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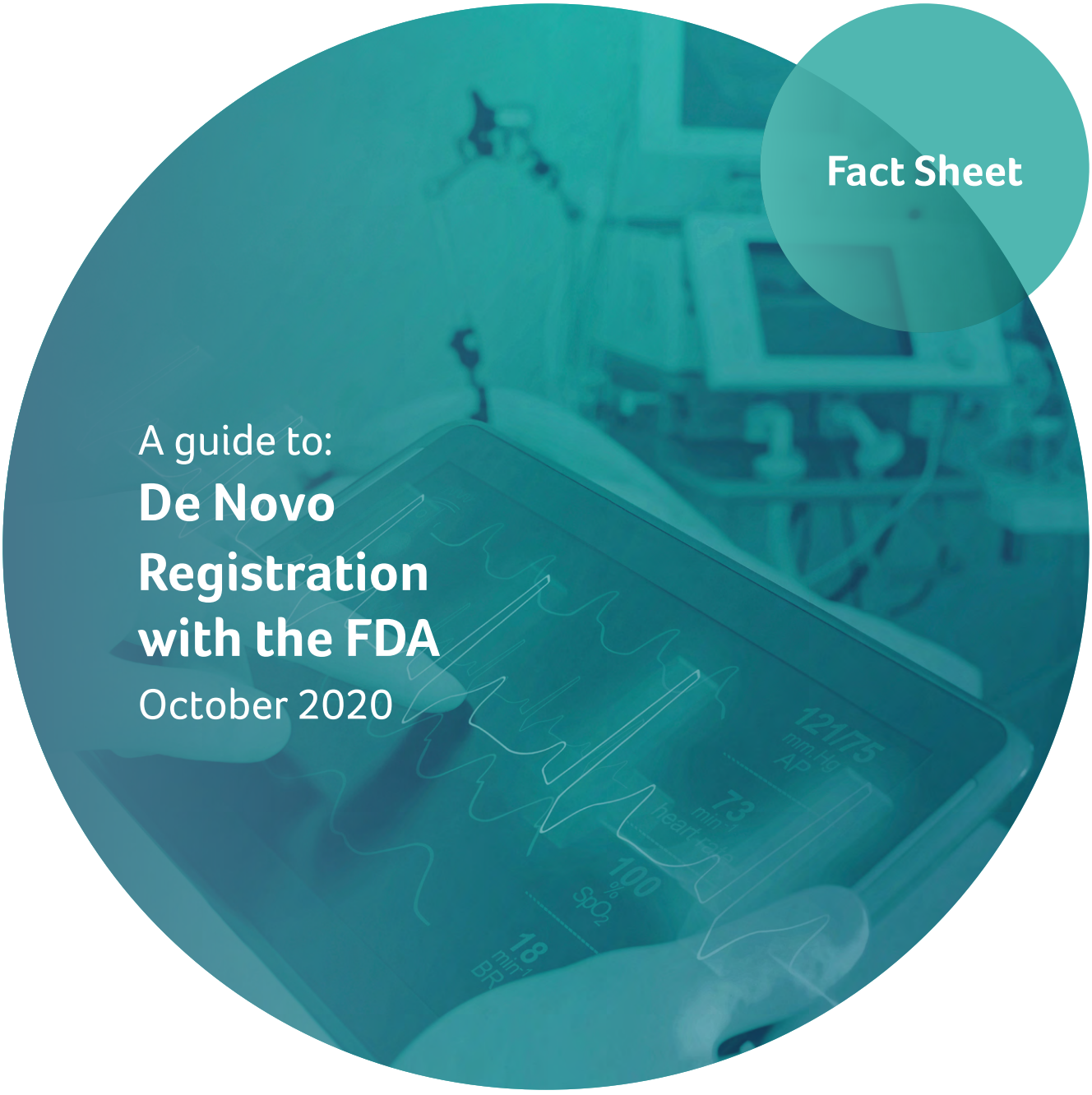

Fact Sheet

A guide to:

De Novo Registration with the FDA

October 2020

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enhanced medical solutions.

A guide to De Novo Registration with the FDA

What is the De Novo classification process?

- De Novo classification is a risk-based classification process
- Devices of a new type that the FDA has not previously classified are “automatically” or “statutorily” classified into class III, regardless of the level of risk they pose or the ability of general and special controls to assure safety and effectiveness
- The De Novo process provides a pathway to classify novel medical devices in class I or II for which general controls alone, or general and special controls, provide reasonable assurance of safety and effectiveness for the intended use, but for which there is no legally marketed predicate device
- Products which have been classified into class II can be used as predicates for future premarket submissions

When is a De Novo Registration required?

- There are two options for when you can submit a De Novo request for the FDA to make a risk-based evaluation for classification of the device into class I or II:

Scenario 1:

Manufacturer submits a 510(k) to FDA for their novel device	Manufacturer receives a high-level not substantially equivalent (NSE) determination, meaning: • No predicate • A new intended use • Different technological characteristics that raise questions of safety and effectiveness	**De Novo request**

Scenario 2:

Manufacturer determines that there`s no legally marketed device upon which to base a determination of substantial equivalence	Manufacturer does not submit a 510(k) Manufacturer does not receive a high-level NSE determination	**De Novo request**

Therefore, the FDA recommends submitting a pre-submission to obtain feedback from the appropriate premarket review division, prior to submitting a De Novo request.

