The Beginner's Guide to

The FDA De Novo Classification Process

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Contents

Introduction

Introduction

Congratulations, you have successfully developed a new medical device! Now you need to take it to market. Normally in the United States this would mean completing a 510(k) submission. However, the 510(k) relies on "substantial equivalence"—a comparison to a similar device already on the market (also called a predicate device) to assess the risk profile of the new device. What if your device is totally new, and there isn't a similar device to compare it to? Enter the FDA De Novo process. The De Novo process provides a pathway to market for novel devices with a low to medium risk profile.

What does De Novo mean?

According to the Merriman-Webster dictionary, de novo is a Latin word meaning "as if for the first time; or anew." Perfectly fitting that the FDA uses this term "De Novo" to describe market approval requests for new medical devices or technology where there is no comparable predicate device on the market.

Chapter 1

What is an FDA De Novo request?

Chapter 1: What is an FDA De Novo request?

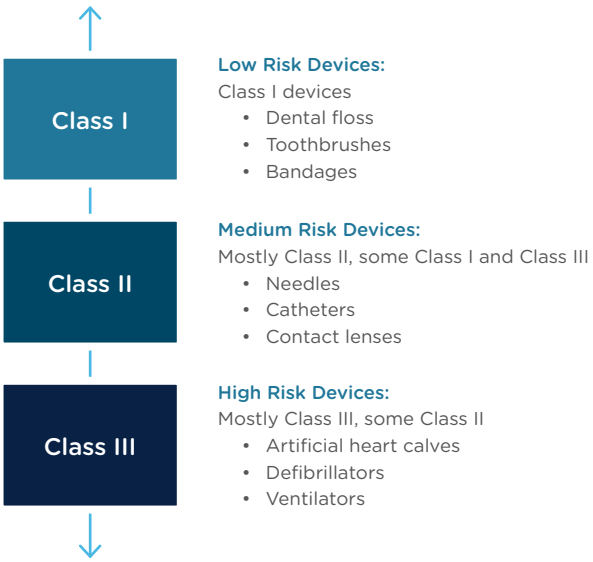
The Food and Drug Administration Modernization Act of 1996 provided the FDA with the authority to create the De Novo Classification Process. It's a process that uses a risk-based strategy for a new, novel kind of medical device, in vitro diagnostic, or medical software solution whose type has previously not been identified and/or classified. It's a process by which a novel medical device can be classified as a Class I or Class II device, instead of being automatically classified as Class III, which may not be appropriate. Before the implementation of the De Novo process in 1997, all the "not substantially equivalent" (NSE) products were required to be initially classified as a Class III device. But for a lot of devices, this risk class didn't really make sense. The De Novo process provides a pathway for more accurate classifications of novel, lower-risk devices.

October, 2021, the FDA released a final guidance document "De Novo Classification Process (Evaluation of Automatic Class III Designation)" to provide guidance to the requester (also known as the manufacturer) and the FDA on the process for the submission and review of a De Novo Classification Request under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act). This process provides a pathway to an initial Class I or Class II risk classification for medical devices for which general controls or general and special controls, provide a reasonable assurance of safety and effectiveness, but for which there is no legally marketed predicate device. This guidance document replaced the "New Section 513(f)(2) – Evaluation of Automatic Class III Designation, Guidance for Industry and CDRH Staff" document, dated February 19, 1998.

Consistent with the final rule, the FDA updated the guidance documents below to provide recommendations for submitting De Novo requests, as well as criteria and procedures for accepting, withdrawing, reviewing, and making decisions on De Novo requests, effective January 3, 2022.

- User Fees and Refunds for De Novo Classification Requests
- FDA and Industry Actions on De Novo Classification Requests: Effect on FDA Review clock and Goals
- Acceptance Review for De Novo Classification Requests

The 510(k) and the De Novo processes are similar in that they are both pathways to market for medical devices with low to moderate risk, which is Class I and Class II. The biggest difference between the two is that the 510(k) heavily relies on the concept of "substantial equivalence" to an existing medical device. You must prove this to get the clearance of your 510(k) submission. In the De Novo process, there isn't a product currently on the market that is "substantially equivalent" to yours, so it's like starting with a clean slate. For more on the 510(k) process, see our Beginner's Guide to the 510(k) ebook.



A result of the De Novo process to be aware of is that a successful submission will lead to a new predicate device type that someone else can reference to bring their product to market through the 510(k) process. You've done all the work, so now it's available for anyone to use to provide "substantial equivalence".

