PMA Checklist

Digital Health
Regulatory
Pathways

As you plan for a PMA Application Submission, check out the table below for a summary of the FDA's PMA acceptance and filing checklist.

Note: Throughout the document, the term "product" refers to a digital health product that entails either a medical device and/or a combination product unless indicated otherwise for specific reasons.

Checklist for Acceptance Review for PMAs

#	Information		Yes	No	N/A
Preliminary questions					
1	Is the product a device or a combination product (device + drug) with a device constituent part subject to review under PMA?		☐	☐	☐
2	If the product is a device or a combination product with a device constituent part, is it subject to review by the Center in which the application was received?		☐	☐	☐
3	Has a Request for Designation (RFD) been submitted? If so: If no, mark N/A *Note: RFD isn't required. FDA reviews use this process to ensure the application is filed with the relevant FDA review division.*	Does the product have the same design/formulation as that presented in the RFD submission?	☐	☐	☐
		Are the products and indications for use the same in the PMA and RFD submission?	☐	☐	☐
4	If the product is a combination product, is the drug component currently approved with exclusivity? If "Yes," then contact the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer, provide a summary of the discussion with them, and indicate their recommendation/action. Choose "N/A" if the product is not a combination product.		☐	☐	☐
5	Is Class III/PMA review required for the device?		☐	☐	☐
6	Is there a pending 510(k) submission for the same device with the same indications for use?		☐	☐	☐

7	Is the manufacturer currently on the FDA's Application Integrity Policy (AIP) list?		☐	☐	☐
Organizational and Administrative Elements					
1	Are all required sections of the application in English or accompanied with an English translation (includes written or translated reports, literature, articles, etc.)?		☐	☐	☐
2	Is there a table of contents?		☐	☐	☐
3	Is a bibliography provided?		☐	☐	☐
4	If a device sample has been requested by the FDA, has it been provided, or, if impractical to submit, has the applicant offered alternatives to allow FDA staff to view or access the device?		☐	☐	☐
5	Is there a summary of the contents of the PMA?		☐	☐	☐
6	Is the description of the product included?	Does the description include pictorial representations and material specifications?	☐	☐	☐
	If no, mark N/A.	Does the provided description include the principles of operation of the device (including components) and properties relevant to clinical function?	☐	☐	☐
7	Is the Device Manufacturing Section included and does it contain a description of the methods, facilities, and controls used in the manufacture, processing, packing, storage, and installation of the device?		☐	☐	☐
8	Are summaries of the nonclinical laboratory studies and full test reports provided? Including, as applicable:	a. Sterilization	☐	☐	☐
		b. Biological/Microbiological	☐	☐	☐
		c. Immunological	☐	☐	☐
		d. Toxicological/Biocompatibility	☐	☐	☐
	If no, mark N/A.	e. Engineering (stress, wear, etc.)	☐	☐	☐
		f. Chemistry/Analytical (typically for In-Vitro Diagnostics)	☐	☐	☐
		g. Shelf Life	☐	☐	☐
		h. Animal Studies	☐	☐	☐

		i. Other Essential Laboratory Testing	☐	☐	☐
9	Is a summary of the clinical investigation(s) and results provided? *If no, mark N/A.*	Are the final versions of the clinical protocols included?	☐	☐	☐
		Is a description of study population demographics provided?	☐	☐	☐
		Is a description of adverse events (e.g., adverse reactions, complaints, discontinuations, failures, replacements) given?	☐	☐	☐
		Have report forms for patients who died or who did not complete the investigation been provided (i.e., to resolve potential bias)?	☐	☐	☐
10	Are statistical analyses of the clinical investigations, as well as their results, provided?		☐	☐	☐
11	Has appropriate draft physician and patient labeling been submitted? *If no, mark N/A.*	**Physician Labeling** 1. Are indications for use included?	☐	☐	☐
		2. Are contraindications, warnings, and precautions included?	☐	☐	☐
		3. Are instructions for use included?	☐	☐	☐
		Patient Labeling (Check "N/A" if FDA indicated that patient labeling is not necessary.)	☐	☐	☐
		Technical/operator's manual	☐	☐	☐
Statements/Certifications/Declarations of Conformity					
1	Does the application utilize voluntary consensus standard(s)? *If no, mark N/A.*	If yes, does the application include: a Declaration of Conformity (DOC) as outlined in the FDA's guidance document, "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices," **or** If citing general use of a standard, the basis of such use is included along with the underlying information or data that supports how the standard was used?	☐	☐	☐

		If the application cites non-FDA-recognized voluntary consensus standard(s), does the application include the basis of use along with the underlying information or data that supports how the standard was used?	☐	☐	☐
2	Investigator Financial Disclosure	Has the applicant provided documentation to establish that they have followed the recommendations in applicable FDA guidance/guidelines or otherwise met applicable statutory or regulatory criteria?	☐	☐	☐
		Has the applicant submitted either a signed and dated Certification Form (3454) or a signed and dated Disclosure Form (3455)?	☐	☐	☐
		For a Certification Form (3454): Is the required list of all investigators and subinvestigators attached to the Form, or does the Form include the reason(s) why financial disclosure information could not be obtained?	☐	☐	☐
		For a Disclosure Form (3455): Does the application provide details of the financial arrangements and interests of the investigator(s) or subinvestigator(s), along with a description of any steps taken to minimize potential bias?	☐	☐	☐
3	Is an environmental assessment included (ONLY required for devices that present new environmental concerns)? Or, if claiming a categorical exclusion, does the application include information to justify the exclusion?		☐	☐	☐
4	FDA Form 3674	Did the application include a completed FDA form 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?	☐	☐	☐
		Does the form indicate if: 1. There are no clinical trials referenced in submission? **or** 2. Requirements are not applicable to	☐	☐	☐

