Welcome to Today’s

FDA/CDRH

Webinar

Thank you for your patience while we register all of today’s participants.

If you have not connected to the audio portion of the webinar, please do so now:

U.S. Callers Dial: 888-603-9072
International Callers Dial: 1-415-228-5032
Passcode: 6375834
Conference Number: PWXW5928261

November 21, 2017 Webinar
De Novo Classification Process 
(Evaluation of Automatic Class III Designation)

Sergio M. de del Castillo  
De Novo Program Lead  
Office of Device Evaluation (ODE)

Scott McFarland, J.D.  
Associate Director, Regulatory Counsel  
Office of In Vitro Diagnostics and Radiological Health (OIR)
Objectives

• Describe the purpose of a De Novo request
• Describe and identify changes to the De Novo classification process since its inception
• Identify the purposes and relevance of the new guidance documents
• Identify additional resources
Outline

• What Is a De Novo Request?
• History and Evolution
• New Guidance Documents
  – FINAL: De Novo Classification Process (Evaluation of Automatic Class III Designation)
  – DRAFT: Acceptance Review for De Novo Classification Requests
• Resources
• Questions
What Is a De Novo Request?
What Is a De Novo Request?

1. A type of premarket submission (marketing authorization)

2. Request to classify a new device into Class I or Class II (risk-based approach)

3. Intended for devices that are automatically classified into Class III (“Evaluation of automatic class III designation”)

4. If granted, creates a new classification regulation for the new device type
A De Novo Request Is Not...

1. A type of premarket notification (510(k))
2. A substantial equivalence (SE) determination
3. A premarket application (PMA)
4. A 513(g) request
De Novo Classification Process

**Goals**

1. Identify probable risks to health for the device
2. Determine level of control needed to mitigate risks:
   - general controls only = *Class I*
   - general controls + special controls = *Class II*
3. Determine if probable benefits outweigh probable risks

*These provide reasonable assurance of safety and effectiveness.*
History and Evolution
History and Evolution

- **FDAMA (1997)**
  - Created De Novo pathway (Section 513(f)(2) of FD&C Act)

- **FDASIA (2012)**
  - MDUFA III
  - Added Direct De Novo option

- **21st Century Cures (2016)**
  - Removed 30-day requirement for post-NSE De Novo requests

- **FDARA (2017)**
  - MDUFA IV
  - Added user fees and performance goals
History and Evolution

FDAMA (1997) – Creation of De Novo

- Added Section 513(f)(2) to FD&C Act
- Evaluation of automatic class III designation
- Authority to classify to class I or II
- Same classification criteria in Section 513(a)
- Decision within 60 FDA days
History and Evolution

1. Submit 510(k)

2. Receive High-level NSE Decision

3. Submit De Novo (within 30 days)
History and Evolution

FDASIA (2012)/MDUFA III

• 510(k) prior to De Novo no longer required
• Two submission options:
  – Post-NSE De Novo (original)
  – Direct De Novo (new)
• Review process is the same for each
• Decision within 120 FDA days
History and Evolution

21st Century Cures Act (2016)

- Removed 30-day requirement for post-NSE De Novo requests
- Clarifies combination products may be classified through De Novo pathway

Policy for De Novo classification of combination products under development.
History and Evolution

FDARA of 2017/MDUFA IV

• Added user fees for De Novo requests
• Added performance goals
• Submission checklist (RTA) guidance
History and Evolution

De Novo User Fees

- Standard fee = 30% of PMA user fee
- Small business fee = 25% of standard fee

<table>
<thead>
<tr>
<th>User Fee</th>
<th>FY 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard Fee</td>
<td>$93,229</td>
</tr>
<tr>
<td>Small Business Fee</td>
<td>$23,307</td>
</tr>
</tbody>
</table>
History and Evolution

**De Novo Performance Goals**

- Based on 150 FDA days
  - Different than statutory deadline of 120 FDA days
- Based on % of De Novo requests reaching final decision (grant or decline)

<table>
<thead>
<tr>
<th>Percentage of De Novos with Final Decision by Day 150</th>
</tr>
</thead>
<tbody>
<tr>
<td>FY 2018</td>
</tr>
<tr>
<td>50%</td>
</tr>
</tbody>
</table>
History and Evolution