De Novo history/timeline

1997	Congress enacted a De Novo classification process to help limit the unnecessary use of FDA and industry resources on devices for which general controls (or general and special controls) would provide a reasonable assurance of safety and effectiveness because a predicate device could not be identified.
1998	Initial De Novo Guidance Document was released.
2012	Congress simplified the De Novo Guidance Document into a 2-step process: 1. The requester may submit a De Novo request directly. 2. The FDA would then decide whether to classify the device from Class III to Class II or Class I for the new classification and regulation.
2014	A draft was created of the De Novo Guidance Document to propose policy and procedures to implement the changes to the De Novo program from FDASIA (The Food and Drug Administration Safety and Innovation Act) of 2012.
2016	Congress further simplified the De Novo process by not requiring a 30-day submission turnaround after receiving an NSE (non-substantially equivalent) determination.
2017	The final Guidance (De Novo Program Guidance) Recommendations was issued.
2018	The FDA proposed a new rule to implement a De Novo Classification Process and define the scope of regulatory procedures when classifying and reclassifying medical devices.
2019	The final De Novo Program Guidance document was made public in September.
2021	The FDA issued a final ruling on the De Novo classification rule in October for implementing a classification process.

Preparing a De Novo request

1. Do your research! Be sure to complete all the necessary research prior to your submission. You want to be sure that your device is not substantially equivalent to an existing device. Resources to review include:

   - The Center for Devices and Radiological Health (CDRH)
   - U.S. FDA Device Classification Database
   - Device Classification Under Section 513(f)(2)(De Novo)

2. A De Novo request can be submitted with or without a preceding 510(k). There are two options for when you can submit a De Novo request:

   - Option A: After receiving a not substantially equivalent (NSE) determination (that is, no predicate, new intended use, or different technological characteristics that raise different questions of safety and effectiveness) in response to a 510(k) submission.
   - Option B: If you've determined, after extensive research, that there is no legally marketed device on which to base a determination of substantial equivalence.

3. Be sure all fees are paid to the FDA in advance of submitting a De Novo request. The FDA's fiscal year begins in October and runs through the following September. Fees have increased each year since they were introduced, but the FDA's percentage of reviews completed within the 150-day window has increased as well.

Fiscal year	De Novo requests received	% of requests completed in 150 days	User fee	Small business fee
2018	56	50%	$93,229	$23,307
2019	61	55%	$96,644	$24,161
2020	69	60%	$102,299	$25,575
2021	63	65%	$109,697	$27,424
2022		70%	$112,457	$28,114

A business that is qualified and certified as a "small business" is eligible for a substantial reduction in most of the FDA user fees, including De Novo. The CDRH is responsible for the Small Business Program that determines whether a business is qualified.

Medical Device User Fee Amendments (**MDUFA**) guidance documents can provide more detailed information about all FDA user fees

4. The initial request process serves only to determine if the De Novo request is administratively acceptable based upon the Acceptance Checklist. The initial acceptance is followed by substantive review which will determine the final risk classification of your device.

5. A Pre-Submission (Pre-Sub) is a formal written request for feedback from the FDA that is provided in formal written form, and then followed by a meeting. Although a Pre-Sub is not required prior to a De Novo request, it can be extremely helpful to receive early feedback, especially for devices that have not previously been reviewed under a 510(k). If you think you would like to submit a pre-sub first, there are suggested guidelines for submission you should consider:

   - Describe your rationale for a Class I or Class II classification for your device.
   - Provide the search results of FDA public databases and other resources used to determine that no legally marketed device and no classification for the same device type exists.
   - Provide a list of regulations and/or product codes that may be relevant.
   - Provide a rationale for why the subject device does not fit within and/or is different from any identified classification regulations, based on available information.
   - Identify each health risk associated with the device and the reason for each risk.
   - Briefly describe any ongoing and/or planned protocols/studies that need to be completed in order to collect the necessary data to establish the device's risk profile.
   - Provide information regarding the safety and effectiveness of the device. Cite the types of valid scientific evidence you anticipate providing in your De Novo request, including types of data/studies relating to the device's safety and effectiveness.
   - Briefly describe any ongoing and/or planned protocols/studies that need to be completed to collect the necessary safety and effectiveness data.
   - Provide protocols for non-clinical and clinical studies (if applicable), including how they will address the risks you anticipate and targeted performance levels that will demonstrate that general controls or general and special controls are sufficient to provide reasonable assurance of safety and effectiveness.
   - Share any proposed mitigation measure(s)/control(s) for each risk, based on the best available information at the time of the submission. Highlight which mitigations are general controls and which are special controls and provide details on each.
   - Include any other risks that may be applicable, in addition to those identified in the Pre-Sub, given the indications for use for the device.
   - If applicable, provide any controls that should be considered to provide a reasonable assurance of safety and effectiveness for the device.
   - Provide any non-clinical study protocols that are sufficient to allow the collection of data from which conclusions about device safety and/or effectiveness can be drawn. These protocols should address:
     - Whether the identified level of concern is the appropriate level of concern for the device software.
     - If any additional biocompatibility and/or sterility testing is required.
   - If clinical data is needed, provide information to show that the proposed study design and selected control groups are appropriate.

