

Complete 510(k) submission guide

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Almost half of all medical devices in the United States have passed through the FDA's 510(k) clearance process.

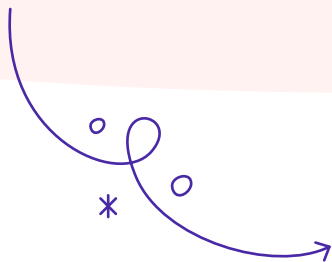
But 30% of submissions aren't even accepted for initial review. It's a long, complex process which any Class II medical device company must follow – and the route is pitted with common mistakes and overlooked steps.

The Qualio quality team has built this end-to-end submission guide to steer you through a successful, right-first-time 510(k) journey. It's full of top tips, insights and best practice to help you get your device to market quickly and safely.



Kelly Stanton

Director of Quality, Qualio



What is an FDA 510(k) submission?

The FDA's [510\(k\) submission process](#) is, in short, a quality and compliance barrier designed to only let safe, effective medical devices onto the U.S. market, and into contact with American patients.

The focus of the 510(k) process is to prove something called 'substantial equivalence'. In other words, the aim of the game is to prove to the FDA that the medical device you want to bring to market is broadly similar to another device that's *already* on the *market*, known as a predicate device.

The logic of your 510(k) submission is clear: *your* device is like *this* predicate device, and here's how. And since *this* predicate device is already on the market and doing its job safely, *your* device must be safe and effective too!

At Qualio, we're big on making quality and compliance as simple as possible. With that in mind, here's a nice easy definition that gets at the heart of what an FDA 510(k) submission is:

510(k)

A technical file given to the FDA proving that your medical device is like another already on the market

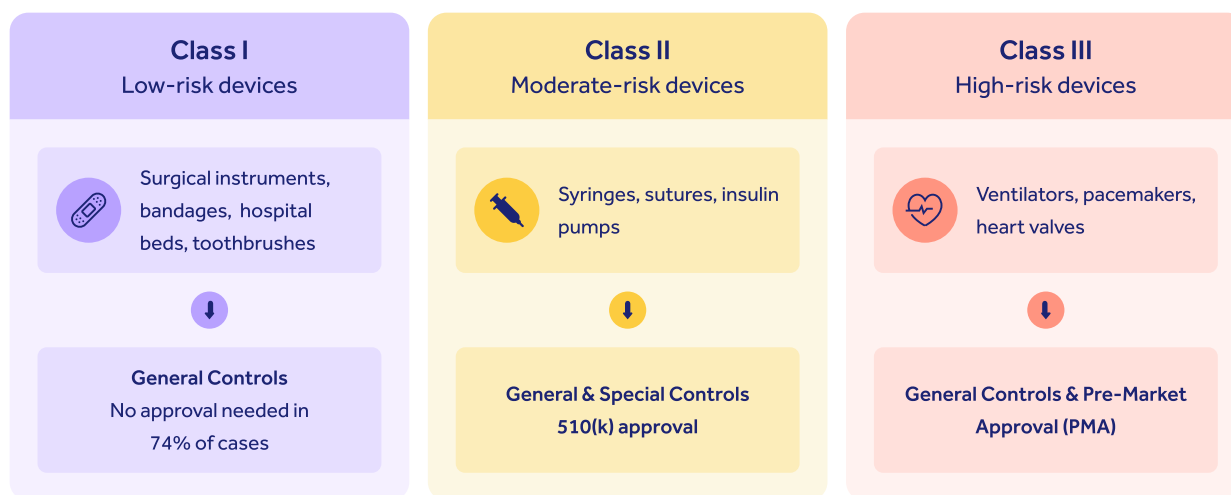
Your 510(k) submission should:

01. Demonstrate your medical device is 'substantially equivalent' to a predicate already on the market
02. House detailed technical, safety and performance device/test information to show your device is safe and effective
03. Prove you have a robust [medical device quality and risk management system](#)

Now that's cleared up, let's dig a little deeper.

The 510(k) submission and medical device classes

The FDA classifies all medical devices marketed in the United States into three risk categories: Class I, low risk, up to Class III, high risk.



