The De Novo Process for In Vitro Diagnostics

510(k) Workshop 2010

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What does “de novo” mean?

What does “de novo” mean?

-from the beginning; anew

History of Device Classification:

- Medical Device Amendments of 1976

  - assigned devices on the market as of May 28, 1976 to one of the three "classes" according to their risk

  - new devices introduced to market after this date – require predicate or automatically become Class III

  - Class III require pre-market approval (PMA)

History of De Novo:

FDA Modernization Act of 1997 (FDAMA) –

New Section 513(f)(2) of the Food, Drug, and Cosmetic Act.

Amended November 21, 1997:

"Evaluation of Automatic Class III Designation"

- **Provides a new mechanism for classifying new devices for which there is no predicate device**
- **Also known as: De Novo Process**

Advantages of De Novo:

- New devices without a predicate
- Allows an automatic class III designation to be evaluated and overturned
- Expedite time to market
- Determined on a case by case basis and is always risk based

Devices for which De Novo is not appropriate:

- Not for high risk IVD's
- De novo process cannot be used to reclassify a device that is already in Class III

How do I determine the classification of my device?

- Search for classified devices
- Ask the FDA: Submit a 513(g)
- Submit a pre-IDE

Finding classified devices:

- **Search by device name, product code or panel**
- **Search the classification database**
  http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/classification.cfm
- **Search the classification regulations (CFR)**
  http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/UCM051530

Product Classification

CDRH SuperSearch

510(k) | Registration & Listing | Adverse Events | Recalls | PMA | Classification | Standards
CFR Title 21 | Radiation-Emitting Products | X-Ray Assembler | Medsun Reports | CLIA

Search Classification Database

Help | Download Files | More About Classification

Device		Product Code	
Review Panel		SubmissionType	
Regulation Number		Third Party Elligible	
Sort By	Device Name (A-Z)	Device Class	

For full-text search, select *Go To Simple Search* button

Search | Clear | 50 Records per Report Page | Go to Simple Search

Page Last Updated: 03/06/2010

CFR - Code of Federal Regulations Title 21

Search CFR Title 21 Database

Help | More About 21CFR

There are 2 kinds of searches available: Enter a *Part & Section Number*
OR
select a *CFR Part* or a *Full-Text Search*. You may also combine the *CFR Part* and the *Full Text Searches*

Title21 Part.Section *(e.g., 862.1385)*

CFR Title 21 - Food and Drugs: Parts 1 to 1499

(861) Procedures for performance standards development
(862) Clinical chemistry and clinical toxicology devices
(864) Hematology and pathology devices
(866) Immunology and microbiology devices
(868) Anesthesiology devices

Full Text Search:

Enter a single word (e.g., catheter), an exact phrase (e.g., catheter line) or multiple words connected by *and* (e.g., catheter *and* tubing).

Search Regulation(s) | Clear

Submit a 513(g)

- **513(g) of the Act is an official request for classification**
  "…the Secretary shall provide such person a written statement of the classification (if any) of such device and the requirements of this Act applicable to the device."

- **Contents should include device description, indications for use statement, and labeling.**

- **Does not constitute FDA clearance or approval**

Submit a Pre-IDE

- Obtain FDA feedback about likely regulatory requirements
- Include detailed device description, intended use, proposed analytical and clinical study protocols

"Does the Agency agree that the De Novo process is appropriate for my device?"

- Risk-based determination (risks associated with poor performance)
- Risk is based on the Intended Use
- Class III device: supports or sustains human life or is of substantial importance in preventing impairment of human health or presents a potential, unreasonable risk of illness or injury.

Examples of Risk-based classification:

Prostate-specific antigen (PSA) testing:

- **Aid in detection of prostate cancer (class III, PMA)**
- **Monitoring prostate cancer patients for disease progress (class II, 510(k))**

Alpha-fetoprotein (AFP) testing:

- **Prenatal screen for neural tube defects (class III, PMA)**
- **Monitoring for testicular cancer (class II, 510(k))**

How will FDA assess the risk of my device?

- Include a description of the intended use/indications for use
- Descibe how the device will be used in patient management
- Describe how the test will impact current guidelines/practice
- Include a description of the possible risks associated with poor performance
- Describe how these risks will be mitigated

Examples of Features that Support De Novo:

- Previously diagnosed patients
- Used in conjunction with other well-accepted methods for diagnosing a condition
- Supporting literature (guidelines, etc.)
- Include limitations (Indications for use, labeling etc.)