6. The FDA will attempt to review the De Novo request submission within 15 calendar days of receipt of the request to make a determination that the submission is declined or accepted for review. If they are unable to complete the review within the 15 days, your submission will automatically move to "accepted for review" status. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/de-novo-classification-process-evaluation-automatic-class-iii-designation

7. There are times when the FDA will refund your application fee. They have created a guidance document "User Fees and Refunds for De Novo Classification Requests" for the purpose of identifying:

    1. the types of De Novo requests subject to user fees
    2. exceptions to user fees
    3. the actions that may result in refunds of user fees that have been paid

When is a De Novo request subject to a user fee?

De Novo request submission type	De Novo fee required
Original De Novo request	Yes
Additional information for a De Novo request that has not yet been accepted	No
Additional information for a pending De Novo request	No
De Novo request intended solely for pediatric population	No
De Novo request for a device for which the previous De Novo request was declined	Yes

When will the FDA refund a De Novo user fee?

FDA determination or submitter action	FDA refund?
I qualify for a fee exception provided by section 738(a)(2)(B)(v) of the FD&C act.	Yes
FDA declines my De Novo request.	No
I withdraw my De Novo request after acceptance for review.	No
FDA considers my De Novo request to be withdrawn after acceptance for review.	No
I fail to submit a valid eCopy before my original De Novo request is accepted for review.	Yes, upon request
I fail to submit a valid eCopy for a De Novo amendment or supplement	No
FDA determines my submission does not meet the acceptance criteria during review	Yes, upon request

What fee must be paid for a new device submission following a De Novo "decline" determination?

Submission type	Is a fee required?
New De Novo Request.	Yes. You must pay the applicable fee for a De Novo request.
510(k)	Yes. You must pay the applicable fee for a 510(k).
Reclassification petition	No.
PMA	Yes. You must pay the applicable fee for a PMA.
HDE	No.

Chapter 2

Contents of a De Novo request

Chapter 2: Contents of a De Novo request

In preparing a request submission, there are many things to consider about the content. In addition to the items listed in The Acceptance Checklist, located in the "Acceptance Review for De Novo Classification Request" guidance document, there are some other elements to include in order to avoid a "refuse-to-accept" (RTA) from the FDA for your submission:

1. A cover sheet identifying the request as a "Request for Evaluation of Automatic Class III Designation" De Novo request.
2. Administrative information, such as the device's intended use, prescription use or over-the-counter use designated, etc.
3. A device description including technology, proposed conditions of use, accessory, components, etc.
4. Classification information and supporting data. This includes:
    a. The classification being recommended for the submission.
    b. A complete discussion of why general controls or general and special controls provide reasonable assurance of the safety and effectiveness of the device, and what special controls, (if proposing a Class II designation), would allow the Agency to conclude there is reasonable assurance the device is safe and effective for its intended use.
    c. Clinical data (if applicable) that's relevant to support reasonable assurance of the safety and effectiveness of the device.
    d. Non-clinical data including bench performance testing.
    e. Information on reprocessing and sterilization, shelf life, biocompatibility, software, electrical safety and electromagnetic compatibility, animal study, literature (if applicable).
    f. A description of the probable benefits of the device when compared to the probable risks when the device is used as intended. You should be able to identify the probable risks (associated with intended use) that you are aware of, and the level of control that is used to minimize those risks. Don't downplay the risks if they do exist. Simply explain what the reasonable control measures are, and show how the benefits outweigh those risks. To understand this better, the FDA has created a comprehensive guidance document, with examples titled, "Factors to Consider When Making Benefit-Risk Determinations in Medical Device Premarket Approval and De Novo Classifications." A summary of the guidance is included below.

Benefit – risk assessment summary

Proposed indications for use:

Assessment of benefit	
1. Is there any evidence of a clinical benefit?	• Yes – go to Q2 • No – Do not approve/grant – continue to Q9
2. What is the level of uncertainty for the benefit?	• High • Medium • Low Continue to Q3
Assessment of risk	
3. Are the known risks more than minimal?	• Yes – assessment complete • No – continue to Q4 • Unable to conclude that benefits outweigh the risks – go to Q6
4. What is the level of uncertainty for the risks?	• High • Medium • Low Continue to Q5
Assessment of benefit-risks	
5. Do the benefits outweigh the risks?	• Yes – assessment complete • Unable to conclude that benefits outweigh the risks – go to Q6
6. Do the benefits outweigh the risks, taking into account additional considerations?	• Yes, assessment complete • Unable to conclude that benefits outweigh the risks – continue to Q7
7. Can the risks be mitigated so that the benefits outweigh the risks?	• Yes, assessment complete • Unable to conclude that benefits outweigh the risks – continue to Q9
8. Do the benefits outweigh the risks consider the use of postmarket actions?	• Yes, assessment complete • Unable to conclude that benefits outweigh the risks – continue to Q9
9. Is there evidence for clinical benefit with modified Indications for Use?	• Yes, assessment complete • Do not approve/grant

Chapter 3

Submitting a De Novo request

Chapter 3: Submitting a De Novo request

You must submit at least one valid copy electronically through the eCopy Program for Medical Device Submission. Requests submitted without a submitted eCopy will be placed on hold until the eCopy is received.