The 510(k) submission process is generally applied to so-called Class II devices, with a medium risk profile.

There are some caveats to this: in some very rare cases, Class I and III devices might require a 510(k) submission. But as a general rule of thumb, only Class II devices require one.

A 510(k) allows you to bring your Class II device to market without clinical trials, by proving the substantial predicate equivalence we've already discussed.

Medium-risk medical device requiring a 510(k) submission are those which come into sustained and significant patient contact.

Example devices include:

- Catheters
- Blood pressure cuffs
- Insulin pumps
- Endoscopes
- Electric wheelchairs
- Pregnancy test kits
- Syringes
- Blood transfusion kits
- Contact lenses
- Surgical gloves
- Absorbable sutures

The first step of any 510(k) submission process is to be sure that it applies to you, and that your device isn't [exempt from the 510\(k\) process](#).

What is a 510(k) predicate device?

A predicate device is the existing marketed device which your 510(k) submission should prove is substantially equivalent to your device.

The predicate device should have:

01. The same intended use as your device
02. Similar technology to that involved in the function and operation of your device
03. The same level of safety and efficacy as your device

Your FDA 510(k) submission should prove all three of these criteria. If your device is definitely Class II and there's really no substantial equivalent at all – which can happen if you have a really innovative medium-risk device – you'll have to go down the [de novo route](#).

510(k) completion can only happen with a suitable predicate at the core.

And of course, substantial equivalence is a slightly loose term which doesn't mean 'identical'. A purely identical medical device would offer no competitive difference or advantage to your business – so there's a tricky balance to strike here. Use your best judgment.

Who needs to submit a 510(k)?

There are 4 groups of actors who would, depending on specific business circumstances, be responsible for completion of an FDA 510(k) submission.

1. American medical device manufacturers

The most common 510(k) submitters. Making a Class II device in the US and bringing it to market? The quality/regulatory lead in your business would complete your 510(k) submission as part of your go-to-market activities.

2. Representatives of non-US manufacturers

The second most common 510(k) submitting group are the appointed representatives of medical device manufacturers outside the U.S.

FDA rules state that non-US manufacturers wanting to market their device in the United States require a representative to submit their 510(k) on their behalf.

3. Specification developers

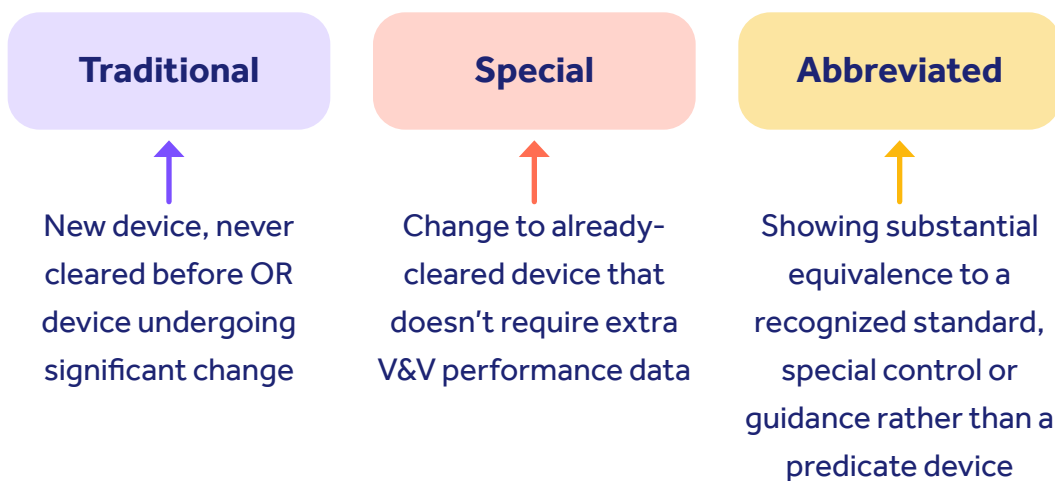
Designed and developed a medical device but outsourcing production to a CMO? The 510(k) submission is still your responsibility, not the CMO's.