Other considerations:

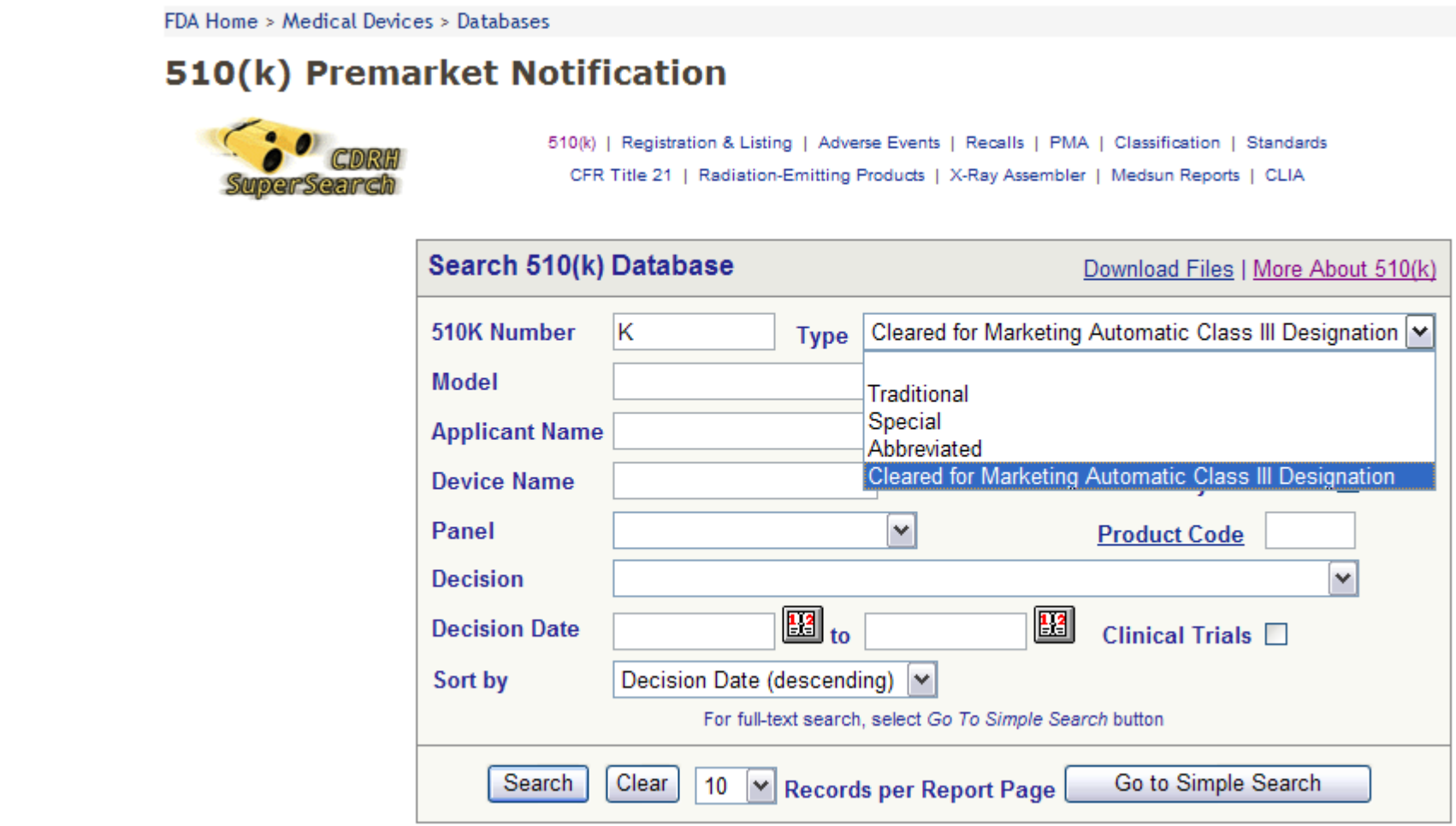
- What are the risks of the device if used off-label?
- Is there a clinical benefit to obtaining the results?
- How reliably can a novel technology be replicated across different users?

To find other De Novo devices:

- Search Federal Register (FR)
- Search 510(k) Database (through OIVD website)

  http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm

  - Under "type" select: "Cleared for Marketing Automatic Class III Designation"
  - Under "panel" select Chemistry, Immunology, etc.