Requests should be mailed to the appropriate Document Control Center using a method that requires a receipt signature.

Once it's received by the control center, a unique document number is assigned.

The De Novo number begins with "DEN", followed by six digits or "BR" followed by six digits. The first two digits represent the calendar year and the last four represent the sequential request number within that year. Ex: a request received in 2021 would read DEN210001 or BR210001.

Remember, the goals of the FDA reviewer should match your goals in that you need to help guide them so that they can easily understand your submission. This is a request for a new product type so be very clear and detailed in your descriptions. They can only review the information you give them so it's extremely important to be organized and thorough when reviewing the Acceptance Checklist.

Goals of the FDA review
= The requestors goals

1. Identify the probable risks to health when used as intended
2. Determine the level of control needed to mitigate those risks
3. Determine that the probably benefits outweigh the risks when controls are applied

Acceptance review process

Upon receipt, the FDA will conduct an **acceptance review**. This is simply a review to determine if the De Novo request is administratively acceptable based upon the Acceptance Checklist. This is NOT the substantive review process that follows later.

The FDA will Refuse to Accept (RTA) a De Novo request if there are missing elements and no explanations as to why the information is missing. In addition, they may RTA your request if the submission is for more than one type of device, incomplete, or you simply do not follow the proper format.

Within 15 calendar days of receipt of the De Novo request, FDA should answer the preliminary questions, which are included on the first page of the Acceptance Checklist. The preliminary questions are intended to be answered by the lead reviewer as an initial screening of the request. Depending upon the answers to these questions, the remainder of the acceptance review may or may not be necessary.

The preliminary questions

1. Is this product a device (or combination) product that is subject to review by the De Novo process?
2. Has the De Novo request been filed with the appropriate Center - either the Center for Devices and Radiological Health (CDRH) or the Center for Biologics Evaluation and Research (CBER)?
3. Has a Request for Designation (RFD) been submitted for this product? If so, are the products and indications for use the same?
4. If the product is a combination product (device plus pharmaceutical), is the drug component currently approved with exclusivity? If so competitive drugs cannot be approved.
5. Is this device type eligible on its face for De Novo classification?
6. Is the requester subject to the Application Integrity Policy (AIP)?

FDA responses

Within 15 calendar days of the FDAs Document Control Center (DCC) receiving the De Novo request, the FDA will notify the requester electronically of the acceptance review result as one of the following:

- the De Novo request has been accepted for substantive review
- the De Novo request has not been accepted for review and the requester has 180 calendar days to fully address the RTA notification.
- the De Novo request automatically goes under substantive review if the FDA did not complete the acceptance review within 15 calendar days

If the responses to the questions and consultation with the CDRH/CBER reviewer indicate that the De Novo acceptance review should not continue, the CDRH lead reviewer or the CBER regulatory project manager will inform the De Novo review team, and notify the requester.

