De Novo Classification Process

AMDM Annual Submission Workshop
April 16, 2018

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Objectives

- FDA Device Classification and Regulatory Requirements
- Role of De Novo Pathway
- Legal Framework for De Novo
- FDA De Novo Review Process and Decisions

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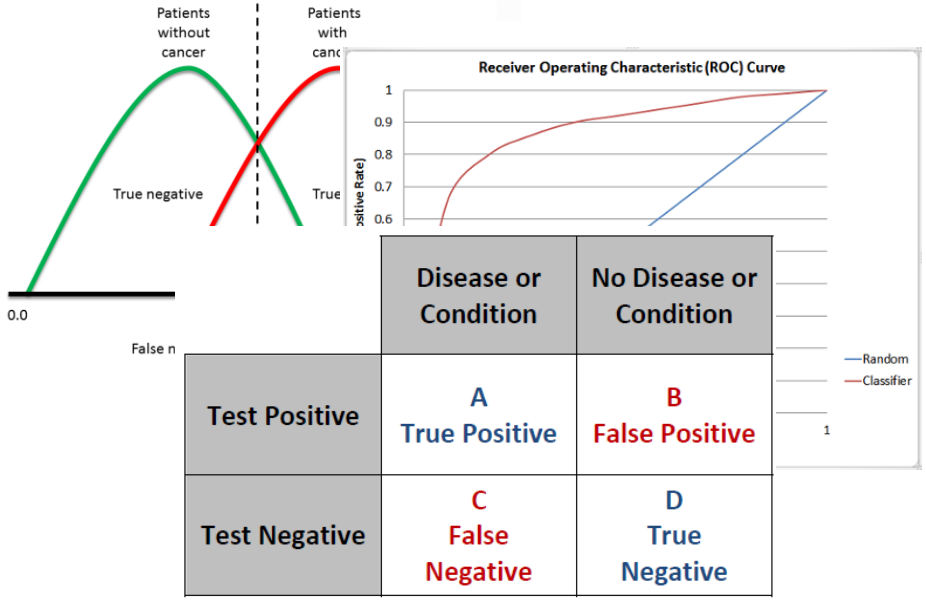
Regulatory Requirements Depend on Risks and Mitigations

Examples of Risks to Health

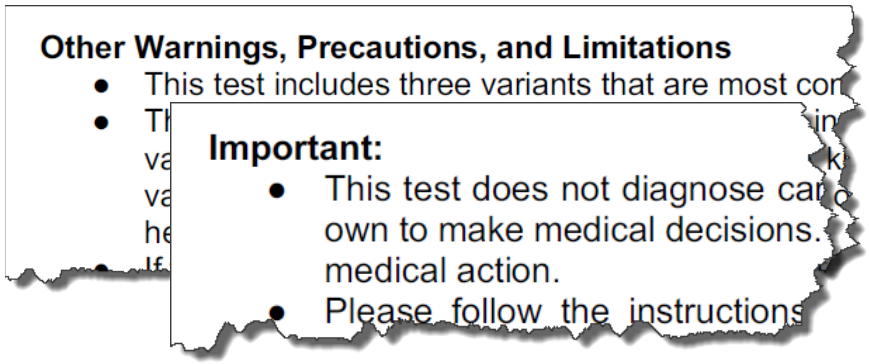
- Incorrect test results
- Failure to correctly interpret test results



	Disease or Condition	No Disease or Condition
Test Positive	A True Positive	B False Positive
Test Negative	C False Negative	D True Negative

Examples of Risk Mitigations

- Performance testing (sample size, results, etc.)
- Specific labeling (warning, limitations, etc.)



