De Novo Checklist

Digital Health
Regulatory
Pathways

As you plan to submit a De Novo Classification Request, check out the table below for a summary of the FDA's Acceptance 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.

#	Information	Yes	No	N/A
Preliminary questions				
1	Is this product an FDA medical device (or combination) product that is subject to review by the De Novo process?	☐	☐	☐
2	Is the De Novo request filed appropriately with the right FDA center via either the Center for Devices and Radiological Health (CDRH) or Center for Drug Evaluation and Research (CDER)?	☐	☐	☐
3	Has a Request for Designation (RFD) been submitted? If so, • Does the product have the same design/formulation as that presented in the RFD submission? • Are the products and indications for use the same? *Note: An RFD isn't required. The FDA is ensuring the application match.*	☐	☐	☐
4	If the product is a combination product (device + drug), is the drug component currently approved with exclusivity (meaning competitive drugs cannot currently be approved)? Choose "N/A" if the product is not a combination product.	☐	☐	☐
5	Is the product type eligible for De Novo classification?	☐	☐	☐
6	Is the manufacturer currently on the FDA's Application Integrity Policy (AIP) list?	☐	☐	☐
Organization and administrative elements				
1	Does the De Novo request contain a table of contents?	☐	☐	☐
2	Are all pages numbered?	☐	☐	☐
3	Is all content written in English (includes written or translated reports, literature, articles, etc.)?	☐	☐	☐

4	Does the request include all the pertinent information about the requester (name, address, phone, and email) and/or their U.S. representative for requesters outside the U.S.?		☐	☐	☐
5	Does the request include both the generic name and proprietary/trade (brand) name of the product?		☐	☐	☐
6	Does the request describe the product indications for use and its designation of availability as prescribed and/or over-the-counter (OTC)?		☐	☐	☐
7	Are there any other open premarket submissions (510(k), PMA, reclassification petition, etc.) for the same product with the same indications for use?		☐	☐	☐
8	Is the request for a single product type? For multiple products (e.g. multiple sizes for the same product), mark "No."		☐	☐	☐
9	If there were prior premarket submissions (e.g., if the product had an initial 510(k) submission where the product was not found to be substantially equivalent to a predicate device): • Are these submissions identified in the request? • Has the requester properly addressed all the deficiencies found by the FDA in those submissions? *Note: If yes, include a separate section with the prior submission number(s), a copy of the FDA feedback (e.g., letter, meeting minutes), and a statement of how or where in the submission this prior feedback was addressed.*		☐	☐	☐
10	Choose "N/A" if the product is not a combination product and skip to the next section	Is the product a combination product?	☐	☐	☐
		If the product is a combination product, are any drug portions of the product approved by the FDA? *Note: Requests should include any patents or certificates for this drug.*	☐	☐	☐
Product description					
1	Does the request include detailed descriptions (e.g. pictorial representations, device specifications, and engineering drawings) about the product's operation and how it will be used? (These descriptions include interfaces, the product's anatomical location, how it interacts with other devices, etc.)		☐	☐	☐

	specifications, and engineering drawings) about the product's operation?	*Note: Include a statement to clarify that any images, diagrams, etc., are not applicable to the device to justify their omission.*			
		Describe the proposed conditions of use and/or how the device interacts with the patient.	☐	☐	☐
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)?		☐	☐	☐
Alternative practices & procedures					
1	Does the request reference any other existing treatments/alternatives for the diagnosis, treatment, prevention, cure, or mitigation of the disease or condition that the device addresses?		☐	☐	☐
Classification summary and proposed classification					
1	If the product did not have a prior 510(k) submission done, have you provided:	Searches that informed no "predicate device" exist to prove substantial equivalence?	☐	☐	☐
		Information about potential predicate devices that were examined?	☐	☐	☐
		Rationale as to why this product is different?	☐	☐	☐
2	If the product had a prior 510(k) submission where no substantial equivalence was determined, does the request include the details of that decision along with confirmation that the product has not been classified or reclassified since the original FDA determination?		☐	☐	☐
3	Benefit-Risk: Does the request properly detail	Is valid scientific evidence included?	☐	☐	☐
		Does the request demonstrate how the benefits of the product outweigh	☐	☐	☐