Total De Novo Requests Received in CDRH

<table>
<thead>
<tr>
<th>Year</th>
<th>Requests</th>
</tr>
</thead>
<tbody>
<tr>
<td>FY 2011</td>
<td>19</td>
</tr>
<tr>
<td>FY 2012</td>
<td>22</td>
</tr>
<tr>
<td>FY 2013</td>
<td>46</td>
</tr>
<tr>
<td>FY 2014</td>
<td>42</td>
</tr>
<tr>
<td>FY 2015</td>
<td>59</td>
</tr>
<tr>
<td>FY 2016</td>
<td>54</td>
</tr>
<tr>
<td>FY 2017</td>
<td>99</td>
</tr>
</tbody>
</table>
History and Evolution

• Need to communicate new statutory requirements
• Need for transparency in review process
• Need for efficient and timely review
New Guidance Documents
New Guidance Documents

De Novo Classification Process
(Evaluation of Automatic Class III Designation)

a.k.a. “De Novo Program Guidance”

Acceptance Review for De Novo Classification Requests (DRAFT)

a.k.a. “Draft De Novo Refuse-to-Accept (RTA) Guidance”
De Novo Program Guidance
De Novo Program Guidance

• **Purpose:** Provide overview of De Novo classification pathway and FDA review process
• Summarizes legal foundation for De Novo classification process and statutory changes (previously described in this webinar)
• Explains when De Novo classification is and is not appropriate (eligibility)
• Emphasizes the importance of early interaction with the Agency (Pre-Submission)
• Identifies recommended content for a De Novo
• Explains what happens when De Novo is granted
De Novo Program Guidance

Classification Summary (Eligibility)

- Must meet medical device definition
- No predicate device (would be found NSE)
- Does not fit into an existing classification regulation (Class I, Class II, or Class III)
- No approved PMA(s) for same device type

If ineligible, we intend to decline the De Novo.
De Novo Program Guidance

Early Interaction (Pre-Submission)

• Verify De Novo is appropriate pathway
• Identify valid scientific evidence needed to support future De Novo request
• Establish working relationship with FDA
De Novo Program Guidance

Recommended Content

• Attachment 2 of guidance document
• Identifies key sections and recommended information/data
• May incorporate information by reference (e.g., reference to testing submitted in a previous 510(k))
De Novo Program Guidance

**Recommended Content**

- **Administrative Information**
  - Requester name, contact name, address, phone, fax, e-mail address

- **Regulatory History**
  - Describe prior submissions to FDA for the same device
  - For previous submissions where we provided feedback, identify how De Novo addresses identified issues
De Novo Program Guidance

**Recommended Content**

- Device Information and Summary
- Indications for Use
- Change Summary
  - Describe in detail any changes made to your device or proposed indications after any prior submission
  - Summary should include changes to the device, as well as changes to test protocols and/or labeling
De Novo Program Guidance

**Recommended Content**

- Classification Summary (Eligibility)
  - Conduct search of legally marketed devices and classification regulations of the same type
  - Provide a list of potentially similar classification regulations, cleared 510(k)s, approved PMAs, and/or product codes
De Novo Program Guidance

Recommended Content

• Classification Summary (Eligibility)
  – Explain why the subject device is different from and/or does not fit within anything identified, for example:
    • New intended use
    • Different technological characteristics raising different safety/effectiveness questions
    • Different risks to health
De Novo Program Guidance

**Recommended Content**

- Classification Recommendation
  - Class I or Class II
- Proposed Special Controls (Class II only)
- Supporting Protocols/Data
- Summary of Benefits and Identified Risks
De Novo Program Guidance

**Recommended Content**

- **Risk and Mitigation Information**
  - Summarize all identified risks to health
  - Identify measure(s) needed to mitigate each identified risk to health
  - Identify location of data supporting each mitigation measure
  - Provide in tabular format
De Novo Program Guidance