Regulatory Requirements Depend on Risks and Mitigations

- Class I- Lowest Risk
  - Class I devices are subject to general controls outlined in Food Drug & Cosmetic Act
- Class II- Moderate Risk
  - Class II devices are subject to general controls and special controls outlined in specific regulation (21 CFR 8XX.XXXX)
- Class III- Highest Risk
  - Class III devices are subject to general controls and premarket approval

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De Novo Limits Unnecessary Expenditures for FDA and Industry

- Devices of new type “automatically” Class III
- Class I or Class II classification may be more appropriate for low to moderate risk devices
- De Novo pathway provides mechanism for Class I or Class II classification of low to moderate risk devices

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De Novo Legal Framework Allows for Two Submission Pathways

Option One: Post-NSE

- Per FDAMA (1997): De Novo may be submitted within 30 days of 510(k) Not Substantially Equivalent (NSE) letter
- Modified by 21st Century Cures (2016) to remove 30 day requirement

Option Two: Direct

- Per FDASIA (2012): De Novo may be submitted *without* prior 510(k) NSE decision

MDUFA IV (2017) Provides for User Fees for De Novo

User fees required beginning 10/1/2017 (User Fees and Refunds for De Novo Classification Requests)

Table 1. When Is a De Novo Request Subject to a User Fee?

De Novo Request Type	De Novo Fee Required
Original De Novo request	Yes
Additional information for a pending De Novo request	No
De Novo request submitted by a state or federal government sponsor, *and* the device will not be commercially distributed	No
De Novo request intended solely for a pediatric population	No
De Novo request for a device for which the previous De Novo request was declined	Yes

MDUFA IV Includes Performance Goals for De Novo

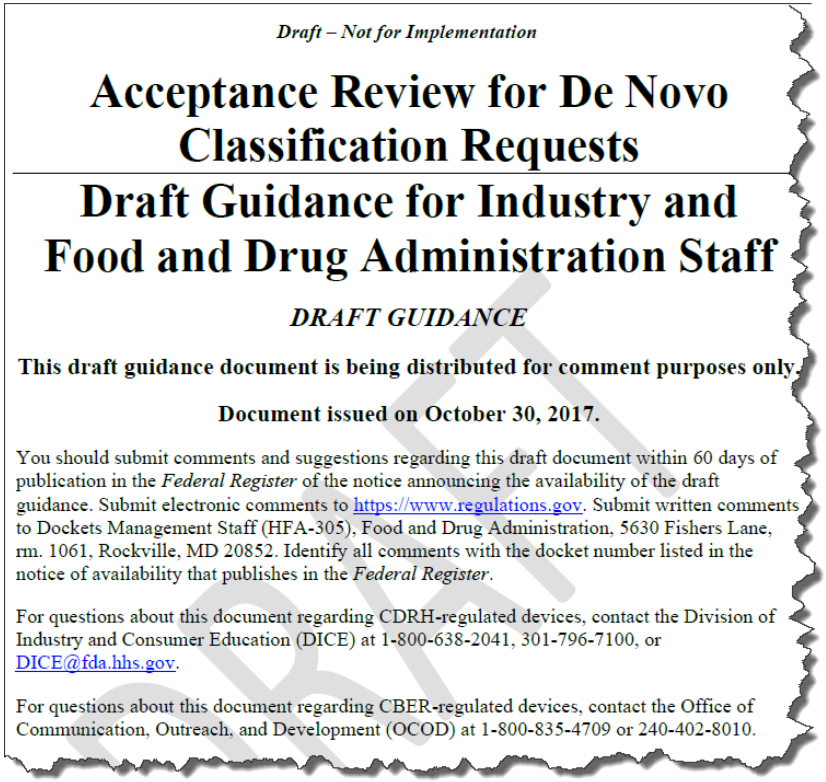
[FDA and Industry Actions on De Novo Classification Requests: Effect on FDA Review Clock and Goals]

Table 1. De Novo Performance Goals

Action	Review Time (FDA days)	Performance Level (by Fiscal Year)				
		FY2018	FY2019	FY2020	FY2021	FY2022
MDUFA Decision (grant/decline)	150	50%	55%	60%	65%	70%

MDUFA IV Includes Development of RTA Policy for De Novo

Refuse to Accept (RTA) policy will be implemented when guidance final (Acceptance Review for De Novo Classification Requests)



Draft – Not for Implementation

Acceptance Review for De Novo Classification Requests

Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

This draft guidance document is being distributed for comment purposes only.