Substantive review process

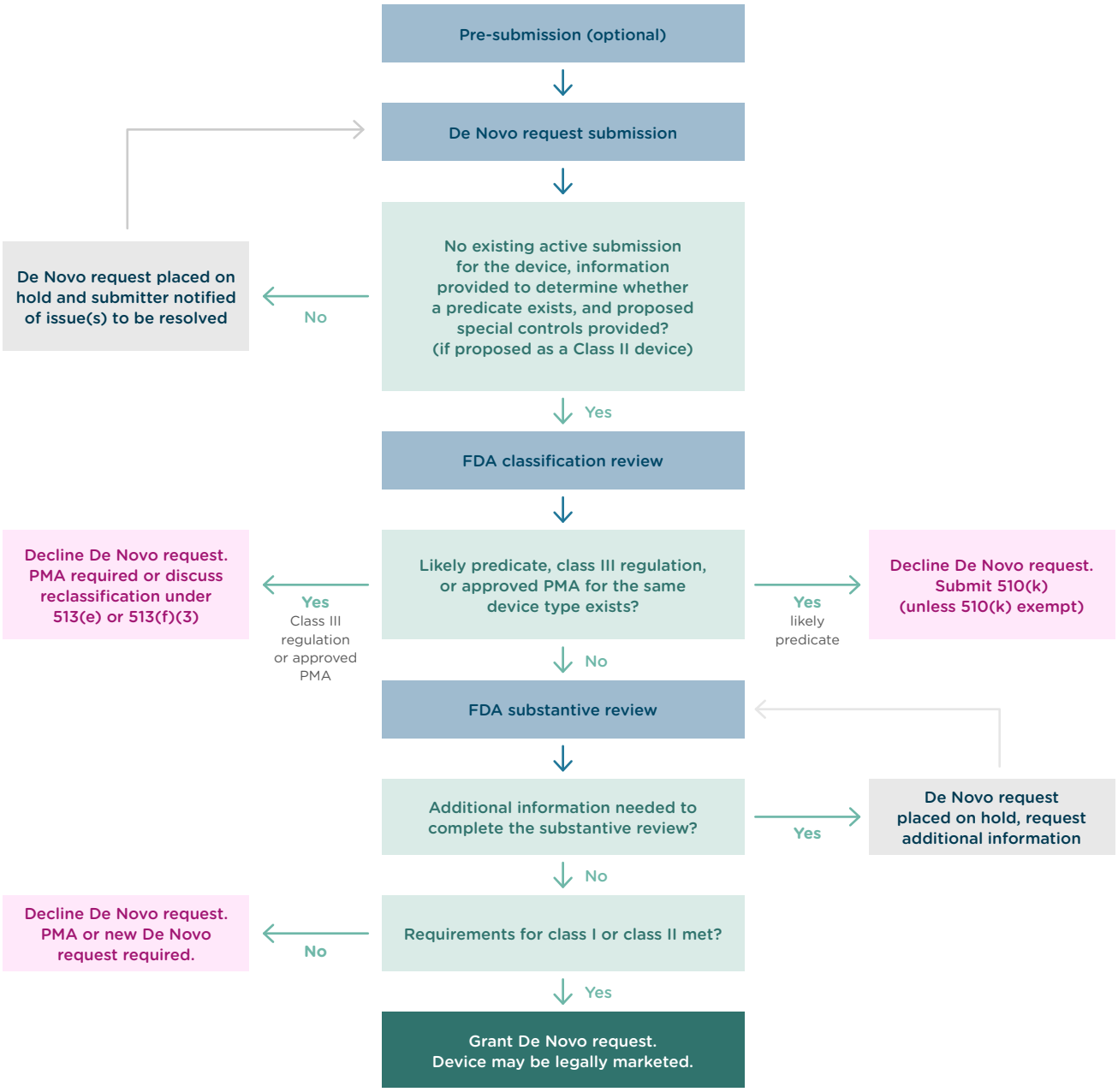
In a **substantive review,** the FDA conducts a review of legally marketed device types and classifications to decide whether an existing, legally marketed device of the same type currently exists. This information is used to confirm if the device is eligible for De Novo classification.

If the FDA identifies any deficiencies in their search, they will address them through an interactive review or a formal request for additional information. The formal request is known as an Additional Information letter. If the issues cannot be addressed through the preferred interactive review, then an Additional Information letter will be sent. Once the letter is sent, the request will be placed on hold. The requester now has 180 calendar days from the date of the letter to submit a complete response to each item identified as a deficiency.

The requester must submit the information in eCopy to the DCC within the appropriate Center (CDRH/CBER) and include requestor's name, De Novo number, identify the submission as a response to the letter, list the date of the letter, and provide all the requested information.

If the FDA does not receive all the required information identified in the letter within 180 days, then the De Novo request will be withdrawn and deleted from the system. A new request would have to be created and the process started over again. The FDA's goal is to complete reviews within 150 review days, minus any days that the request was on hold. So, the whole process could be delayed for almost a year, due to information deficiencies. This emphasizes the importance of submitting a complete request at the beginning of the process.

De Novo request review process



FDA decisions

If the data and information provided to the FDA demonstrate that general controls or general and special controls are adequate to provide reasonable assurance of safety and effectiveness, and the probable benefits of the device outweigh the probable risks, then the FDA will **grant** the De Novo request and establish a new classification regulation for the device.

If the data and information provided to the FDA do not demonstrate the general controls or general and special controls adequately provide reasonable assurance of safety and effectiveness, then the FDA will **decline** the De Novo request.

The final rule, updated guidelines, and the RTA checklist will become effective January 3, 2022. Any submission before that date will be evaluated under the current process. Both current and updated guidance documents are available for review on the FDA's website.

