PMA At-a-Glance

Digital Health **Regulatory Pathways**

What is a PMA Classification Request?	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) for products that support or sustain human life, are of substantial importance in preventing impairment of human health, or that present a potential, unreasonable risk of illness or injury. PMA is the most stringent type of device marketing application required by the FDA, and fewer than 10% of marketed devices have been approved using the PMA pathway.
When is a PMA typically required?	1. For devices with a Class III risk level designation 2. For novel devices for which there is not a substantially similar marketed equivalent product
What kind of products qualify for a PMA?	1. Products that support or sustain human life, are of substantial importance in preventing impairment of human health, or that present a potential, unreasonable risk of illness or injury 2. Novel devices for which there is not a substantially similar marketed equivalent product (however, novel devices with a lower risk profile may qualify for De Novo status)
What are the types of PMA submissions?	**Traditional PMA**: Applicable where the full content submission happens in a single application. Typically used when a product has already undergone clinical testing. **Modular PMA**: Submissions where the FDA allows companies to submit the application in parts (or modules). The FDA collaborates with innovators to develop a PMA "shell" which lays out an outline with timelines, contents, etc. **Product Development Protocol (PDP)**: PDP is a method to secure a clinical evaluation of the product, the development of necessary information for marketing approval, and marketing approval itself all merged into one regulatory mechanism.

How long does the PMA process take?	180 days (or less)
How much does the PMA process cost?*	• **Standard Fee** $441,547 • **Small Business Fee** $110,387
What are the steps to a PMA review?	There are 4 steps to the review process: 1. Administrative and limited scientific review by FDA staff to determine completeness (aka acceptance and filing reviews) 2. In-depth scientific, regulatory, and Quality System review by appropriate FDA personnel (a substantive review) 3. Review and recommendation by the appropriate advisory committee (aka panel review) 4. Final deliberations, documentation, and notification of the FDA decision.
Where can I access a list of PMA classified products?	Check out a list of legally marketed products in the PMA database.

How can I provide valid scientific evidence of safety and effectiveness of my digital health product?	1. Ensure your application does not contain
	  ○ isolated case reports
	  ○ random experience
	  ○ insufficient details to permit scientific evaluation
	  ○ unsubstantiated opinions
	2. Ensure that clinical study data were collected and analyzed per the protocol
	3. Ensure nonclinical and clinical data were collected on the final design of the device (i.e., the device design intended to be marketed)
	4. Ensure the study population and endpoints are consistent with the proposed indications for the product

**Small Business Fee: For businesses certified by the FDA Center for Devices and Radiological Health (CDRH) as a small business.*

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