market review regulatory pathway for new devices received in the Center for Devices and Radiological Health (CDRH). In 2017, CDRH cleared 3,173 devices making up 82% of the FDA's cleared or approved devices. In a 510(k) submission, the submitter is required to provide adequate performance data to confirm that their new device is as safe and effective as the chosen predicate device. To address continuously changing needs, the FDA has worked to improve the 510(k) Program to meet both patient needs and changes to the device marketplace. This document outlines several of the improvements made to the 510(k) Program over the last several years.

# 1. THE FDA HAS INCREASED ITS PREMARKET EXPECTATIONS FOR 510(K) SUBMISSIONS

The FDA has taken important steps to modernize its approach to 510(k) review. In 2014, we issued our [510\(k\) Program Guidance](#) to identify, explain, and clarify the decision-making process the FDA uses to determine substantial equivalence. In 2017, we updated our [510\(k\) Modifications Guidance](#) to clarify and describe in greater detail the regulatory framework, policies and practices companies should follow when making changes to their existing devices, including [software](#). We also clarified how to incorporate [Benefit-Risk Factors](#) into certain 510(k) decisions.

Since 2009, CDRH has published more than 50 final cross-cutting and device specific [guidance documents](#). The purpose of the FDA's guidance documents is to help improve predictability, consistency, and transparency of submission content while clarifying expectations, policies and procedures surrounding review of the submission. Some of the guidances impacting 510(k) review are listed in the box (to the right).

As a result of actions taken by CDRH, including these policies to clarify and strengthen 510(k) submission content expectations, the average number of pages for each 510(k) has increased 150% since 2009.

**1185** AVERAGE NUMBER OF PAGES FOR EACH 510(K) SUBMISSION IN 2017

**150%** INCREASE IN THE NUMBER OF PAGES FOR EACH 510(K) SINCE 2009

## SELECTED GUIDANCES IMPACTING 510(K) REVIEW EXPECTATIONS

Reprocessing Medical Devices in Health Care Settings

Sterility Information in 510(k) Submission

Biological Evaluation of Medical Devices

Acceptance of Clinical Data to Support Medical Device Applications

Technical Considerations for Additive Manufactured Medical Devices

Pediatric Information for X-ray Imaging Device Premarket Notifications

Interoperable Medical Devices

Use of Real-World Evidence to Support Regulatory Decision-Making

Design Considerations for Devices Intended for Home Use

Content of Premarket Submissions for Management of Cybersecurity in Medical Devices

Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices

Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with FDA Staff

Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices

## 2. THE FDA IMPLEMENTED A REFUSE-TO-ACCEPT POLICY TO IMPROVE THE QUALITY OF 510(K) SUBMISSIONS

---

The FDA introduced a [Refuse to Accept policy](#), most recently updated in January 2018, implementing procedures and criteria for assessing whether a 510(k) submission meets a quality threshold of acceptability for review. The acceptance review is conducted for all incoming 510(k)s and evaluates the submission for completeness related to 52 elements, including biocompatibility, software, shelf life, electrical safety, electromagnetic compatibility, and performance data. If one or more of the 52 items is missing, the FDA notifies the 510(k) submitter that its submission is not accepted for review.

This quality check does not reflect whether or not the FDA will ultimately clear the 510(k) but rather assures that the FDA only reviews 510(k) submissions that are complete. Since we started the policy, the quality of 510(k) submissions has improved allowing the FDA to be more efficient in its reviews.

