

Complete FDA premarket approval (PMA) submission guide

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What is an FDA PMA submission?

The FDA premarket approval (PMA) process is a US regulatory pathway for the approval of high-risk medical devices before they can be marketed and sold.

The PMA process is applicable to medical devices that are considered to have a high risk to patients, such as life-sustaining or life-supporting devices.

The FDA PMA process involves a comprehensive review of scientific data and evidence submitted by the device manufacturer.

You need to provide detailed information about your device's design, manufacturing process and performance and clinical data, demonstrating safety and efficacy throughout. The FDA then assesses this information to determine whether your device meets the required standards for clearance.

The PMA process, reflecting the high-risk nature of the devices it scrutinizes, is rigorous and typically involves multiple stages of review, including a quality management system review as well as a thorough scientific and clinical evaluation, usually including clinical trials.

It also includes inspection of your manufacturing facilities. The FDA assesses the benefits and risks of your device based on the data provided, as well as the potential impact on patient health and safety.

Upon successful completion of the PMA process, the FDA clears your device for marketization, allowing it to be sold and used in the United States.

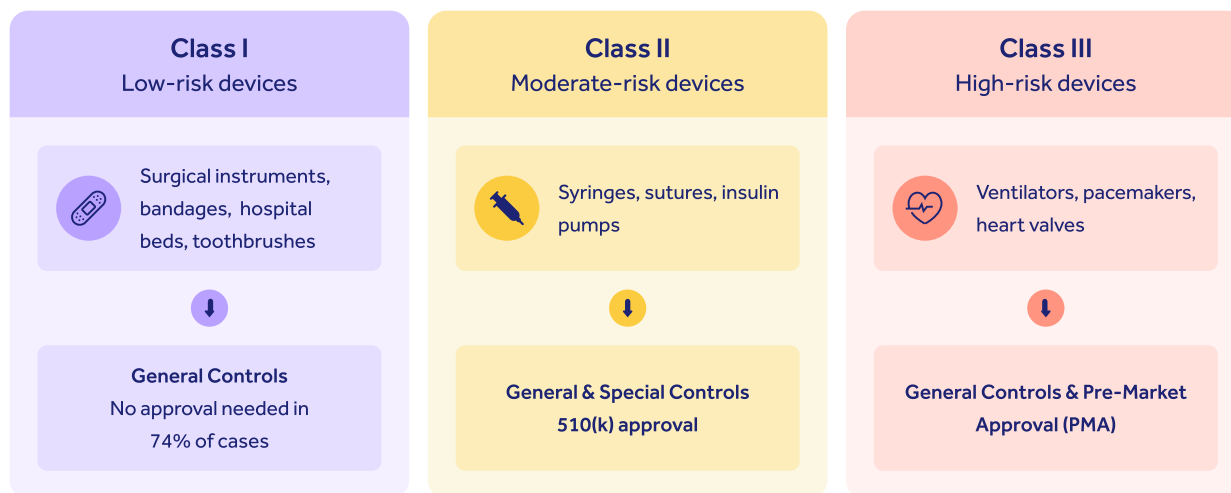
Your PMA submission should:

01. Demonstrate that your medical device has been designed, developed and manufactured with robust quality and compliance
02. Offer detailed technical, safety and performance device/test information to show that your device is safe and effective
03. Prove you have an effective medical device quality and risk management system

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

The PMA 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.



As we can see here, so-called Class III devices with a high risk profile require the completion of premarket approval in order to be legally marketed in the US.

That's about 10% of devices.

The FDA defines Class III medical devices as those that:

"... usually sustain or support life, are implanted, or present potential unreasonable risk of illness or injury..."

Class III medical devices that fall under the FDA PMA umbrella include:

- Active implantable medical devices (AIMDs)
- Artificial organs
- Pacemakers
- Defibrillators
- Ventilators
- Heart valves
- Breast implants
- Implanted prosthetics

As you'd expect, a PMA is much more detailed and in-depth than a 510(k). Device manufacturers are typically required to present human clinical trial data, in addition to laboratory testing data.

