Digital Health Regulatory Pathways

De Novo Checklist

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

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				
Pre	liminary 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 <u>Application</u> <u>Integrity Policy (AIP) list</u> ?							
Or	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 the requester (r U.S. representat						
5	Does the reques						
6	•	st describe the product indications for use tion of availability as prescribed and/or er (OTC)?					
7	_	ther open premarket submissions (510(k), PMA, petition, etc.) for the same product with the is for use?					
8		or a single product type? For multiple nultiple sizes for the same product), mark					
9	If there were prehad an initial 51 found to be sub. Are these Has the redeficience Note: If yes, inclunumber(s), a copy and a statement feedback was additional and the statement feedback was additi						
10	Choose "N/A" if the product	Is the product a combination product?					
	is not a combination product and skip to the next section	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.					
Pr	Product description						
1	Does the request include detailed descriptions (e.g. pictorial representation s, device	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	Note: Include a statement to clarify that any images, diagrams, etc., are not applicable to the device to justify their omission.					
	drawings) about the product's operation?	Describe the proposed conditions of use and/or how the device interacts with the patient.					
2	Does the requesting diagnosis, treating disease or conditions.						
3	Does the requestional parts description sho marketed with the						
4	If the product w parts or access FDA, does the r reference numb						
Alternative practices & procedures							
1	Does the reque	П	П				
		rnatives for the diagnosis, treatment, e, or mitigation of the disease or condition that esses?					
Cla	prevention, cure the device addr	e, or mitigation of the disease or condition that					
Cla	prevention, cure the device addr assification sum If the product did not have a	e, or mitigation of the disease or condition that esses?					
	prevention, cure the device addr assification sum If the product did not have a prior 510(k) submission done, have	e, or mitigation of the disease or condition that esses? mary and proposed classification Searches that informed no "predicate device"					
	prevention, cure the device addr assification sum If the product did not have a prior 510(k) submission	e, or mitigation of the disease or condition that esses? mary and proposed classification Searches that informed no "predicate device" exist to prove substantial equivalence? Information about potential predicate					
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1	prevention, cure the device addressification summers. If the product did not have a prior 510(k) submission done, have you provided: If the product h substantial equinclude the detathat the product	e, or mitigation of the disease or condition that esses? mary and proposed classification 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? and a prior 510(k) submission where no ivalence was determined, does the request ails of that decision along with confirmation at has not been classified or reclassified since					