Preparing your De Novo request

What you should include in your De Novo Request

A De Novo request should include all the content elements listed in Appendix A of the "Acceptance Review for De Novo Classification Request" guidance document. The FDA intends to Refuse to Accept a De Novo request that does not include these elements. Important elements of a De Novo request are listed below:

- ✓ A coversheet clearly identifying the request as a "Request for Evaluation of Automatic Class III Designation" under 513(f)(2) De Novo request
- ✓ Administrative Information, such as the device's intended use, prescription use or over-the-counter use designated
- ✓ Device description, including technology, proposed conditions of use, accessories, and components
- ✓ Classification Information and Supporting Data:
    - The classification being recommended under section 513 of the Food, Drug, and Cosmetic Act (FD&C Act)
    - 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
    - Relevant clinical data (if applicable) to support reasonable assurance of the safety and effectiveness of the device
    - Non-clinical data including bench performance testing
    - Information on the reprocessing and sterilization, shelf life, biocompatibility, software, electrical safety and electromagnetic compatibility, animal study, literature as applicable
    - A description of the probable benefits of the device when compared to the probable or anticipated risks when the device is used as intended

Tip: *Although not required, consider including the recommended elements in Appendix B of the guidance (as applicable). This may decrease the number of questions posed by the FDA during the substantive review of a De Novo request.*

The fees for your De Novo request

De Novo requests are subject to user fees:

Standard Fee

(Fiscal Year 2020)

$102,299

Small business fee

(if your gross sales are $30 million or less)

(Fiscal Year 2020)

$25,575

Submitting your De Novo Request

Prepare your request in an electronic format

Find the address of the appropriate Document Control Centre (DCC) on the eCopy Program for Medical Device Submissions web page

Send your request via registered mail with a return receipt or via a commercial delivery service

The review and decision process

Step 1 - Acceptance Review submission

- The FDA will conduct an acceptance review within **15 calendar days** of the DCC receiving your request which assesses the completeness of the application and whether it meets the minimum threshold of acceptability
- You should submit the FDA Acceptance Checklists with your request that identify the location of supporting information for each checklist element, and if you have omitted any of the acceptance elements, make sure to provide justification

Step 2 - Acceptance Review outcome

- **Outcome 1:** Your De Novo request is **accepted for substantive review**
- **Outcome 2:** The De Novo request has **not been accepted for review** (i.e. considered Refuse to Accept RTA) because one or more of the elements noted as RTA items in the Acceptance Checklist are not present and no explanation is provided for the omissions. You now have **180 calendar days to fully address the RTA notification**
- **Outcome 3:** The De Novo request is **under substantive review** and the FDA did not complete the acceptance review within 15 calendar days

Step 3 - Classification review

- The FDA conducts a classification review of legally marketed device types and analyses whether an existing legally marketed device of the same type exists
- This information is used to confirm your device is eligible for De Novo classification

Step 4 - Substantive review

- After the classification review is complete, the FDA will begin the substantive review which serves to identify any issues or deficiencies
- The Lead Reviewer may decide that the issues/ deficiencies identified can be adequately addressed through interactive review and not require a formal request for additional information (Additional Information letter)
- If the issues/deficiencies cannot be addressed through interactive review, an Additional Information letter will be sent to the requester
- If an Additional Information letter is sent, then the De Novo request will be placed on hold. The requester has **180 calendar days from the date of the Additional Information letter** to submit a complete response to each item in the Additional Information letter. No extensions beyond 180 days will be granted
- If the FDA does not receive a complete response to all deficiencies in the Additional Information letter within **180 days of the date of the Additional Information letter,** the request will be considered withdrawn and deleted from the FDA's review system. If the De Novo request is deleted, the De Novo requester will need to submit a new request to pursue the FDA's marketing authorisation for that device.

Submitting your De Novo Request (continued)

Step 5 - The request decision

- The FDA's goal is to grant or decline a De Novo request in **150 review days**
- Review days are calculated as the number of calendar days between the date the De Novo request was received by the FDA and the date of the FDA's decision, excluding the days a request was on hold for an Additional Information request

If the FDA grants a De Novo request:

✓

Grant

- The new device is authorised 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 device for 510(k) submissions of future devices of the same type
- The FDA publishes 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 we have granted marketing authorisation
- The FDA generates and publicly discloses a decision summary

The FDA will decline a De Novo request if:

✗

Decline

- General controls or general and special controls are insufficient to provide reasonable assurance of 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 safety and effectiveness of the device
- The probable benefits of the device do not outweigh the probable risks
- If the De Novo request is declined, your device remains in class III and you may not legally market the device
- The FDA will issue a written order to you identifying the reasons, which can include lack of performance data that warrant declining the De Novo request
- Generally, you should either submit an application for premarket approval under section 515 of the FD&C Act or collect additional information to address the issues and submit a new De Novo request that includes the additional information

Publication date of FDA information: 20.11.2019

Information Reference: https://www.fda.gov/medical-devices/premarket-submissions/de-novo-classification-request

Guidance Document Reference: "Acceptance Review for De Novo Classification Requests" September 2019, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/acceptance-review-de-novo-classification-requests