Document issued on October 30, 2017.

You should submit comments and suggestions regarding this draft document within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions about this document regarding CDRH-regulated devices, contact the Division of Industry and Consumer Education (DICE) at 1-800-638-2041, 301-796-7100, or DICE@fda.hhs.gov.

For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach, and Development (OCOD) at 1-800-835-4709 or 240-402-8010.

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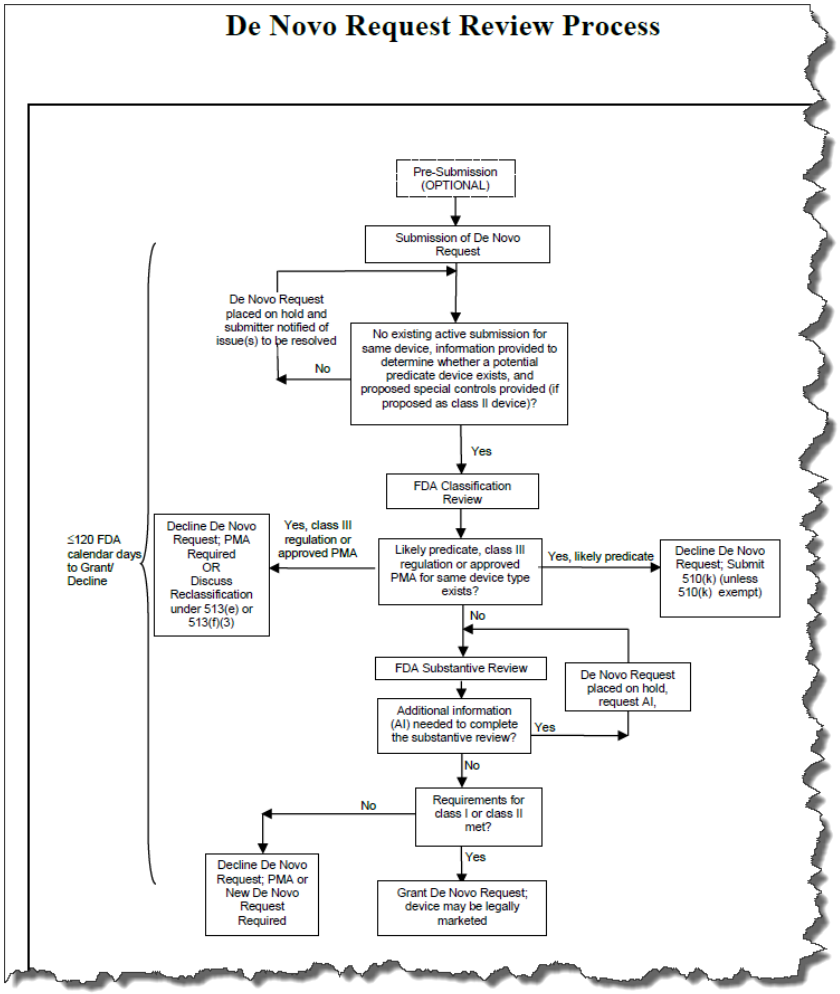
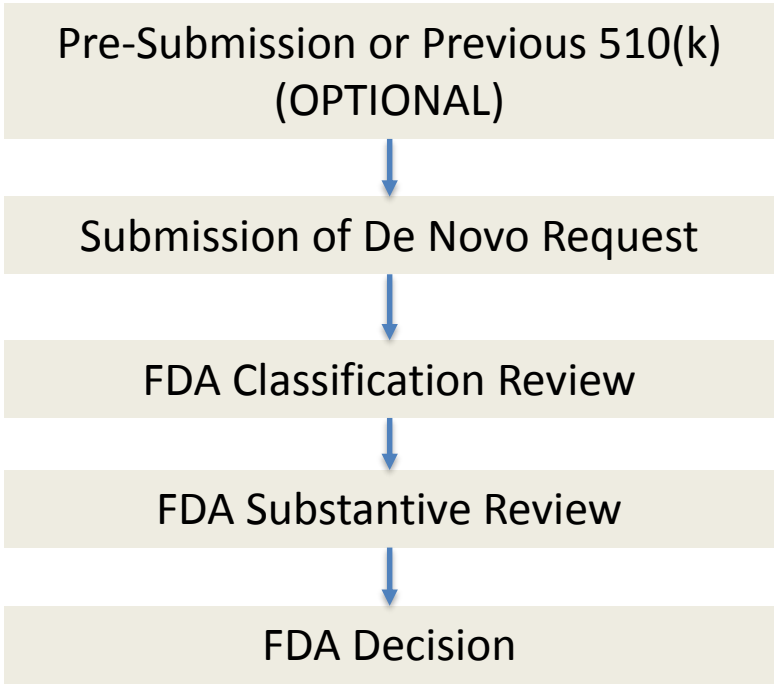
FDA De Novo Review Process Outlined in Guidance

