The content on this webpage is developed by NIH SEED based on its collective experience working with the NIH innovator community. This information has been developed, for informational purposes, to address questions frequently asked by NIH awardees, and represents the experiences of the subject matter experts who contributed to its development.

510(k) Documentation and Application

Context

It is important for medical device innovators to become familiar with the types of FDA Market Authorization applications and identify the one most applicable to their development program. The most commonly used path to market for medical devices is called 510(k) Premarket Notification, through which developed receive "clearance" to legally market a new product in the US.

To obtain 510(k) clearance, a medical device manufacturer submits a package of documents to FDA for review. The objective of the documentation is to support the substantial equivalence of the new device to one that is already on the market (known as a predicate device). This equivalence hinges upon the information submitted to FDA demonstrating that:

a) the devices have the same general purpose/function ("intended use")
b) the devices have the same technological characteristics – or – any differences in technology do not raise different questions in safety and effectiveness.

A wide variety of documentation is required to demonstrate substantial equivalence, ranging from administrative forms to technical data. This article is meant to provide an overview of those contents for a *Traditional* 510(k) application, though similar content should be included in other types of 510(k) submissions.

For information on how to discuss with FDA what be contained in the 510(k) application, please refer to the NIH SEED article on 510(k) pre-submission interactions.

Contents of the Application

For more detail, please refer to Section V of the FDA guidance document on 510(k) submission.

Content	Description	Notes on Requirement
RTA (Refuse-to-Accept) Checklist	A checklist for all parts of the 510(k) submission to ensure it meets the minimum threshold of acceptability for FDA review. Best practice is to annotate this checklist with the corresponding page numbers.	Highly Recommended
Medical Device User Fee Cover Sheet	A form that connects your application to the fee payment.	Required
CDRH Cover Sheet	Form 3514 indicates to CDRH the type of application/request being submitted. Among other details, this document should include a list of all referenced standards (if applicable).	This and/or below are required
Cover Letter	A free form letter can replace the Form 3514 if it includes all attributes found there. Both can be included, and the letter may serve as an introduction/ overview of the new device directly to the FDA review team.	This and/or above are required
Table of Contents	The table of contents connects all parts of a submission and highlights where information might be found in separate PDFs.	Highly Recommended
Truthful and Accurate Statement	This statement should stand within its own section.	Required
Clinical Investigation Forms	Various forms certifying any related clinical studies should be provided.	If Applicable*
Reference to Prior Submissions	It is recommended that a direct point-by-point response is included for any feedback already received from FDA. (If the feedback was on a previous 510(k), then this is required.)	If Applicable*

Content	Description	Notes on Requirement
Indications for Use Statement	This form specifies the final indications for use of the device. It also states whether the device is for prescription or over-the-counter use.	Required
510(k) Summary	The 510(k) Summary is an overview of the device with sufficient detail to understand the basis for FDA's clearance (substantial equivalence). Therefore, it should include, among other details, a table that compares similarities and differences between the device and the predicate. This Summary will be made public after FDA authorizes marketing of the device.	This or the Statement (described below) are required
510(k) Statement	Though the 510(k) Summary is far more commonly used, manufacturers have the option of including a 510(k) Statement instead (only one can be submitted). The Statement is an open agreement to make available a duplicate of the full 510(k) application to any interested person upon inquiry.	This or the Summary (described above) are required
Device Description	This section of the 510(k) is necessary for FDA to understand what they are being asked to review. What are the device's functions? How are those functions achieved? How is the device operated? What are the key inputs and outputs? Another consideration for this section is if FDA has published relevant device specific guidance documents. If so, they may indicate additional information expected by FDA to inform their review.	Required

Content	Description	Notes on Requirement
Substantial Equivalence Discussion	The comparison between the predicate and subject devices is often included within one extensive and in-depth table. This allows the applicant to address the similarities and differences between the devices line by line. An abridged version of this discussion must be included within the 510(k) Summary, but the version that is included as a standalone section within the 510(k) application should include full details and technical information as needed.	Required
Final Draft Labeling	This should include the user manual, instructions for use, and brochures, in addition to package inserts and physical labels. Unless the device is for over-the-counter use, labeling should include the prescription use statement.	Required
Conformity to Consensus Standards	The guidance document linked here provides complete information of what and how FDA expects to receive test reports in accordance with consensus standards.	If Applicable*
Performance Testing	Unless the validation of the device is entirely covered by consensus standards, the 510(k) should include one, two, or three sections on bench, animal, or human testing. These sections should highlight the results of the studies as well as their design and methodologies.	If Applicable*
Safety	The listed sections within the RTA Checklist are Sterilization, Shelf-Life, Biocompatibility, Electrical Safety and Electromagnetic Compatibility, as well as Software and Cybersecurity (see below). In each case the 510(k) should include evidence of device safety, using standards where possible.	If Applicable*

Content	Description	Notes on Requirement
Software	Based on the level of risk associated with the device, varying degrees of software documentation are required within a 510(k) application.**	If Applicable*
Cybersecurity	If the device contains software, FDA expects a risk mitigation plan has been established and documented to ensure cyber resiliency.	If Applicable*

* in each instance where the contents are *not* applicable for the device at hand, best practice is to include a one page section stating that the content is not included. For example, a software device could contain a section on biocompatibility which simply states, "Biocompatibility testing was not performed because there is no physical contact with the device."
** for more information on software documentation, please refer to the NIH SEED Knowledge Guide on Digital Health.

Submitting the 510(k)

Once all aspects of the application have been drafted, revised, cleanly formatted, and integrated into one document (or one organized collection of PDF documents); CDRH currently offers one method for submitting the 510(k):

- eSTAR – an interactive PDF form that guides applicants through the comprehensive process. This template is designed to align the structure of the 510(k) with the CDRH internal review templates. Because the template automatically ensures aspects of the submission are present, when using eSTAR the Cover Sheet (row 3 from table above), Indications for Use Statement (row 9), and Conformity to Consensus Standards (row 15) are not necessary.
  The eSTAR is saved on a USB drive, CD, or DVD which is mailed to CDRH. FDA offers an informational overview of the eSTAR program.

In 2021, CDRH initiated a platform for manufacturers to voluntarily submit their documents online (rather than through mail). The platform is called the CDRH Portal, and 510(k) submitters can register an account to upload and track their application online.

The Center for Biologics Evaluation and Research (CBER) is responsible for review of 510(k) applications for regulated blood products, and these documents should not be sent to CDRH. For the most up to date information on submitting a 510(k) to CBER, you can review the information on their website.

Milestones

Though the FDA review timeline is subject to change based on new agreements with industry every five years, the most recent process is as follows:

Timeline	Action
Day 1	FDA receives the 510(k) application
By Day 7	FDA acknowledges that the 510(k) format is acceptable and the fees have been paid. Otherwise, FDA sends a “Hold” letter explaining the issue.
By Day 15	FDA ensures the 510(k) is administratively complete (see table above). Otherwise, they send a “Refuse-to-Accept Hold” letter explaining what is missing from the submission.
By Day 60	FDA will have conducted their substantive review of the 510(k). In some cases, issues uncovered can be simply resolved via email interactions. In most cases, an “Additional Information (AI) Hold” letter is sent, requesting the manufacturer to address more complex deficiencies in the 510(k).
By Day 90	FDA strives to make their final decision: substantially equivalent (SE) or not substantially equivalent (NSE). If the process takes longer than 100 days, then FDA will issue a letter explaining reasons for the delay, and an estimated time of completion.

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