Granted

- The new device is authorized to be marketed and must be in compliance with applicable regulatory controls
- A new classification regulation is established
- The new device may now serve as a predicate for 510(k) submissions of future devices of the same type
- The FDA publishers in the Federal Register a notice that announces the new classification regulation, and for class II devices, the new special controls
- The FDA posts on its website a copy of the granting order notifying the requester that marketing authorization is granted
- The FDA generates and publicly discloses a decision summary

Declined

- General controls or general and special controls are insufficient to provide reasonable assurance of the safety and effectiveness of the device
- The data provided in the De Novo request are insufficient to determine whether general controls or general and special controls can provide a reasonable assurance of the safety and effectiveness of the device
- The probable benefits of the device do not outweigh the probably risks
- If the De Novo request is declined, the device remains in class III and may not be legally marketed
- The FDA will issue a written order identifying the reasons for the denial which can include lack of performance data
- The device must either be approved via the PMA process, or additional information collected a re-submitted via a new De Novo request

Let's clarify some very important, but frequently misused terminology: Clearance vs. Approval vs. Granted – no, they do not all mean the same thing.

1. **Clearance:** When a medical device is cleared, this means it has undergone a 510(k) submission, which FDA has reviewed and provided clearance.
2. **Approval:** For Class III medical devices to be legally marketed they must undergo a rigorous review and approval process. Following a successful submission of a premarket approval (PMA) or a Humanitarian Device Exemption (HDE), the device is given Approval by FDA.
3. **Granted:** Medical devices using the De Novo processed must be Granted by FDA before they can be legally marketed in the United States.

Congratulations! Now that your De Novo has been granted and is entered into the FDA website, you can search the Device Classification under Section 513(f)(2)(De Novo) Database to locate your granted submission.

Appendix A

Acceptance review checklist

Appendix A: Acceptance review checklist

The following table provides a summary of the Acceptance Checklist used by the FDA for the acceptance review process and is not intended to serve as a comprehensive review. This is the core set of criteria used to determine if your De Novo application has been submitted appropriately, and your device is eligible for review.

	Complete?		
Preliminary questions	**Yes**	**No**	**N/A**
1. Is this product a device (or combination) product that is subject to review by the De Novo process?	Yes	No	N/A
2. Is the De Novo request with the correct center (meaning has it been filed appropriately with either the CDRH or CBER)?	Yes	No	N/A
3. Has a Request for Designation (RFD) been submitted for this product? If so, are the products and indications for use the same? Note that an RFD isn't required, the FDA is simply checking here to make sure that the applications match	Yes	No	N/A
4. If the product is a combination product (device plus pharmaceutical), is the drug component currently approved with exclusivity (meaning competitive drugs cannot currently be approved)?	Yes	No	N/A
5. Is the device type eligible for De Novo classification?	Yes	No	N/A
6. Is the requester/manufacturer currently on the FDA's Application Integrity Policy list?	Yes	No	N/A
Elements for a complete De Novo Request – Checklist criteria			
Each element on the checklist should be addressed within the request. The requester may provide a rational for omission for any criteria that are not applicable. If a rationale is provided the criterion is considered present. **Check "Yes" if the item is present** **Check "N/A" if it is not needed** **Check "No" if it is not included but needed** **Requesters should identify the page numbers where requested information is located. Use the comments section if additional space is needed to identify the location of supporting information.**			

A. Organization elements	Yes	No	N/A
1. Does the request contain a table of contents?	Yes	No	N/A
2. Are all pages numbered?	Yes	No	N/A
B. Administrative information			
1. Is all content, including reports, literature, and articles written in or translated to English?	Yes	No	N/A
2. Does the request include all the pertinent information about the requester (name, email, phone, address, etc.) and/or their U.S. representative (for countries outside the U.S.)?	Yes	No	N/A
3. Does the request include both the generic name and proprietary/trade (brand) name of the device?	Yes	No	N/A
4. Does the request describe the device's indications for use, and whether it would be prescribed or available over the counter (OTC)?	Yes	No	N/A
5. Are there any other or open premarket submissions for the device (510(k), PMA, reclassification petition, etc.)?	Yes	No	N/A
6. Is the request for a single device type?	Yes	No	N/A
7. If there were prior premarket submissions (for example, if the device had an initial 510(k) submission where the device was not found to be substantially equivalent to a predicate device) are these submissions identified in the request?	Yes	No	N/A
A. If there were prior submissions, has the requester properly addressed all the deficiencies found by the FDA in those submissions?	Yes	No	N/A
8. "N/A" if the product is not a combination product. The remaining criteria in this section will be omitted from the checklist if "N/A" is selected.	Yes	No	N/A
A. If the device is a combination product, does the request indicate this?	Yes	No	N/A
B. If the device is a combination product, are any drug portions of the device approved by the FDA? Requests should include any patents or certificates for this drug.	Yes	No	N/A