Attachment 1 of [De Novo Classification Process (Evaluation of Automatic Class III Designation)]

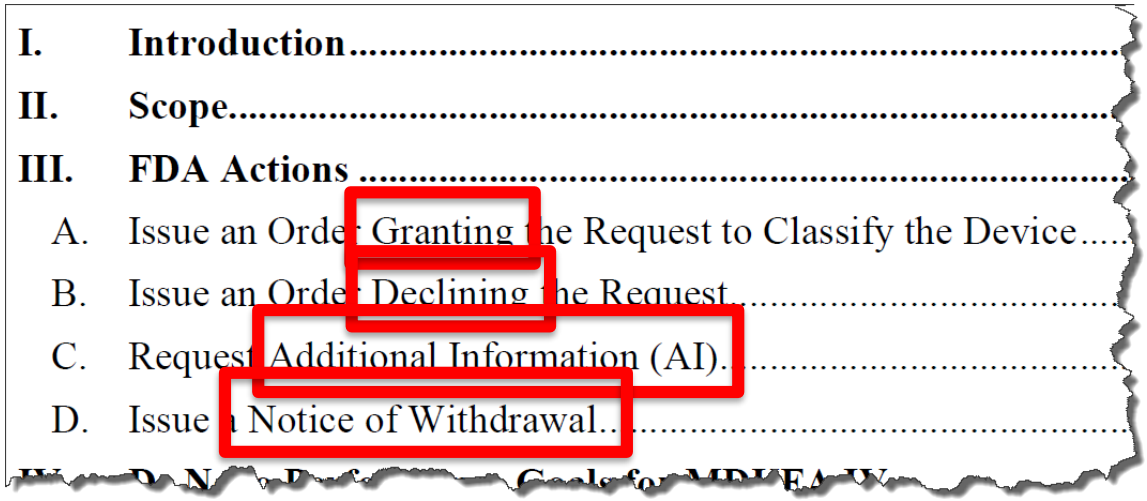


FDA Review Includes Several Steps After De Novo Submission



FDA De Novo Review Decisions Outlined in Guidance

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



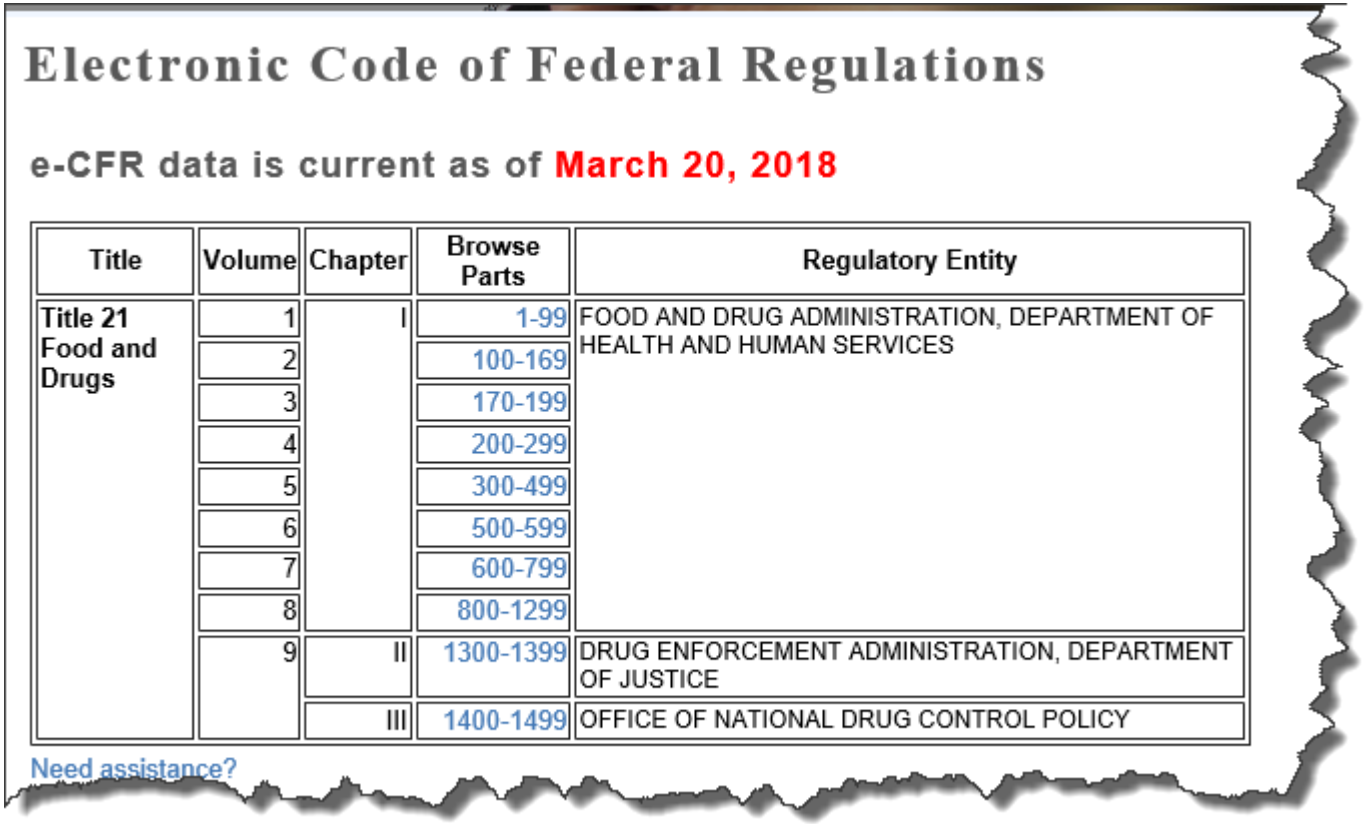
FDA Publishes De Novo Grant Decision Summaries and Letters Online

- Device may be used as predicate as soon as De Novo is granted
- Classification order and Decision Summary posted on CDRH Transparency Website

Device Name	DEN#	Classification Order	Decision Summary
PrimeStore MTM	DEN170029	Classification Order	
Acumen Hypotension Prediction Index (HPI) Feature Software	DEN160044	Classification Order	
ContaCT	DEN170073	Classification Order	Decision Summary
NSS-2 BRIDGE	DEN170018	Classification Order	Decision Summary
CipherOx CRI™ Tablet	DEN160020	Classification Order	Decision Summary

FDA Updates CFR After De Novo Grant Decision

CFR updated to include new regulation



Electronic Code of Federal Regulations

e-CFR data is current as of March 20, 2018

Title	Volume	Chapter	Browse Parts	Regulatory Entity
Title 21 Food and Drugs	1	I	1-99	FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES
	2		100-169	
	3		170-199	
	4		200-299	
	5		300-499	
	6		500-599	
	7		600-799	
	8		800-1299	
	9	II	1300-1399	DRUG ENFORCEMENT ADMINISTRATION, DEPARTMENT OF JUSTICE
		III	1400-1499	OFFICE OF NATIONAL DRUG CONTROL POLICY

Need assistance?

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Thank You!

OIR-Policy@fda.hhs.gov