Who needs to submit a PMA?

There are 3 groups of actors who would, depending on specific business circumstances, be responsible for completion of an FDA PMA submission.

1. American medical device manufacturers

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

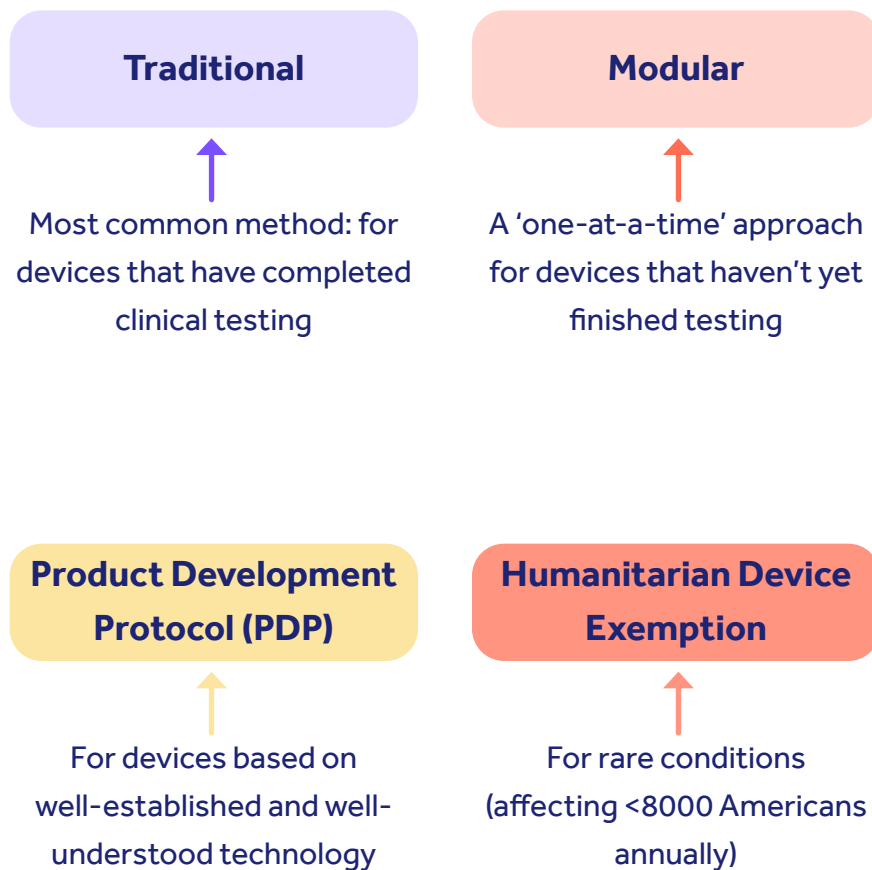
2. Owner of rights to the device and its data

If you aren't making the device yourself, but legally own the rights to it, the device is your responsibility as its owner.

3. Device/trial sponsors

Designed and developed a medical device but outsourcing production to a CMO, or clinical trials to a CRO? The PMA submission is still your responsibility, not your contracted partner.

The 4 types of PMA submission



It's most likely that you'll go down the traditional PMA route. This is for Class III devices that have already completed clinical tests, and therefore for companies that already have the requisite clinical data to give to the FDA.

But you can also start your PMA early, before clinical testing is complete, and go down the modular PMA route. This 'one-at-a-time' approach lets you complete sections of your PMA as your device's development and testing unfolds, submitting them individually into an overarching 'Shell'. Once all ingredients are submitted, you have a complete FDA PMA submission ready for review.

The PDP option follows a similar vein of substantial equivalence that we see in the 510(k) submission process, and it's for companies bringing a device to market that uses technology already widely established and understood. A PDP maps out in advance the design and development milestones expected of you, which you can then work through at your own pace until completion.