4. Repackers/relabellers

It's not very common, but in certain cases repackers and relabellers in a medical device logistical supply chain could be responsible for a 510(k) submission. This typically only happens as a kind of update 'special' submission (more on that below) in the event of a significant process change, such as if significant labelling changes are made (like adding a new use or warning to a manual), or if significant repacking changes are made in a way that could affect the safety and integrity of the device (like in a sterilization operation).

The three types of 510(k) submission

There are three types of 510(k) route:



It's more than likely that you'll fall into the traditional route, which is what we'll be covering in detail here.

Don't get too excited by the possibility of an 'abbreviated' route: this option actually takes around twice as long as the traditional process for the FDA to review and doesn't require any less work on your part.

It's only performed where you think it's easier to prove that your device meets certain regulatory standards or guidance than it is to prove equivalence to a predicate.

The FDA 510(k) submission process

Now we've covered the basics of the FDA 510(k), let's take a look at the submission process itself.

1. Finding your predicate device

Don't overthink this first step. Just Google your medical device type and see what comes up! Find an existing business and device and compare:

- Intended use
- Design
- Materials
- Safety
- Labeling

Performance considerations: engineering, sterility, compatibility, software validation, etc. This should give you a broad feel for your device category and how other potential predicate devices work.

Once you've done this, head to the FDA's [510\(k\) database](#). Do the same again: type in your device type and see what comes up.

Here, for instance, I can see 316 potential predicates for my pregnancy test kit:

510(k) Premarket Notification

FDA Home Medical Devices Databases

1 to 10 of 316 Results
 Device Name: pregnancy Decision Date To: 10/17/2022

1 2 3 4 5 6 7 8 9 10 > Results per Page 10

[New Search](#) [Export to Excel](#) [Download Files](#) [More About 510\(k\)](#)

Device Name	Applicant	510(K) Number	Decision Date
Clearblue® Early Pregnancy Test	SPD Swiss Precision Diagnostics GmbH	K213379	09/21/2022
Hcg One Step Pregnancy Test	Healstone Biotech Inc.	K212418	06/30/2022
One Step Pregnancy Test	SPD Swiss Precision Diagnostics GmbH	K210341	03/10/2022
Sejoy Hcg One Step Pregnancy Test Strip, Sejoy Hcg One Step Pregnancy Test Cassette, Sejoy Hcg One Step Pregnancy Test Midstream	Hangzhou Sejoy Electronics & Instruments Co., Ltd.	K212447	02/18/2022
Alltest Pregnancy Rapid Combo Test Cassette	Hangzhou AllTest Biotech Co., Ltd	K203272	01/31/2022
Clearblue® Early Digital Pregnancy Test	SPD Swiss Precision Diagnostics GmbH	K200913	08/13/2021
Atlas One Step Hcg Urine Pregnancy Test (Strip), Atlas One Step Hcg Urine Pregnancy Test (Cassette), Atlas One Step Hcg Urine Pregnancy Test (Midstream)	Atlas Link Technology Co., Ltd.	K203246	08/04/2021
Distinct® Early Detection Pregnancy Test	Acon Laboratories Inc.	K193318	08/20/2020
Clungene Hcg Pregnancy Rapid Test Cassette, Clungene Hcg Pregnancy Rapid Test Strip, Clungene Hcg Pregnancy Rapid Test Midstream	Hangzhou Clongene Biotech Co.,Ltd.	K193132	12/11/2019
Innovita Hcg Pregnancy Rapid Test Strip, Innovita Hcg Pregnancy Rapid Test Cassette, Innovita Hcg Pregnancy Rapid Test Midstream	Innovita (Tangshan) Biological Technology Co., Ltd	K192843	11/22/2019

Homing in on a single predicate device, I can see everything I need to start my 510(k):

[New Search](#) [Back To Search Results](#)