C. Device description	Yes	No	N/A
1. If the device is a combination product, are any drug portions of the device approved by the FDA? Requests should include any patents or certificates for this drug.	Yes	No	N/A
A. Does the request include detailed descriptions of how it will be used? (This includes interfaces, where it's located anatomically, how it interacts with other devices, etc.) Include a statement to clarify that any images, diagrams, etc., are not applicable to the device to justify their omission.	Yes	No	N/A
B. Describe the proposed conditions of use and how the device interacts with the patient.	Yes	No	N/A
2. Does the request describe how the device is relevant to the diagnosis, treatment, prevention, cure, or mitigation of a disease or condition?	Yes	No	N/A
3. Does the request provide a complete description of all the functional parts or components of the device? (This includes any parts or accessories that are marketed with the device)	Yes	No	N/A
4. If the device will be marketed with other devices (such as parts or accessories) that have already been approved by the FDA, does the request include their FDA-assigned reference number(s)?	Yes	No	N/A
D. Alternative practices and procedures			
1. Does the request reference any other treatments / alternatives for the diagnosis, treatment, prevention, cure, or mitigation of the disease or condition that the device addresses (If any alternatives exist)?	Yes	No	N/A
E. Classification summary and proposed classification			
1. If the device has not has a prior 510(k) submission does the request:			
A. Provide detail of what searches were done to determine the lack of substantial equivalence	Yes	No	N/A
B. have information about potential predicate devices that were examined	Yes	No	N/A
C. have a clear rationale as to why this device is different?	Yes	No	N/A
2. If the device 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 device has not been classified or reclassified since the original determination?	Yes	No	N/A
3. Benefit-Risk: Does the request properly detail the expected health benefits and risks associated with the device?	Yes	No	N/A
A. Is scientific evidence included to back-up the benefit claims?	Yes	No	N/A
B. Does the request demonstrate how the benefits outweigh the potential risks of the device? Guidance document	Yes	No	N/A
4. Does the request outline all the probable health risks associated with the device. Does it include controls or mitigation for these risks?	Yes	No	N/A
5. Does the request recommend a Class I or Class II classification for the device? For each class designation, does the request document the appropriate level of safety and effectiveness for the device?	Yes	No	N/A

F. Summary of studies	Yes	No	N/A
1. Does the request include a summary of all the test and clinical data that is included?	Yes	No	N/A
2. Does the summary of each study include the objectives, a description of the experimental design, how data was collected and analyzed, and a description of the results of the study (for both clinical and non-clinical studies)?	Yes	No	N/A
3. Provide a summary of each non-clinical study Guidance document	Yes	No	N/A
4. Provide a summary of each clinical investigation and identify any clinical investigations under an IDE.	Yes	No	N/A
5. Does the summary of any clinical study with human subjects include subject selection (and exclusion) criteria, investigation population, time period, safety and effectiveness data, any adverse reactions or complications, subject complaints or discontinuations, and device failures? Does the summary provide a statistical analysis of the results?	Yes	No	N/A
G. Non-clinical studies			
1. Does the request provide a complete test report (including results) for any non-clinical studies? Guidance document 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. Guidance document	Yes	No	N/A
2. If the device is intended to be sterile and/or reusable, does the request include information on:			
A. identification of components and/or accessories?	Yes	No	N/A
B. the sterilization method, parameters, validation method and SAL?	Yes	No	N/A
C. Reprocessing information, including protocols and test reports of validation of instructions for reprocessing?	Yes	No	N/A
D. Test information on pyrogenicity?	Yes	No	N/A
E. Packaging information and package test methods?	Yes	No	N/A
3. Shelf life: Explain why storage conditions are not expected to affect shelf life or device safety	Yes	No	N/A
4. Biocompatibility - If the device comes into contact with a patient:			
A. Identify each component that is patient-contacting and its associated materials.	Yes	No	N/A
B. Identify contact classification of the component that is patient-contacting.	Yes	No	N/A
5. Electrical safety or EMC:			
A. Identify electrical safety standards or explain an evaluation using alternate methods or standards with a rationale.	Yes	No	N/A
B. Provide an evaluation for EMC or an evaluation using alternate methods or standards with a rationale.	Yes	No	N/A