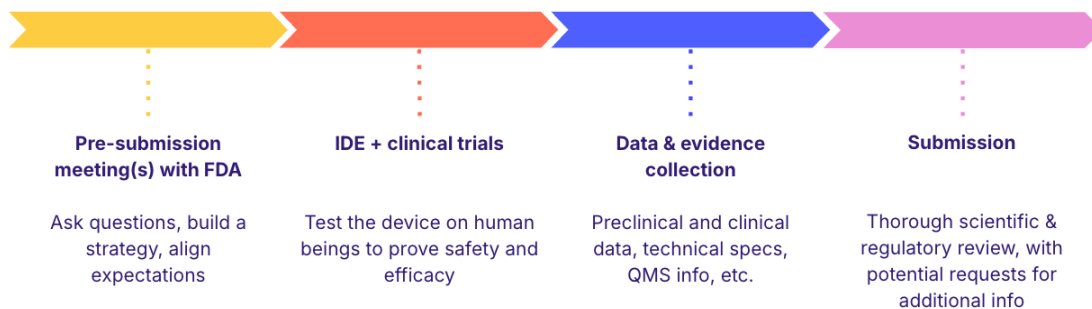
The final, and rarest, option is the Humanitarian Device Exemption (HDE) process. It's for devices used to treat rare conditions, affecting <8000 Americans annually. The HDE process places limits on profitability, allowing it only if intended for use on children, and even then only up to a designated finite amount.

Whichever option you go for, ensure your data and scientific writing is robust, logical and easy to follow and trace.

The FDA expects an electronic 'eCopy' submission of your PMA, ensuring all the data ingredients above are ticked off and included. Once you've submitted, it's time to sit back for the review process.

The FDA PMA submission process

Now we've covered the basics of the FDA PMA, let's take a look at the end-to-end process itself.



1. The 'pre-sub'

Manufacturers typically begin with a pre-submission meeting.

It's a kind of strategy session with the FDA where businesses can pose questions, clarify expectations, and get aligned on what needs to be done.

2. The IDE

Prior to testing in human beings, businesses have to obtain an Investigational Device Exemption (IDE) approval from the FDA. That requires:

- an investigational plan approved by an institutional review board (IRB). If the study involves a significant risk device, the IDE must also be approved by FDA;
- informed consent from all patients;
- labeling stating that the device is for investigational use only;
- monitoring of the study and;
- required records and reports

3. Data & evidence collection: the QMS

An effective medical device quality management system with documented, standardized processes and procedures is crucial for underpinning your PMA submission and proving your device's safety and integrity with trustable, high-integrity data.

In contrast to the 510(k) pathway, the PMA application process includes a review of manufacturing information for compliance with FDA QMS requirements. While manufacturers of devices covered by a 510(k) must also comply with QSR requirements and may be selected for inspection at any time, the FDA does not scrutinize the manufacturer's QMS as part of the premarketing authorization. Readiness for FDA QMS review is, though, a critical part of your preparation for PMA submission.

Think of your QMS compliance and your device submission pathway as two interacting halves of the same coin: you'll need some evidence of your QMS processes for producing, storing, and installing the device in your submission (more on that later), and having a robust QMSR-compliant QMS will make it much easier to get accurate, reliable device data to feed into your submission dossier.