Device Classification Name	kit_test_pregnancy_hcg_over the counter
510(k) Number	K213379
Device Name	Clearblue® Early Pregnancy Test
Applicant	SPD Swiss Precision Diagnostics GmbH 47 Route De Saint Georges, Petit-Lancy Geneva, CH CH-1213
Applicant Contact	Joanne Scaife
Correspondent	SPD Development Company Limited Priority Business Park, Stannard Way Bedford, GB MK44 3UP
Correspondent Contact	Kamila Przedmojska
Regulation Number	862.1155
Classification Product Code	LCX
Date Received	10/13/2021
Decision Date	09/21/2022
Decision	Substantially Equivalent (SESE)
Regulation Medical Specialty	Clinical Chemistry
510k Review Panel	Clinical Chemistry
Summary	Summary
FDA Review	Decision Summary
Type	Traditional
Reviewed by Third Party	No
Combination Product	No

I've found a predicate device, and I can even see that that device itself has its own predicate device and was found to be 'substantially equivalent' (SESE) to another marketed pregnancy test.

Crucially, I can see the three-lettered product code (LCX) for this entire category of devices. So I can always go back and search this code if I want to check the entire group of substantially equivalent devices.

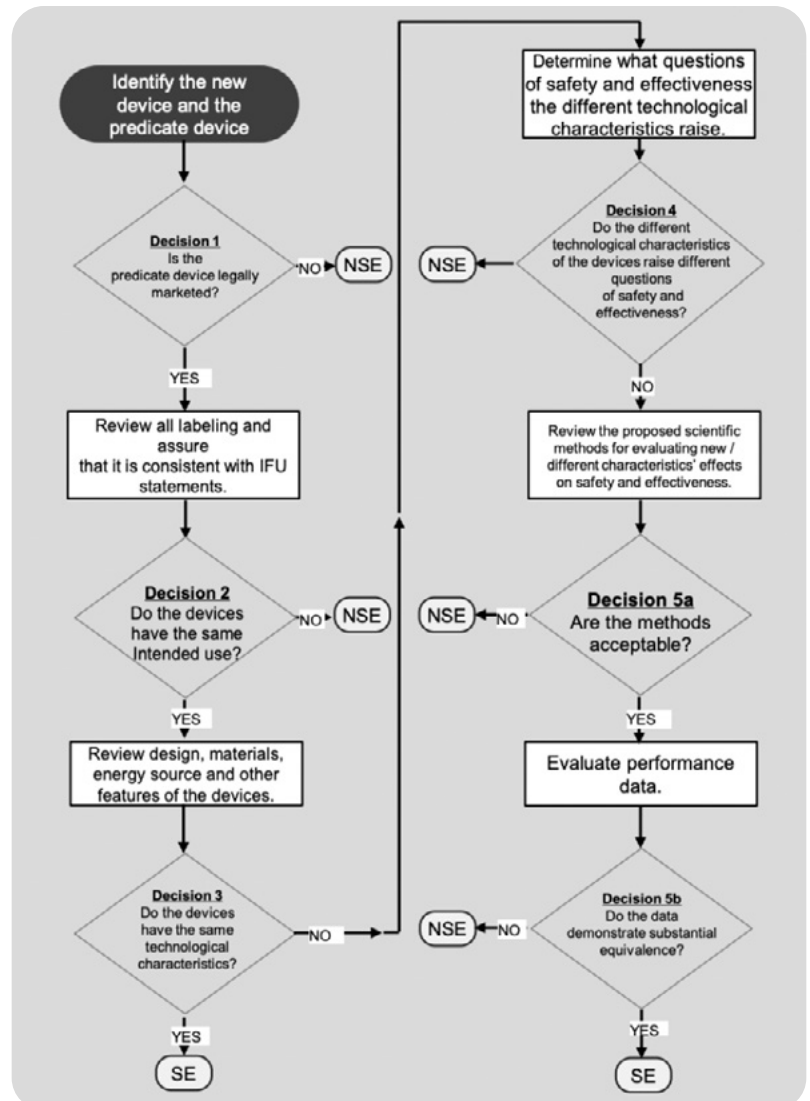
Remember: the wrong predicate device can scupper your submission and send you back to Square 1. So do some careful consideration here, always ensuring that the 'substantial equivalence' threshold is being met.