		referenced clinical trials? **or** 3. Requirements are applicable and have been met?			
5	For all clinical investigations conducted in the U.S., does the application include one of the following for each investigation:	1. A statement of compliance with 21 CFR parts 50, 56, and 812, OR	☐	☐	☐
		2. A brief statement of the reason for noncompliance with 21 CFR parts 50, 56, and 812?	☐	☐	☐
6	For all clinical investigations conducted outside of the U.S., does the application includes one of the following for each investigation:	1. A statement that the clinical investigations were conducted in accordance with good clinical practice (GCP) as described in 21 CFR 812.28(a)(1), OR	☐	☐	☐
		2. A brief statement of the reason for not conducting the investigation in accordance with GCP and a description of steps taken to ensure that the data and results are credible and accurate and that the rights, safety, and well-being of subjects have been adequately protected, OR	☐	☐	☐
		3. A waiver request in accordance with 21 CFR 812.28(c)?	☐	☐	☐
Pediatric Use Provisions					
1	Does the application include a description of any pediatric subpopulations that suffer from the disease or condition that the device is intended to treat, diagnose, or cure, **or** A statement that no pediatric subpopulation exists for the disease or condition for which the device is intended, as well as the number of pediatric patients affected? *NOTE: This statement does not mean the device is indicated for treating pediatric patients.*		☐	☐	☐

Combination Product Provisions					
1	If your product is a combination product:	Does the application identify it as such?	☐	☐	☐
		Does the application include an appropriate patent statement or certification and a statement that the applicant will give notice, as applicable?	☐	☐	☐
2	Does the request describe how the device is relevant to the diagnosis, treatment, prevention, cure, or mitigation of a disease or condition?		☐	☐	☐
3	Does the request provide a complete description of all the functional parts or components of the product? (This description should include any parts or accessories that are marketed with the device.)		☐	☐	☐
4	If the product will be marketed with other devices (such as parts or accessories) that have already been approved by the FDA, does the request include a list of relevant FDA-assigned reference number(s)?		☐	☐	☐
History of the Application					
1	Does the applicant list prior submissions or state that there were no prior submissions? If so, which of these are included? If no, mark N/A	1. **510(k)** If this device has been the subject of an not substantially equivalent (NSE) decision, does the pre-market approval (PMA) address any issues relating to safety or effectiveness?	☐	☐	☐
		2. **IDE** (Investigational Device Exemption) Have the data presented in the PMA taken into account any safety or effectiveness concerns (e.g. “future considerations”) previously communicated through IDE correspondence?	☐	☐	☐
		3. **Prior PMA** (includes Modular PMA) If a previously submitted PMA for this device has been withdrawn, does the current PMA address any issues related to safety or effectiveness raised during review of the prior PMA?	☐	☐	☐

2	If a modular PMA was submitted, has the number of modules in the following categories been included in the application, as applicable? *If no, mark N/A.*	1. Does it have number of modules submitted	☐	☐	☐
		2. Does it have number of modules closed	☐	☐	☐
		3. Does it have number of modules on hold	☐	☐	☐
3	Further, If there are modules that are on hold, does the PMA address outstanding deficiencies?		☐	☐	☐
4	Does the applicant list Q-Submission(s) regarding the device or this application in which FDA feedback regarding data or information related to safety and/or effectiveness in the PMA was provided by email or during a meeting (in person or by phone), or state that there were no prior Q-Submission interactions with the FDA regarding this application? *If no, mark N/A.*	If applicant lists Q-Submissions, does the application include, as applicable: • Q-Submission #,	☐	☐	☐
		• Meeting date(s),	☐	☐	☐
		• Copy of minutes from each meeting or other written feedback?	☐	☐	☐
		Were all staff concerns or action items previously presented to the applicant in the Q-Submission minutes or feedback addressed in the PMA, **or** has the applicant provided a detailed scientific or clinical justification for an alternative approach?	☐	☐	☐

Checklist for Filing Review for PMAs

#	Information		Yes	No	N/A
Technical Elements					
1	Is study data consistent with the following, as applicable: 1. The protocol in the approved IDE (if one was required) or the sponsor's study protocol for a foreign study (i.e., conducted solely outside of the U.S.); **or**		☐	☐	☐
	2. Recommendations from a Q-Submission interaction; **and/or**		☐	☐	☐
	3. A device specific guidance document?		☐	☐	☐
2	Does the application include a description of the following elements: *If no, mark N/A.*	1. Sample size/number of patients enrolled and completing the study?	☐	☐	☐
		2. Follow-up duration for the primary analysis?	☐	☐	☐
		3. Follow-up evaluations for the primary analysis?	☐	☐	☐
		4. Study Objectives?	☐	☐	☐
		5. Study Population/Enrollment Criteria?	☐	☐	☐
		6. Study Endpoints?	☐	☐	☐
		7. Study Design?	☐	☐	☐
		8. Hypothesis?	☐	☐	☐
		9. Statistical Analysis?	☐	☐	☐
3	Does the patient/study population match the intended use?		☐	☐	☐
4	Have clinically significant endpoints been selected?		☐	☐	☐
5	If the primary study is based on foreign clinical data, does the application include a justification with respect to how the data are applicable to the U.S. patient population?		☐	☐	☐

Pre-Market Approval (PMA)

Search FDA PMA Database	*DiMe Resources*			
	At-a-Glance	Preparation Guide	Checklist	FAQs

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