Equally, getting robust, well-documented design controls and risk management

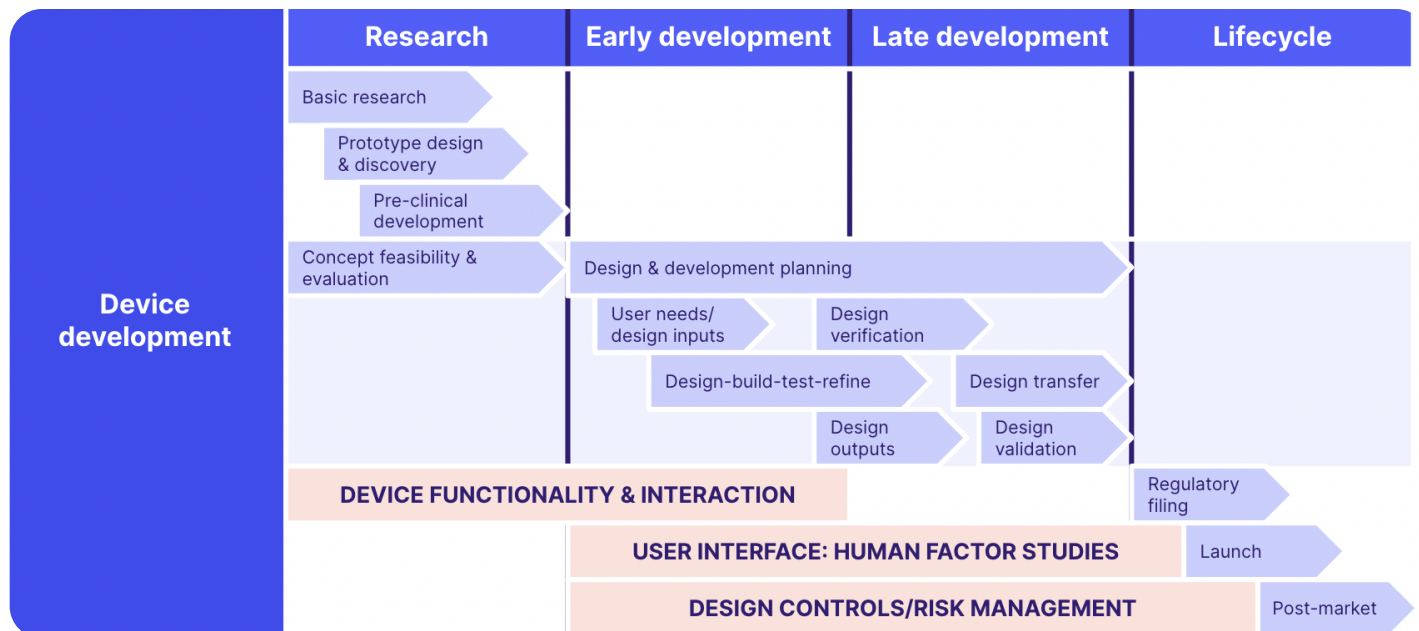
processes in place will help your device through its PMA submission and make your FDA inspector happy when they come to perform an inspection. A strong, functional quality system should be the cornerstone of your entire operation, and this is absolutely unavoidable for Class III manufacturers.

Before submitting your PMA, you should focus on embedding compliance with [the FDA QMSR](#).

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 build early, the easier your FDA PMA submission will be.



4. Submission

The FDA PMA submission itself is comprised of some 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) PMA submission.

Since 2023, all 510(k) submissions require an eSTAR and since October 2025, all *de novo* submissions require one too. We can expect the PMA process to eventually follow suit - so it's best to prepare your submission with an eSTAR in mind.

The eSTAR is simply 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 PMAs faster and easier than ever before. Let's dive into the key documents your 510(k) submission should include.

I. Cover letter

- Identification of submission type
- Reference numbers for any related submissions/docs
- Contact details
- Indication for use
- Indication of whether submission includes environmental assessment



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

II. Cover sheet (Form 3514)

- Optional summary of administrative data to streamline submission

III. Table of contents

- Section and page numbers for all submission data

IV. Summary

- Indications for use
- Device description
- Any current, commercially available alternatives for same indication of use
- US and international marketing history (if applicable)
- Summary of clinical and nonclinical data, with any additional technical info/data
- Conclusions drawn

V. Detailed descriptions of...

- Device & components
- Properties
- Usage & operation
- QMS processes for producing, storing, and installing the device (if you have them built already)

Save \$435,000 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 **\$144,818** for PMA submissions in 2026, compared to the **\$579,272** standard fee.

Businesses of all sizes also pay the annual establishment registration fee of **\$11,423**.

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

Plus: small businesses qualified through the Small Business Determination program with gross receipts or sales of \$30 million or less are also eligible to have the fee waived on their first Premarket Approval Application!

VI. Performance & voluntary standards

For more information on consensus standards, see the FDA's Standards and Conformity Assessment Program. You can also search the Recognized Consensus Standards database. Performance standards typically are more applicable to a 510(k) submission, but may apply in certain circumstances to a PMA.