Once you've found a predicate with provable substantial equivalence, use these key ingredients to learn as much as you can about your predicate device:

- 510(k) submission summary
- A sample (probably lots of samples...)
- Diagrams
- Operating instructions
- Labels
- Marketing literature



[Read the official FDA guidance for determining substantial equivalence](#)



2. Building a quality management system

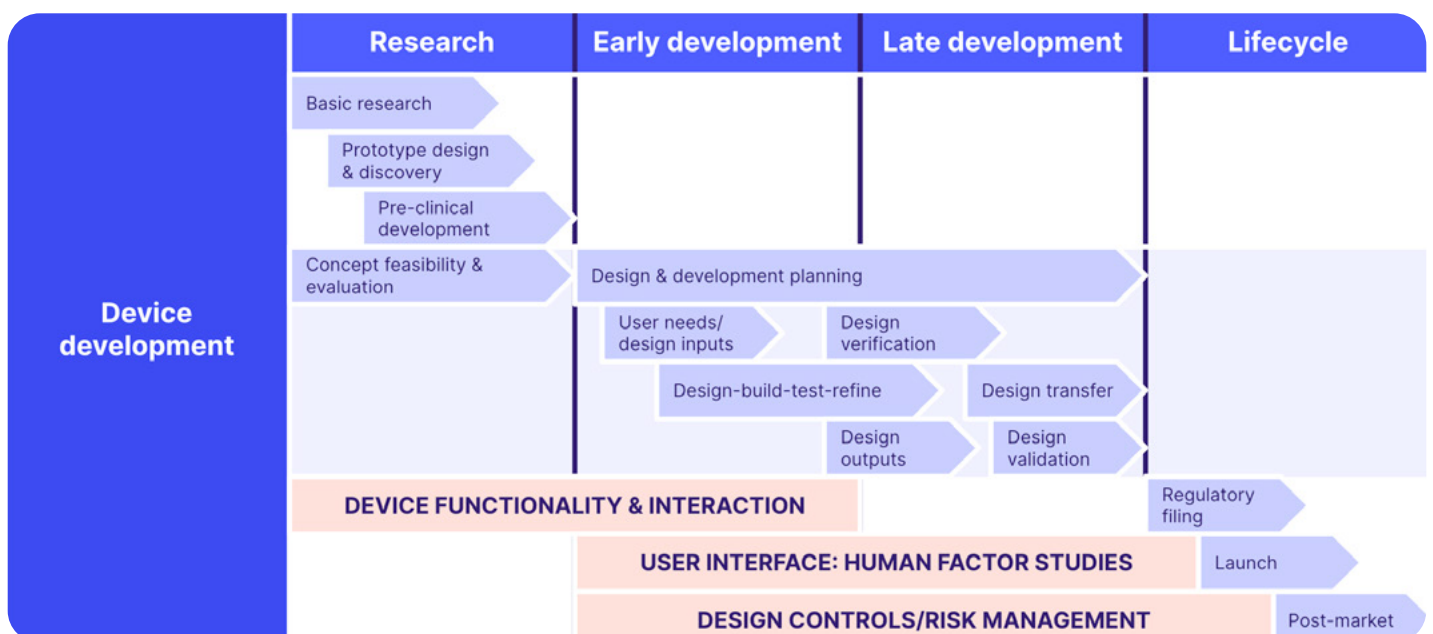
An effective medical device quality management system with documented, standardized processes and procedures is crucial for underpinning your 510(k) submission and proving your device's safety and integrity.

Before submitting your 510(k), you should focus on embedding compliance with FDA 21 CFR 820, [as well as](#) ISO 13485. Your QMS should house clear SOPs for all of the following areas:

- Regulatory and compliance strategy
- General safety and performance requirements (GSPR)
- Management responsibility
- Resource management

- Risk management
- Performance evaluation
- Product realization
- Unique Device Identification (UDI)
- Post-market surveillance
- Communication with competent authorities
- Incident reporting & field safety corrective action
- CAPA management
- Monitoring & measurement

Your QMS should also be supported by strong [design](#), [document](#) and [change control](#), with careful recording of your device lifecycle as the research, design and development stages unfold. The more documentation you perform early, the easier your FDA 510(k) submission will be.