**Recommended Content**

<table>
<thead>
<tr>
<th>Identified Risk</th>
<th>Recommended Mitigation Measures</th>
<th>Supporting Data Contained in De Novo</th>
</tr>
</thead>
<tbody>
<tr>
<td>EXAMPLE: Adverse tissue reaction</td>
<td>Specified Biocompatibility Testing Requirements (special control)</td>
<td>Testing in compliance with recognized standard (Section XX, page XXX)</td>
</tr>
<tr>
<td>EXAMPLE: Device failure due to XXX (mechanical failure, software anomaly, use error, etc.)</td>
<td>Specified Non-clinical Testing (special control), Device Specific Labeling Requirements (special control), Medical Device Reporting (MDR) (general control)</td>
<td>Test protocols and results (Section XX, pages XXX)</td>
</tr>
<tr>
<td>EXAMPLE: Failure to properly interpret test results</td>
<td>Device Specific Labeling Requirements (special control)</td>
<td>Draft device labeling (Section XX, pages XXX)</td>
</tr>
</tbody>
</table>
De Novo Program Guidance

Recommended Content

• Benefit-Risk Considerations
  – Benefit/risk assessment
  – See guidance “Factors to Consider When Making Benefit-Risk Determinations in Medical Device Premarket Approval and De Novo Classifications”

• Device Labeling
De Novo Program Guidance

Granted De Novo Request

• Issue granting order
  – May legally market device
  – May serve as predicate device for future 510(k)s
  – Identifies new classification regulation
  – Identifies risk/mitigation table and special controls (if Class II)

• Post granting order and decision summary on FDA website

• Publish Federal Register notice
Draft De Novo RTA Guidance

This draft guidance is not final and not in effect at this time.
Draft De Novo RTA Guidance

- Purpose: Ensure De Novo request is acceptable for substantive review
- Facilitates efficient and timely review
- Similar to RTA policies for 510(k) and PMA
- MDUFA IV commitment ("submission checklist")
Draft De Novo RTA Guidance

- Determine if De Novo is administratively complete
- Not intended to be a substantive review
- Intend to complete RTA review within 15 calendar days of receiving De Novo
- De Novo is considered accepted if RTA review is not completed within 15 calendar days
- May have up to a 60-day transition period after final guidance published
# Draft De Novo RTA Guidance

<table>
<thead>
<tr>
<th>Appendix A</th>
<th>Appendix B</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acceptance Checklist</td>
<td>Recommended Content Checklist</td>
</tr>
<tr>
<td>Required</td>
<td>Not Required</td>
</tr>
<tr>
<td><strong>Examples:</strong></td>
<td><strong>Examples:</strong></td>
</tr>
<tr>
<td>Intended use</td>
<td>Prior submissions</td>
</tr>
<tr>
<td>Device description</td>
<td>Classification summary (eligibility)</td>
</tr>
<tr>
<td>Proposed special controls (if</td>
<td>Device labeling</td>
</tr>
<tr>
<td>recommending class II)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Draft De Novo RTA Guidance

• Not in effect at this time
• For comment purposes only
• Submit comments electronically: https://regulations.gov
• Docket #: FDA-2017-D-6069
• Comment period open now through December 29, 2017
Resources
Resources

• De Novo Classification Process (Evaluation of Automatic Class III Designation)

• Acceptance Review for De Novo Classification Requests (DRAFT)
Resources

• Factors to Consider When Making Benefit-Risk Determinations in Medical Device Premarket Approval and De Novo Classifications

• User Fees and Refunds for De Novo Classification Requests
Resources

• FDA and Industry Actions on De Novo Classification Requests: Effect on FDA Review Clock and Goals

• MDUFA IV Commitment Letter
Resources

• CDRH Device Advice – De Novo
  https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm462775.htm

• De Novo Classification Requests Database
  https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/denovo.cfm
General questions about this webinar?
Contact Division of Industry and Consumer Education: DICE@fda.hhs.gov

Slide presentation, transcript and webinar recording will be available at:
http://www.fda.gov/training/cdrhlearn
Under Heading: How to Study and Market Your Device; Subheading: De Novo

Please complete a short survey about your FDA CDRH webinar experience. The survey can be found at www.fda.gov/CDRHWebinar immediately following the conclusion of the live webinar.