VII. Technical sections

- Nonclinical lab studies: human or animal, with GLP statement
- Clinical investigation info, including:
 - Clinical protocols
 - Number of investigators/subjects per investigator
 - Selection/exclusion criteria
 - Population demographics
 - Study period
 - Safety and effectiveness data
 - Adverse reactions/patient discontinuation data
 - Patient complaints
 - Device failures and replacements
 - Data from all individual subject reporting forms
 - Contraindications for device use

If your PMA is supported by data from a single investigator, you must also justify in this section that this is sufficient to demonstrate the safety and effectiveness of the device.

VIII. Published report biography

- Any published report (not already referenced) concerning safety or effectiveness of the device

IX. Samples

- Physical, or location for FDA to examine

X. Labeling

- Copies of all proposed labels
- See CFR 801 for labeling definition

XI. Environmental assessment

- Required unless a similar device has already been approved

XII. Financial certification/ disclosure statement

Any arrangements/financial interests that exist between clinical investigator and device manufacturer, certifying that they don't compromise study result validity.

Include a financial certification or disclosure statement, or both, as required by 21 CFR 54:

- Certification: Financial Interests and Arrangements of Clinical Investigators (Form FDA 3454)
- Disclosure: Financial Interests and Arrangements of Clinical Investigators (Form FDA 3455)

XIII. Additional info

- Anything else the FDA requests from you

XIV. Other references

- Reference any information already filed with the FDA (from the same PMA applicant, or with signed authorization if different)

XV. Omissions

- With statements of justification

XVI. Color additives

- List any dyes/pigments/colorations on your device

XVII. Updates

Periodic updates are required when new information is learned from ongoing or completed studies that may affect the evaluation of the safety or effectiveness of a device.

Three copies of each updated report must be submitted and must reference the PMA number assigned by the FDA. Each such update is considered to be an amendment to the original PMA, and as such will not cause any extension to the review timeframe.

These amendments must be submitted 3 months after receipt of the PMA approvable letter, and at any other time as requested by the FDA.

The wait

The difference in complexity between a PMA and 510(k) affects the time needed to process the submissions.

The FDA typically accepts or rejects a 510(k) submission within about 90 days, at which point the device is posted to the FDA's 510(k) database.

A PMA submission takes about a year to be processed, at which point the FDA can approve or deny the application. The FDA may also issue an “approvable” or “not approvable” letter, which the applicant can choose to respond to, thereby adding time to the submission process.

Despite the FDA's target 180-day timeframe, the average PMA submission review timeframe stands at around 400 days.

After approval is confirmed by the FDA, you'll receive a letter (no certificate).

You can now market your Class III 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)

Pour yourself a drink. But remember, this is the beginning not the end!

Top 8 PMA submission mistakes

70% of PMA submissions are knocked back after initial review.

A right-first-time PMA 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 PMA submissions.

01. Incorrect templates/
document versions
02. False or unsubstantiated
statements
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

05. Incomplete trial/
investigational info
(summaries without
protocols/reports)
06. Wasting money by not
applying for small business
status
07. Immature quality/risk
management
08. Simultaneous 510(k)
application for same device

5 top tips

As a [life science quality and compliance 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 PMA submission process even smoother, here are 5 top tips from the team.

01. Ensure you're aligned with the FDA's new QMSR model from February 2026
02. Engage with the FDA frequently through the Q-Submission, STeP or Breakthrough Devices programs as appropriate
03. The more design control, risk and quality documentation you can organically build as you develop your device, the faster and easier your PMA assembly will be
04. Put Good Clinical Practice (GCP) at the center of your device investigations
05. Use supporting guidance documents to assist your PMA strategy, from ISO 10993-1 to FDA benefit-risk guidance docs

Ace your FDA PMA submission

Want a faster, more controlled PMA process? Qualio's quality & compliance software helps Class III medical device manufacturers get best-in-class quality and compliance activity in place.

AI-powered gap analysis, electronic documentation and flexible, configurable workflows simplify all aspects of your FDA PMA submission process and get you to market faster.

[Learn more](#)



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