3. Device testing

Now we move onto the key 510(k) submission activity: performing your device tests to prove safety, efficacy and substantial equivalence.



[Learn more about the core requirements any medical device QMS needs for regulatory compliance](#)

The predicate device you chose in Step 1 will determine the tests you need to perform on your medical device. Your predicate is your benchmark and sets the acceptance criteria for your medical device testing.

Typical testing examples include:

- Mechanical/thermal/electrical
- Materials & make-up
- Wear/fatigue/durability
- Cleaning/sterilization
- Biocompatibility
- Electromagnetic compatibility

4 top testing tips

1. Use the product claims of your predicate device to set your test criteria
2. Use [ISO 14971](#) as your benchmark
3. Look for historic recalls in your product category: use the faults as inspiration
4. Give yourself a [digital mechanism](#) for managing your design control activity

- Feature performance: normal and abnormal conditions

It's important that your business budgets wisely for this testing phase. Testing activity will form the bulk of your 510(k) expenses.

Get the right people and tools to maximize your in-house capability; typical third-party testing prices can quickly stack up:

- Third-party biocompatibility testing: **\$13,000**
- Third-party sterilization testing: **\$15,000**
- Third-party bench testing: **\$30,000**
- Third-party electrical/EMC testing: **\$50,000**
- Third-party implantation testing: **\$100,000+**

If your device is an SaMD, you'll need to account for software validation activity too.

4. Submission

The FDA 510(k) submission itself is comprised of 20 key ingredients.

The FDA no longer requires a hard copy of the submission, and launched its [Electronic Submission Template](#) in September 2022 as part of a broad push towards digital submissions.

Following early success, in October 2022 the FDA announced its CDRH Customer Collaboration Portal would allow either an electronic copy (eCopy) or electronic Submission Template And Resource (eSTAR) 510(k) submission. If you're planning to submit before October 1, 2023, you can choose an old-fashioned mail submission, or an eCopy or eSTAR submission.

But after October 1 2023, only the eSTAR will be accepted. The eSTAR is a templated dynamic PDF you complete and submit electronically through the [CDRH Portal](#) (which you'll need to sign up for). This more guided process

is part of the FDA's push to make 510(k)s faster and easier than ever before. Let's dive into the key documents your 510(k) submission should include.

I. Cover sheets

The first two ingredients of your FDA 510(k) submission are your cover sheets:

- The FDA 3601 form (Medical Device User Fee Cover Sheet)
- The FDA 3514 form (CDRH Premarket Review Submission Cover Sheet)

The user fee cover sheet is your receipt for payment to enter the 510(k) process. The FDA website contains [instructions](#) for how to complete it.

Save \$14,903 with a form

Make less than \$100m annually?

Complete [FDA Form 3602](#) (or 3602A for non-US firms) to register as a small business.

Small businesses pay just **\$4,967** for 510(k) submissions in 2023, compared to the **\$19,870** standard fee.

Businesses of all sizes also pay the annual establishment registration fee of **\$6,493**.

Complete the Form 3602 every year to maintain small business status!

The Premarket Review sheet is a basic summary of your submission, including company/device information, reason for submission, type of device, and so on.

II. Summary documents

Next come your summary documents:

- Cover letter

- Statement of indications for use
- 510(k) summary OR statement

Your cover letter is a broad summary of your 510(k) submission.

Your indications of use statement **MUST** match the indications for use of your predicate device. It's made public after 30 days – so don't reveal too much if your device is designed to fill a market niche!

For the final summary document, choose *EITHER*:

- **Summary:** combination of information that your SE claim is based on
- **Statement:** certification that you'll provide safety/effectiveness information to any requester within 30 days

III. Statement documents

The 510(k) 'statement' documents are:

- Truthful & accurate statement
- Class III summary
- Financial certification/disclosure statement
- Declaration of conformity & summary reports

Not all of these documents may be relevant to you, depending on the

I certify that, in my capacity as (the position held in company) of (company name), I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted. (Signature, date, time).