	the expected health benefits and risks associated with the product?	the potential risks of injury or illness?			
4	Does the request outline a summary of all the probable health risks associated with the product? Does it include controls or mitigation for these risks? Learn more.		☐	☐	☐
5	Does the request recommend a Class I or Class II classification for the product? For each class designation, does the request document the appropriate level of safety and effectiveness for the product?		☐	☐	☐
Study summaries					
1	Does the request include a summary of results of the technical data?		☐	☐	☐
2	Does each study summary include the objectives, a description of the experimental design, data collection, and analysis method, and results?		☐	☐	☐
3	Does it include a summary of each non-clinical study? Learn more.		☐	☐	☐
4	Does it include a summary of each clinical investigation and identify any clinical investigations under an Investigational Device Exemption (IDE)?		☐	☐	☐
5	Does it include a summary of each clinical study with human subjects, including subject selection, exclusion criteria, investigation population, time period, safety and effectiveness data, adverse reactions or complications, subject complaints or discontinuations, product failures, contraindications, precautions of use, and other information as appropriate?		☐	☐	☐
6	Does the request provide a complete test report (including results) for any non-clinical studies? Learn more. Note: if an applicant is appropriately declaring conformity with a voluntary consensus standard, it may not be necessary to submit full test reports with respect to those requirements. Learn more.		☐	☐	☐
7	If the product is intended to be sterile	Identification of components and/or accessories?	☐	☐	☐

	and/or reusable, does the request include information on:	Sterilization method, parameters, validation method, and sterility assurance level?	☐	☐	☐
		Reprocessing information, including protocols and test reports of validation of instructions for reprocessing? Learn more.	☐	☐	☐
		Pyrogenicity test information?	☐	☐	☐
		Packaging information?	☐	☐	☐
8	Does the request include information on the product's shelf life or proposed shelf life, i.e. an evaluation of product performance demonstrating the product is not adversely affected by aging, or an explanation of why storage conditions are not expected to affect shelf life or device safety?		☐	☐	☐
9	In regards to biocompatibility, If the product includes patient-contact components, have you:	Identified each component that is patient-contacting and its associated materials?	☐	☐	☐
		Identified contact classification of the component that is patient-contacting?	☐	☐	☐
		Provided biocompatibility patient-contacting components?	☐	☐	☐
10	In regards to electrical safety or Electromagnetic Compatibility (EMC), have you:	Provided an evaluation for electrical safety or an evaluation using alternate methods or standards with a rationale explaining why those alternate methods or standards were used?	☐	☐	☐
		Provided an evaluation for EMC or an evaluation using alternate methods or standards with a rationale explaining why those alternate methods or standards were used?	☐	☐	☐
Software information					
1	Is all the relevant software information provided, including:	The level of concern and rationale for such concern?	☐	☐	☐
		The hazard analysis, hardware, and system information? Learn more.	☐	☐	☐
Standards and declaration of conformity					

1	Does the request include the Declaration of Conformity? Learn more.		☐	☐	☐
2	Are the non-FDA recognized consensus standards included?		☐	☐	☐
Animal studies					
1	Does the request include a statement that the study was conducted in compliance with Good Laboratory Practice, or if not, the reason for the noncompliance?		☐	☐	☐
Clinical studies					
1	Does the request contain results from each clinical investigation of the device, including:	All study protocols?	☐	☐	☐
		Number of investigators and subjects per investigator?	☐	☐	☐
		Investigation design, including study population and investigation period?	☐	☐	☐
		Subject selection and exclusion criteria?	☐	☐	☐
		Data from individual subject report forms?	☐	☐	☐
		Effectiveness data?	☐	☐	☐
		Safety data (includes adverse reactions, death subject complaints, product failures, and replacements)?	☐	☐	☐
		List of individual subject report forms for patients who died and did not complete the investigation?	☐	☐	☐
		A statement for each investigation that has been completed or a summary of any protocol deviation?	☐	☐	☐
		Results of any statistical analyses performed?	☐	☐	☐
		Statements on contraindications, warnings, precautions, etc., that are relevant to the use of the product?	☐	☐	☐
		If the request relies primarily on data from a single investigator at one investigation site, a justification showing that these data and other information are sufficient to	☐	☐	☐

		demonstrate the safety and effectiveness of the product when subject to general controls or general and special controls?			
		Explanation of clinical investigation data representing significant results?	☐	☐	☐
		A statement of Compliance for Clinical Investigations? Select N/A if there is no clinical data required. For multicenter clinical investigations outside of the US: Learn more.	☐	☐	☐
Financial disclosure					
1	Have you provided financial information if clinical studies were performed by submitting either a Certification Form (Form FDA 3454) or Disclosure Form (FDA 3455)? Learn more.		☐	☐	☐
Additional information					
1	Does the submission include a bibliography of all published reports, whether adverse or supportive, that addresses the safety or effectiveness of the product? If not, does it include a statement to justify the omission?		☐	☐	☐
2	Does it include an identification, discussion, and analysis of any other data, information, or report relevant to an evaluation of the safety and effectiveness of the product, foreign or domestic, including information derived from investigations other than those in the request and from commercial marketing experience?		☐	☐	☐
For IVD					
1	For an IVD (in vitro diagnostic) product, does the submitted labeling describe the performance characteristics of the device including precision, accuracy, specificity, and sensitivity?		☐	☐	☐
Labeling					
1	Does the request include labels, labeling, and advertisements sufficient to describe the product, its intended use, and the directions for its use?		☐	☐	☐

De Novo Toolkit

Search FDA De Novo 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