**52** ELEMENTS IN THE  
FDA'S REFUSE-TO-ACCEPT  
510(K) CHECKLIST

**30%** OF 510(K)  
SUBMISSIONS ARE NOT  
ACCEPTED FOR INITIAL  
REVIEW

### 3. THE FDA HAS IMPROVED CONSISTENCY AND THOROUGHNESS OF 510(K) REVIEW

---

The FDA has taken actions intended to improve the decision-making consistency, including issuance of numerous foundational and device-specific guidances and implementation of the Refuse-to-Accept policy. In addition, the FDA created the 510(k) SMART memo template used by the FDA’s reviewers to guide device review during the 510(k) premarket process. The template guides the FDA’s review staff through the device review and completion of a formatted review memo by providing helpful links to applicable regulations and guidances and facilitating consistent analysis and documentation of scientific, clinical, administrative and regulatory information. The SMART memo template is frequently updated to incorporate new review practices and policies, such as those published in final guidance to ensure a contemporary approach to 510(k) review. The FDA has incorporated SMART memo template training into its Reviewer Certification Program.



**MANDATORY SMART MEMO  
TEMPLATE USE BY THE  
FDA’S REVIEWERS BEGAN  
IN OCTOBER 2015**

**32% INCREASE IN THE  
TIME SPENT BY THE FDA’S  
STAFF REVIEWING EACH  
510(K) SUBMISSION SINCE  
2009**

In addition to the FDA’s increased premarket expectations and a 150% increase in the number of pages for each 510(k) submission since 2009, the FDA’s staff spend more time reviewing each 510(k) submission than ever before.

Since 2009, the time spent reviewing each 510(k) submission has increased 32%, and it has almost doubled in the past 15 years. Despite these increases, the FDA has continued to meet its Congressionally established review performance timelines.

## 4. THE FDA HAS TAKEN STEPS TO ELIMINATE THE USE OF 510(K) FOR CLASS III DEVICES

---

Medical device regulations place devices into three classes, with [Class III](#) including those with the greatest risk to patients. Class III devices must generally obtain an approved Premarket Approval ([PMA](#)) application, but some device types on the market prior to the 1976 Medical Device Amendments were placed into Class III and may be cleared via the 510(k) process until the FDA issues regulations either requiring submission of a Premarket Approval application or down-classifying the device types into Class I or Class II. Between 2003 and 2009, the FDA annually cleared approximately 80 submissions for Class III devices through the 510(k) process. As of August 2009, [25 Class III device types](#) were still eligible for the 510(k) process.

Between 2011 and 2016, the FDA published [24 final rules and orders](#), either down-classifying the device types to Class I or Class II or requiring the submission of a Premarket Approval application and eliminating the use of the 510(k) process for evaluation of these high risk medical devices. In addition, the FDA held [Medical Device Advisory Committee Panel](#) Meetings and issued proposed orders for the two remaining class III device types eligible for 510(k).

As a result of these actions, not a single Class III device was cleared via the 510(k) process in FY 2018.

**0** NUMBER OF CLASS III DEVICES CLEARED FOR MARKETING VIA THE 510(K) PATHWAY IN FY 2018

## 5. THE FDA HAS ELIMINATED THE USE OF MORE THAN 1000 510(K)S AS LEGAL PREDICATES

---

The FDA will take action to eliminate the use of a 510(k) cleared device as a predicate when it raises safety concerns. For example, the FDA may pursue reclassification (from Class II to Class III) and issue a call for Premarket Approval applications when we determine that a device type should be regulated as high risk because general and special controls are not sufficient to assure its safety and effectiveness. This process eliminates the use of previously cleared 510(k)s as legal predicates.

Since Congress enacted the Medical Device Amendments in 1976, the FDA has eliminated the use of 1,758 devices as predicates in the 510(k) process. Of these, 1,477 (84%) have been eliminated since 2012.

**1477** NUMBER OF 510(K) CLEARED DEVICES ELIMINATED FOR USE AS LEGAL PREDICATES SINCE 2012

**84%** OF DEVICES ELIMINATED FOR USE AS 510(K) PREDICATES HAVE BEEN ELIMINATED IN THE PAST 7 YEARS

**30-FOLD** INCREASE IN THE ANNUAL RATE OF ELIMINATION OF 510(K) PREDICATES SINCE 2012