FDA Home > Medical Devices > Databases
510(k) Premarket Notification
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510(k) | Registration & Listing | Adverse Events | Recalls | PMA | Classification | Standards
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510K Number
K
Type
Cleared for Marketing Automatic Class III Designation
Traditional
Special
Abbreviated
Cleared for Marketing Automatic Class III Designation
Model
Applicant Name
Device Name
Panel
Product Code
Decision
Decision Date
to
Clinical Trials
Sort by
Decision Date (descending)
For full-text search, select Go To Simple Search button
Search
Clear
10
Records per Report Page
Go to Simple Search

510(k) Premarket Notification

1 2 3 4 5 6 >

55 records meeting your search criteria returned - **Type:** *Cleared for Marketing Automatic Class III Designation*

New Search

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Device	Applicant	510(k)	Decision Date
Ova1 Test	Vermillion	K081754	07/16/2009
Snap Wound Care Device	Spiracur, Inc.	K081406	10/28/2008
Allomap Molecular Expression Testing	Xdx	K073482	08/08/2008
Ulthera System, Model 8850-0001	Ulthera, Inc.	K072505	03/14/2008
Id-Tag Respiratory Viral Panel	Luminex Molecular Diagnostics, Inc.	K063765	11/30/2007
Neurostar System	Neuronetics	K061053	04/26/2007
Impedimed-Extracellular Fluid Analysis	Impedimed Pty Ltd.	K050415	03/30/2007
Xpert Ev, Model Gxev-100n-10; Genexpert	Cepheid	K061062	03/09/2007
Binax Now Malaria Test; Model 660-000, 6	Inverness Medical Professional Diagnosti	K061542	02/22/2007
Mammaprint	Agendia Bv	K062694	01/19/2007

510(k) Premarket Notification

New Search Back To Search Results

Device Classification Name	Respiratory Virus Panel Nucleic Acid Assay System
510(K) Number	K063765
Device Name	ID-TAG RESPIRATORY VIRAL PANEL
Applicant	LUMINEX MOLECULAR DIAGNOSTICS, INC. 439 University Ave. Toronto, Ontario,
Contact	Gloria Lee
Regulation Number	866.3980
Classification Product Code	OCC
Date Received	01/08/2007
Decision Date	11/30/2007
Decision	Cleared For Marketing Automatic Class Iii Designat (AN)
Classification Advisory Committee	Microbiology
Review Advisory Committee	Microbiology
FOI ITEM	LETTER
FDA Review	Decision Summary
Type	Cleared For Marketing Automatic Class III Designation
Reviewed By Third Party	No
Expedited Review	No

De Novo Process Overview:

- FDA and sponsor discuss possibility of de novo application informally through a teleconference or Pre-IDE
- Sponsor submits a pre-market notification 510(k) to the FDA
- FDA reviews the 510(k) application
- The 510(k) application will result in an NSE (not substantially equivalent) letter (because of lack of predicate device).

De Novo language from NSE letter:

The Food and Drug Administration Modernization Act of 1997 (FDAMA), in section 207, deals with the Evaluation of Automatic Class III Designation. Under this section a manufacturer, whose device is found to be not substantially equivalent to a predicate device, can request FDA to make a risk-based classification for their device. I believe that based on the review of your device, it may be a candidate for Evaluation of Automatic Class III Designation. Therefore, you may wish to make such a request of this agency.

Request for De Novo letter to FDA:

- Within 30 days of receipt of the NSE letter, the sponsor sends a petition requesting classification of the new device
  - Cover sheet indicating "Request for Evaluation of Automatic Class III Designation"
  - 510(k) number on the NSE letter
  - Statement of cross reference to the information in the 510(k)

Request for De Novo letter contents, cont'd:

- Classification being requested
- A discussion of the risks vs. benefits
- Discussion of proposed controls that would be needed to assure the safety and effectiveness of the device
- Any additional data not included in the 510(k) that are relevant to the request

Request for De Novo letter contents, cont'd:

- For devices recommended to be placed in class I, sponsors should also indicate if device should be exempt from:
  - the 510(k) requirements and,
  - the design controls provisions of the Quality Systems Regulation (QSR).

Examples of General Controls for Class I devices:

- Registration and listing
- Good manufacturing practices
- Labeling

Examples of Class II Special Controls

- Guidance Document
- Performance standards
- Device labeling
- Postmarket surveillance/data

After receiving the Letter, FDA has 60 days to:

- Review the request
- Evaluate the risk
- Identifies deficiencies and ensures they are addressed
- Identify applicable controls
- Create a new product code
- Classify the device
- Write the Approval Order

FDA Final Actions:

- Write Special Controls Guidance Document
- Write FR Notice of Availability of SCGD
- Send signed Approval Order classifying the device
- (Class I, II, or III)
  - Indicates New device can be marketed
- Approval Order published in Federal Register within 30 days of signed letter

The De Novo Process Summary:

- A risk-based classification process
- Talk with FDA prior to beginning studies
- Utilize resources on OIVD web site
- Requires a premarket submission and other regulatory elements
- Provides faster and less expensive route to market for future devices with the same use

Additional Information:

- Guidance document "New Section 513(f)(2) - Evaluation of Automatic Class III Designation" (Feb 19, 1998): http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080197.pdf

- De Novo Classification for In Vitro Diagnostic (IVD) Devices (questions and answers): http://www.amdm.org/amdm/051502-DeNovo.html