H. Software	Yes	No	N/A
1. Is all the relevant software information provided including:			
A. The level of concern and rationale	Yes	No	N/A
C. The device hazard analysis, hardware, and system information? Guidance document	Yes	No	N/A
I. Standards and declaration of conformity			
A. Does the submission include the Declaration of Conformity?	Yes	No	N/A
B. Are the non-FDA recognized consensus standards included? Guidance document	Yes	No	N/A
J. Animal			
1. Provide a statement that the study was conducted in compliance with Good Laboratory Practice, or if not, provide a reason why GLP was not used.	Yes	No	N/A
K. Clinical			
Does the request contain results from each clinical investigation of the device including each investigation below:			
1. Include all study protocols.	Yes	No	N/A
2. How many investigators and subjects were there per investigation?	Yes	No	N/A
3. What is the investigation design, including study population and investigation period?	Yes	No	N/A
4. Describe the subject selection and exclusion criteria.	Yes	No	N/A
5. Provide data from individual subject report forms.	Yes	No	N/A
6. Provide effectiveness data.	Yes	No	N/A
7. List safety data including adverse reactions, death subject complaints, device failures, and replacements.	Yes	No	N/A
8. Provide a list of individual report forms for patients who did or did not complete the investigation.	Yes	No	N/A
9. Provide a statement for each investigation that has been completed or a summary of any deviation from the protocol.	Yes	No	N/A
10. List any results of any statistical analyses performed.	Yes	No	N/A
11. List all statements such as contraindications, warnings, precautions, etc. relevant to the use of the device	Yes	No	N/A
12. If a De Novo request relies primarily on data from a single investigator at one investigation site, provide a justification showing that these data and other information are sufficient to demonstrate the safety and effectiveness of the device when subject to general controls or general and special controls.	Yes	No	N/A
13. Explain how the clinical investigation data represents significant results. Statement of Compliance for Clinical Investigations.	Yes	No	N/A

14. Statement of Compliance for Clinical Investigations. Select N/A if there is no clinical data required. For multicenter clinical investigations involving both United States (US) and outside the United States (OUS) sites, part (a) should be addressed for the US sites, and part (b) should be addressed for the OUS sites. Guidance document			
A. For each clinical investigation conducted in the US, the De Novo request should include either a statement that the investigation was conducted in compliance (or, that it was not subject to the regulations), OR a brief statement of the reason for noncompliance.	Yes	No	N/A
B. For each clinical investigation conducted outside the USA, the De Novo request should include a statement that the clinical investigations were conducted in accordance with good clinical practice (GCP), OR a waiver request, OR a brief statement of the reason for not conducting the investigation in accordance with GCP and a description of the steps taken to ensure that the data and results are credible/accurate and that the rights, safety, and well-being of subjects have been adequately protected.	Yes	No	N/A

L. Financial disclosure information

1. Provide financial information if clinical studies were performed. Submit either a signed and dated Certification Form (Form FDA 3454) or a signed and dated Disclosure Form (FDA 3455) Guidance document			
A. If using a Certification Form (Form FDA 3454) attached a list of all investigators and sub-investigators.	Yes	No	N/A
B. If using a Certification Form (Form FDA 3454) and box (3) is checked, does the form include an attachment with the reason(s) why financial disclosure information could not be obtained?	Yes	No	N/A
C. Did you submit a Disclosure Form (Form FDA 3455) detailing the financial arrangements and interests of the investigator(s) or sub-investigator(s), along with a description of any steps taken to minimize potential bias?	Yes	No	N/A

M. Other information

1. Attach a bibliography of all published reports, whether adverse or supportive, that addresses the safety or effectiveness of the device. If there are no additional published reports, include a statement to justify the omission.	Yes	No	N/A
2. An identification, discussion, and analysis of any other data, information, or report relevant to an evaluation of the safety and effectiveness of the device, foreign or domestic, including information derived from investigations other than those in the request and from commercial marketing experience.	Yes	No	N/A

N. In vitro diagnostic (IVD) devices

1. For an IVD product, is the labeling being submitted describing the performance characteristics of the device including precision, accuracy, specificity, and sensitivity? The technical sections of the De Novo request should provide the results of the studies, as well as associated protocols and line data, corresponding to the information on performance characteristics of the device from above, including, linearity, calibrator or assay traceability, calibrator and/or assay stability protocol and acceptance criteria, assay cut-off, method comparison or comparison to clinical outcome, matrix comparison, and clinical reference range or cutoff.	Yes	No	N/A

O. Labeling	Yes	No	N/A
1. The De Novo request should include labels, labeling, and advertisements sufficient to describe the device, its intended use, and the directions for its use. In addition, attach photographs or engineering drawings where applicable.	Yes	No	N/A

About Rimsys

Rimsys is bringing regulatory order to the medtech industry. The Rimsys Regulatory Information Management (RIM) platform digitizes and automates regulatory activities, freeing teams from inefficient administrative work, and helping them confidently establish and secure global regulatory compliance. Unlike complex spreadsheets, or expensive consultants, Rimsys centralizes all regulatory information, automates submission processes, and monitors relevant expirations, standards, and global regulations. Overburdened regulatory affairs teams struggle to keep pace with the increasingly complex global landscape. Rimsys streamlines all regulatory activities in an integrated platform, helping medtech companies get to market more quickly and reduce risk of non-compliance, product recalls, and unexpected expirations.

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