— GAMP 5 Enabling Innovation Good Practice Guide

circumstances of your submission.

The truthful and accurate statement is a standard, templated declaration as follows:

As we've seen, most 510(k) submissions are for Class II devices – so the Class III summary is a simple declaration that you aren't a Class III device. If yours is one of the rare Class III 510(k) submissions, you'll need extra safety/effectiveness data here in line with your device's higher risk profile.

The financial statements are only required if you conducted clinical trials for your medical device.

If you paid your investigators, complete the disclosure statement.

If you didn't, complete the financial certification.

And finally, the declaration of conformity & summary reports aren't required for the Traditional 510(k) route – they're for showing conformity with relevant standards in the Abbreviated route.

IV. SE documents

The SE documents, as you might expect, are for proving your device's substantial equivalence to its predicate. We do this with three separate documents:

- Executive summary
- Device description
- Substantial equivalence comparison

The executive summary is a more detailed version of your 510(k) summary, elaborating on your completed testing activity.

Your device description should include your key technical information:

Design History File, design outputs, drawings, specs, dimensions, and so on. And your SE comparison is a side-by-side mapping of your device and its predicate, including the use, technology and performance of both devices.

V. Safety documents

The safety documents in your FDA 510(k) submission are:

- Proposed labeling
- Sterilization and shelf life
- Biocompatibility

Your labeling proposal should include your device label, patient labeling, in-package inserts and operating instructions. Your Unique Device Identification (UDI) code isn't mandatory at this stage, but you should include a sample barcode of where it will go.

If your device isn't sterilized or with a shelf life, you can skip the next section. If it is, include your test data for these areas here.

And for the biocompatibility section, include your test protocols and reports for any areas in patient contact (direct or indirect).

VI. Digital/electrical documents

If your device has a digital or electronic component, you'll need to include these next sections, Sections 16 and 17, in your 510(k) submission. If not, don't ignore them – briefly explain why they aren't relevant for you.

There are two documents to consider:

- Software
- Electromagnetic compatibility/
electrical safety

Helpful software reference docs

- [Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices](#)
- [IEC 62304](#)

For the software documentation, establish your device's Level of Concern (LOC) and add your test data accordingly.

Your EMC document should prove your device won't interfere with, or be jeopardized by, other nearby devices. The electrical safety document should prove that the electrical components in patient contact aren't a threat to patient safety. It's important to note that your device can still be a hardware device and include a software element. If your device falls here, you still need to account for all software operation in your 510(k) submission, even if you aren't an 'SaMD' or 'SiMD' by definition.

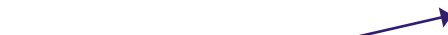
Firmware-related software will still need documentation; your device's Level of Concern will determine what level of documentation is needed.

Helpful EMC/EC reference documents

- [IEC 60601-1](#)
- [IEC 60601-2](#)

Briefly explain why Section 16 doesn't apply to you

Don't neglect Section 16 if your device sits here!



VII. Performance documents

Finally, we arrive at your device's performance documents. These are arranged in 3 sections:

- Bench
- Animal
- Clinical

Only the first is mandatory; the other two may not apply to your operation.

All completed tests should have protocol descriptions, summaries, methodologies and clear results.

5. The wait

You've assembled the sections of your 510(k) submission.

You've gone over the [FDA's Refuse to Accept policy](#) to make sure you're meeting all of its 56 requirements and won't receive a refuse-to-accept letter.