	the expected health benefits and risks associated with the product?	the potential risks of injury or illness?		
4	health risks ass	st outline a summary of all the probable ociated with the product? Does it include gation for these risks? <u>Learn more</u> .		
5	classification fo does the reques	st recommend a Class I or Class II or the product? For each class designation, st document the appropriate level of safety ss for the product?		
St	udy summaries			
1	Does the requestechnical data?	st include a summary of results of the		
2	Does each stud description of the analysis method			
3	Does it include 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 subjects, includ investigation podata, adverse reor discontinuati precautions of u			
6	Does the requeresults) for any applicant is appropriately consessible tearn 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: Reprocessing information, including protocols and test reports of validation of instructions or reprocessing? Learn more. Pyrogenicity test information?							
include information on: Reprocessing information, including protocols and test reports of validation of instructions for reprocessing? Learn more. Pyrogenicity test information? Packaging information? Information provided, including protocols and test reports of validation of instructions of validation of instructions of instructions of validation? Information Reprocessing information, including protocols and test reports of validation of instructions of validation? Information provided, including and test reports of validation on the product's shelf life or device safety? Identified each component that is patient-contacting and its associated materials? Identified each component that is patient-contacting or device safety? Identified each component that is patient-contacting or device safety? Identified each component that is patient-contacting or device safety? Identified each component that is patient-contacting or device safety? Identified each component that is patient-contacting or device safety? Identified each component that is patient-contacting or device safety? Identified each component that is patient-contacting or device safety? Identified each component that is patient-contacting or device safety? Identified each component that is patient-contacting or device safety? Identified each component that is patient-contacting or device safety? Identified each component that is patient-contacting or device safety? Identified each components? Information? Provided biocompatibility patient-contacting or device safety? In regards to affect shelf life or device s		reusable, does	·				
Packaging information?		include information	and test reports of validation of instructions				
B 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-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 electrical safety or electrical safety or electromagnet ic 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 with a rationale explaining why those 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.			Pyrogenicity test information?				
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 t components, have you: 10 In regards to electrical safety or electrical safety or Electromagnet ic Compatibility (EMC), have you: 10 In regards to electrical safety or an evaluation using alternate methods or standards with a rationale explaining why those alternate methods or standards were used? 10 In regards to electrical safety or an evaluation using alternate methods or standards with a rationale explaining why those alternate methods or standards were used? 10 In regards to electrical safety or an evaluation using alternate methods or standards were used? 11 In regards to electrical safety or an evaluation using alternate methods or standards were used? 12 Provided an evaluation for EMC or an evaluation using alternate methods or standards were used? 13 Is all the relevant software information provided, including: 14 Is all the relevant software information provided, including: 15 Is all the relevant software information? Learn more.			Packaging information?				
biocompatibili ty, If the product includes patient-contac t components, have you: Provided biocompatibility patient-contacting components? In regards to electrical safety or Electromagnet ic 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 with a rationale explaining why those alternate methods or standards were used? Software information The level of concern and rationale for such concern? The hazard analysis, hardware, and system information? Learn more. including:	8	life or proposed performance de affected by agir	shelf life, i.e. an evaluation of product emonstrating the product is not adversely ng, or an explanation of why storage conditions				
includes patient-contact t components, have you: Provided biocompatibility patient-contacting components? Provided an evaluation for electrical safety or electrical safety or Electromagnet ic 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 were used? Provided an evaluation for EMC or an evaluation using alternate methods or standards were used?	9	biocompatibili ty, If the	patient-contacting and its				
Provided biocompatibility patient-contacting components? 10 In regards to electrical safety or electrical safety or Electromagnet ic Compatibility (EMC), have you: Provided an evaluation for electrical safety 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?		includes patient-contac	component that is				
electrical safety or Electromagnet ic Compatibility (EMC), have you: Software information 1 Is all the relevant software information provided, including: Provided an evaluation for EMC or an evaluation using alternate methods or standards were used? The level of concern and rationale for such concern? The hazard analysis, hardware, and system information? Learn more.		have you:	. , ,				
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	10	electrical safety or Electromagnet ic	an evaluation using alternate methods or standards with a rationale explaining why those alternate methods or standards were				
Is all the relevant software information provided, including: The level of concern and rationale for such concern? The heaver and system information? Learn more.		(EMC), have	evaluation using alternate methods or standards with a rationale explaining why those alternate methods or standards were				
relevant concern? software information provided, including: concern? The hazard analysis, hardware, and system information? Learn more.	Software information						
information provided, including: The hazard analysis, hardware, and system information? Learn more.	1	relevant					
Standards and declaration of conformity		information provided,					
	St	andards and dec	laration of conformity				

1	Does the request include the Declaration of Conformity? <u>Learn more</u> .			
2	Are the non-FD	A recognized consensus standards included?		
An	imal 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?			
Cli	inical studies			
1	Does the	All study protocols?		
	request contain results from	Number of investigators and subjects per investigator?		
	each clinical investigation of the device,	Investigation design, including study population and investigation period?		
	including:	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: <u>Learn more</u> .		
Fir	nancial disclosur	е		
1	were performed	ed financial information if clinical studies by submitting either a Certification Form or Disclosure Form (FDA 3455)? <u>Learn more</u> .		
Ad	ditional informa	tion		
1	Does the submi reports, whethe safety or effecti a statement to			
2	Does it include any other data, evaluation of th foreign or dome investigations of commercial man			
Fo	r IVD			
1	labeling describ	tro diagnostic) product, does the submitted e the performance characteristics of the precision, accuracy, specificity, and		
La	beling			
1		st include labels, labeling, and advertisements scribe the product, its intended use, and the s use?		

De Novo Toolkit





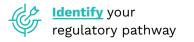


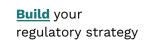






Access DiMe's Digital Health Regulatory Pathway Resources







Interact with regulators