FDA U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES & RADIOLOGICAL HEALTH

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Acceptance Review for De Novo Classification Requests

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Agenda

- Objectives
- Background
- Summary of Final Guidance
- Transition Period for Final Guidance
- Resources
- Questions

Objectives

After this training, you should be able to:

- Understand the acceptance review policy and process for original De Novo requests
- Identify the content elements necessary for acceptance of De Novo requests
- Identify the actions the FDA may take during the acceptance review

Definitions

- ***RTA*** : Refuse to Accept
- ***De Novo RTA Guidance*** : Acceptance Review for De Novo Classification Requests
- ***De Novo Actions/Clock Guidance*** : FDA and Industry Actions on De Novo Classification Requests: Effect on FDA Review Clock and Goals
- ***De Novo User Fees Guidance*** : User Fees and Refunds for De Novo Classification Requests

Background

- With the enactment of the Medical Device User Fee Amendments of 2017 (MDUFA IV), the U.S. Food and Drug Administration (FDA) agreed to performance goals based on the timeliness of reviews of De Novo classification requests.

- To facilitate a more efficient and timely review process, the FDA committed to developing draft and final guidance that includes a “submission checklist.”

- The FDA issued the draft guidance “Acceptance Review for De Novo Classification Requests” on October 30, 2017.

Summary of De Novo RTA Guidance

Goal: Ensure original De Novo request is acceptable for substantive review

- Identifies content necessary for acceptance of De Novo requests
- Facilitates efficient and timely review
- Modeled after RTA policies for 510(k) and PMA
- Honors MDUFA IV commitment (“submission checklist”)
- Only a few minor changes compared to draft guidance

Summary of De Novo RTA Guidance

Appendix A	Appendix B
Acceptance Checklist	**Recommended Content Checklist**
Necessary for acceptance	Optional
Examples: Intended use Device description Proposed special controls (if recommending class II)	*Examples:* Prior submissions Classification summary (eligibility) Device labeling

Summary of De Novo RTA Guidance

The Recommended Content Checklist will <u>NOT</u> be used to conduct RTA reviews.

Summary of Updates to Other Guidances

De Novo Actions/Clock Guidance

- Identifies actions the FDA and requester may take during RTA review
- Explains how these actions impact review clock

De Novo User Fees Guidance

- Identifies criteria for requesting user fee refund if De Novo is not accepted for review
- Explains how to request a user fee refund

Overview of De Novo RTA Policy and Process

- Determine if De Novo is administratively complete based only on Acceptance Checklist (Appendix A)
- Not intended to be a substantive review
- Intend to complete RTA review within 15 calendar days of receiving original De Novo
- De Novo is considered accepted if RTA review is not completed within 15 calendar days

Overview of De Novo RTA Policy and Process

Refuse to Accept (RTA) Decision

- De Novo is incomplete; will not begin substantive review.
- The FDA will email requester that De Novo is not accepted.
- The FDA will identify those items that are missing.
- De Novo is placed on hold until missing elements are provided.
- Review clock resets to Day 0.
- The Requester has 180 days to provide missing elements.

Overview of De Novo RTA Policy and Process

Accepted Decision

- De Novo is administratively complete; substantive review begins.
- The FDA will email requester that De Novo is accepted.
- Review clock continues from date of original submission (or date of submission of missing elements).

De Novo RTA Guidance – Transition Plan

September 8, 2019

- Publication of final De Novo RTA Guidance
- Updates to De Novo Actions/Clock and De Novo User Fees Guidances

September 8 through November 7

- 60-day transition period
- FDA intends to accept all original De Novo requests
- No formal RTA review will be conducted

November 8, 2019

- Formal RTA reviews will begin
- Applies to new original De Novos received on or after this date

Resources

- CDRH Device Advice – De Novo
- Acceptance Review for De Novo Classification Requests
- FDA and Industry Actions on De Novo Classification Requests: Effect on FDA Review Clock and Goals
- User Fees and Refunds for De Novo Classification Requests
- Consideration of Uncertainty in Making Benefit-Risk Determinations in Medical Device Premarket Approvals, De Novo Classifications, and Humanitarian Device Exemptions

Questions?

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