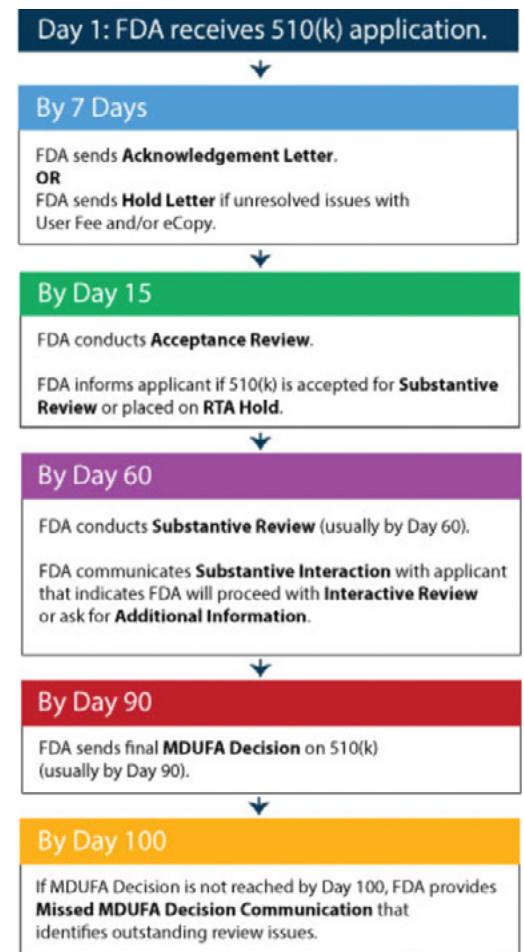
Now it's time to press the button and wait.

How long does an FDA 510(k) submission review take?

The FDA's official timeline is as follows:



[Read FDA guidance on bench testing](#)



Despite the 'ideal' 100-day timeframe, the average approval time after submission is **175 days**.

This is skewed by some excessively long device approvals however, with the median approval time standing at **85 days**.

The average number of days it takes to clear a device via 510(k) also varies according to the device category.

Anesthesiology devices have the longest average length to approval, averaging 245 days.

Toxicology devices are the shortest on average, at just 163 days. In short, your business is looking at a 3-6-month waiting time after submission.

Clearance!

A medical device is never 'approved' by the FDA after a 510(k) submission.

Instead, you'll receive a letter (no certificate) confirming your device is cleared for marketization in the United States.

You can now market your device, but must still comply with other requirements like:

- Registration and listing (21 CFR Part 807)
- Labeling (21 CFR Part 801)
- Reporting (21 CFR 803)
- GMP requirements (21 CFR Part 820)

Well done! Pour yourself a drink.

Top 8 510(k) submission mistakes

As we've already seen, a full 30% of 510(k) submissions in 2022 weren't even accepted for initial review.

A right-first-time 510(k) approach gets you to market faster, eliminating wasted time and effort while generating revenue more quickly.

To help you, we've assembled the 8 most common mistakes made by medical device manufacturers in their FDA 510(k) submissions.

01. Incorrect templates/
document versions

02. Choosing an unsuitable
predicate

03. Inconsistent information in
areas where information is
repeated in the submission

04. Skipping non-applicable
sections, instead of
documenting why they aren't
applicable

06. Incomplete test information
(summaries without
protocols/reports)

07. Wasting money by not
applying for small business
status

08. Immature quality/risk
management

09. Generally disorganized
submission documents
(no ToC, lax sectioning/
numbering, etc.)

5 top tips

As an [electronic quality management software](#) provider, Qualio works with international medical device organizations every day. Our team is full of experts with decades of collective quality and regulatory experience.

To make your FDA 510(k) submission process even smoother, here are 5 top tips from the team.

- 01.** Try and use a fairly recent device as a predicate. Devices older than a decade are frowned upon!
- 02.** Ensure everything is covered – nearly two-thirds of submissions are slowed by Additional Information (AI) requests
- 03.** The more design control, risk and quality documentation you can organically build as you develop your device, the faster and easier your 510(k) assembly will be
- 04.** Substantial equivalence is everything! 15% of submissions fail because of the wrong predicate
- 05.** Familiarize yourself with the eSTAR now, so you're prepared for the October 2023 transition date

Accelerate your FDA 510(k) submission

Want a faster, more controlled 510(k) process? Qualio provides electronic quality management software to help medical device manufacturers digitize, automate and strengthen their quality management activities.

Electronic documentation, controls, workflows and records simplify all aspects of your FDA 510(k) submission process and get you to market faster.

[Download free guide](#)



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