U.S. FOOD & DRUG ADMINISTRATION

Welcome to Today's FDA/CDRH Webinar

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

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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.

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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

User Fee	FY 2018
Standard Fee	$93,229
Small Business Fee	$23,307

History and Evolution

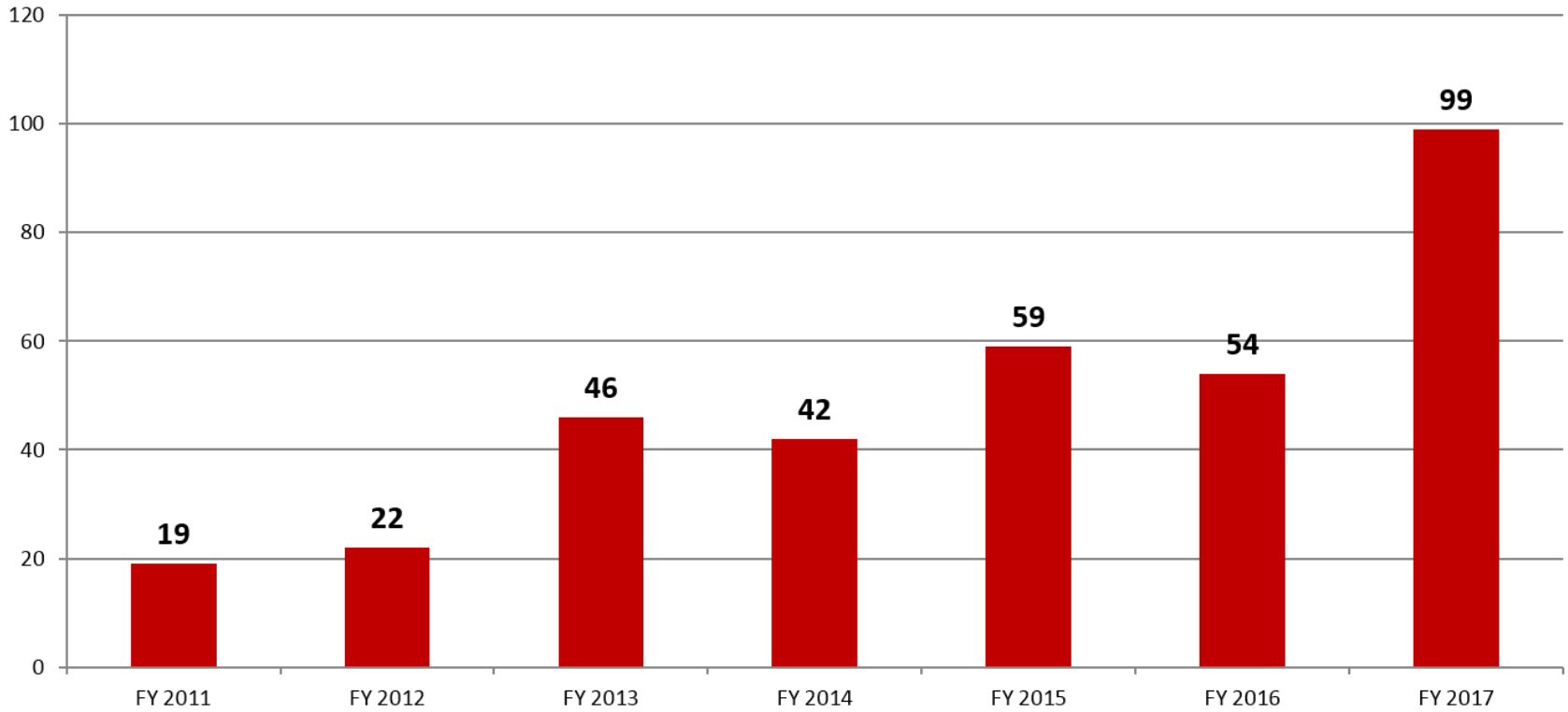
De Novo Performance Goals

- 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)

Percentage of De Novos with Final Decision by Day 150				
FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
50%	55%	60%	65%	70%

History and Evolution

Total De Novo Requests Received in CDRH



History and Evolution

- Need to communicate new statutory requirements
- Need for transparency in review process
- Need for efficient and timely review

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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”

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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

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

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

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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

Appendix A	Appendix B
Acceptance Checklist	**Recommended Content Checklist**
Required	Not Required
Examples: Intended use Device description Proposed special controls (if recommending class II)	*Examples:* Prior submissions Classification summary (eligibility) Device labeling

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

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Resources

Resources

- De Novo Classification Process (Evaluation of Automatic Class III Designation) https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM080197.pdf

- Acceptance Review for De Novo Classification Requests (DRAFT) https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM582251.pdf

Resources

- Factors to Consider When Making Benefit-Risk Determinations in Medical Device Premarket Approval and De Novo Classifications https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm506679.pdf

- User Fees and Refunds for De Novo Classification Requests https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM576306.pdf

Resources

- FDA and Industry Actions on De Novo Classification Requests: Effect on FDA Review Clock and Goals https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM576305.pdf

- MDUFA IV Commitment Letter https://www.fda.gov/downloads/ForIndustry/UserFees/MedicalDeviceUserFee/UCM535548.pdf

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; Sub-heading: De Novo

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