FAQs for **PMA Pathway**

Digital Health **Regulatory** Pathways

1 What is the Premarket Approval (PMA) Pathway?

Premarket approval (PMA) is the process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices used by the US Food and Drug Administration (FDA). PMA is the most stringent type of marketing application required by the FDA, and fewer than 10% of marketed digital health products have been approved using the PMA pathway.

2 What kind of digital health products are eligible for the PMA pathway?

Digital health products that are not substantially equivalent to any legally marketed predicate device and are classified as Class III (high-risk) are eligible for the PMA pathway. These products must be novel and must support or sustain human life, be of substantial importance in preventing impairment of human health, or present a potential, unreasonable risk of illness or injury.

3 Can PMA and De Novo applications be filed at the same time?

No – Novel digital health products for which there are not a substantially similar marketed equivalent typically qualify for PMA status; however, novel digital health products with a lower risk profile may qualify for De Novo status. Sponsors can determine if their product meets the criteria for a PMA classification using the FDA's product classification database.

4 Should "Pre-Submission" be considered before submitting a PMA application?

Yes – the FDA strongly recommends filing a "Pre-Submission" if no products similar to yours have been reviewed via the regulatory process. Learn more about the Pre-Sub process.

5 How long does it take to process a PMA application?

A PMA application can take up to **180 days** to be processed, with interim reviews, such as the Acceptance and Filing reviews detailed in the DiMe PMA Checklist.

6 Where can I find a list of historic PMA approvals?

You can find a list of all PMA products approved by the FDA since 2013 here. This list is useful in determining if substantially similar products exist on the market, the risk status of your product, and whether you qualify for the PMA pathway.

7 Is there a fee associated with a PMA Application?

Yes – For 2023, the standard user fee is $441,547 and the small business fee is $110,387. The fees are determined by fiscal year. Check out for the most updated fee here.

8 When may the FDA refuse to accept a PMA Application?

FDA may refuse to file a PMA during the Agency's Acceptance review if any of the following applies:

1. The PMA is incomplete because it does not on its face contain all the information required under section 515(c)(1)(A)-(G) of the FD&C Act.
2. The PMA does not contain each of the items required under section 814.20 and justification for omission of any item is inadequate.
3. The applicant has a pending premarket notification under section 510(k) of the FD&C Act with respect to the same device, and FDA has not determined whether the device falls within the scope of section 814.1(c).
4. The PMA contains a false statement of material fact.
5. The PMA is not accompanied by a statement of either certification or disclosure as required by 21 CFR Part 54.

Click through DiMe's PMA Checklist and check FDA's PMA Acceptance and Filing guidance to get a better understanding of the FDA's PMA application requirements.

9 Can a PMA application be withdrawn?

Yes – a PMA application can be withdrawn before a decision is made by the FDA.

10 What are common reasons the FDA might decide not to approve a PMA Application?

FDA may deny approval of a PMA if the applicant fails to follow the requirements of the PMA regulation or if the FDA determines that any of the grounds for denying approval of a PMA specified in section 515(d)(2)(A)-(E) of the FD&C Act apply.

Common reasons the FDA might refuse to approve a PMA application:

General

- Omission or false statement of material fact
- Labeling noncompliance
- The applicant does not permit an FDA inspection of facilities and controls associate with device manufacturing or does not

permit access to all records pertinent to the application

- A nonclinical laboratory study or a clinical investigation involving human subjects described in the PMA was not conducted in compliance with appropriate regulation

Data

- The application does not meet the data requirements of the FDA in the technical, non-clincal laboratory, and clinical investigations sections
- The application lacks valid scientific evidence necessary to determine if the device is safe and effective for its intended use

11 What happens if a PMA application is denied and can an appeal be submitted in the case of a denial?

If a PMA application is denied, the FDA will issue a nonapproval letter describing why the application cannot be approved, or if there is insufficient information to make a determination.

The applicant may resubmit the PMA with additional information necessary to comply with the requirements of section §515(c)(1)(A)-(G) of the FD&C Act and 21 CFR 814.20. A resubmitted PMA must include the PMA reference number of the original submission.

Yes – a PMA application can be appealed if it is denied by the FDA.

12 What happens after a PMA application is approved?

After a PMA application is approved:

- The new product is authorized to be marketed and must now comply with applicable regulatory controls
- A new classification regulation is established for the product
- The FDA publishes a notice in the Federal Register announcing the new classification regulation and related controls
- The FDA generates and publicly discloses a decision summary and posts a copy of the granting order notifying the requester about marketing authorization
- Continued approval of the PMA is contingent upon the submission of required postapproval annual reports

Pre-Market Approval (PMA)

Search FDA PMA Database

DiMe Resources


At-a-Glance


Preparation Guide


Checklist


FAQs

Access DiMe's Digital Health Regulatory Pathway Resources


Identify your regulatory pathway


Build your regulatory strategy


Interact with regulators