

# The *De Novo* Program

**FDA Small Business  
Regulatory Education for Industry (REdI)**  
Silver Spring, MD  
September 27, 2016

**Sergio M. de del Castillo**  
*De Novo* Policy Analyst (Acting)  
Office of Device Evaluation  
Center for Devices and Radiological Health  
U.S. Food and Drug Administration

# DigniCap™ - Is this a PMA device?



# Learning Objectives

- Describe the legal basis for the *de novo* pathway
- Identify the criteria for determining if a device is eligible for the *de novo* pathway
- Identify the information that should be included in a *de novo* request
- Describe the overall *de novo* review process

# Poll Question

**What experience do you have with the de novo pathway?**

View Votes

Edit

End Poll

**What experience do you have with the de novo pathway?**

<input type="radio"/> No experience	<div></div>	0%	(0)
<input type="radio"/> Submitted a pre-submission to discuss a future de novo request	<div></div>	0%	(0)
<input type="radio"/> Currently preparing a de novo request	<div></div>	0%	(0)
<input type="radio"/> Submitted a de novo request	<div></div>	0%	(0)
<input checked="" type="radio"/> No Vote			

☒ Broadcast Results

# What is a *de novo*?

1. A unique type of premarket submission
2. Intended for novel and innovative devices that would be automatically classified into Class III
3. Request for classification into Class I or II (risk-based approach)
4. Creates new classification regulation

# History and Background

# History and Background

- FDA Modernization Act (FDAMA) 1997
  - Added Section (f)(2) to Section 513 of the FD&C Act
- “Evaluation of automatic class III designation”  
(a.k.a. *de novo*)
- Authority to classify to Class I or II

# History and Background

1. Submit 510(k)



2. Receive NSE decision



3. Submit *de novo* (within 30 days)



# History and Background

- FDA Safety and Innovation Act (FDASIA) 2012
- Changed *de novo* process:
  - Review set at **120 days (FDA days)**
  - 510(k) prior to *de novo* not required

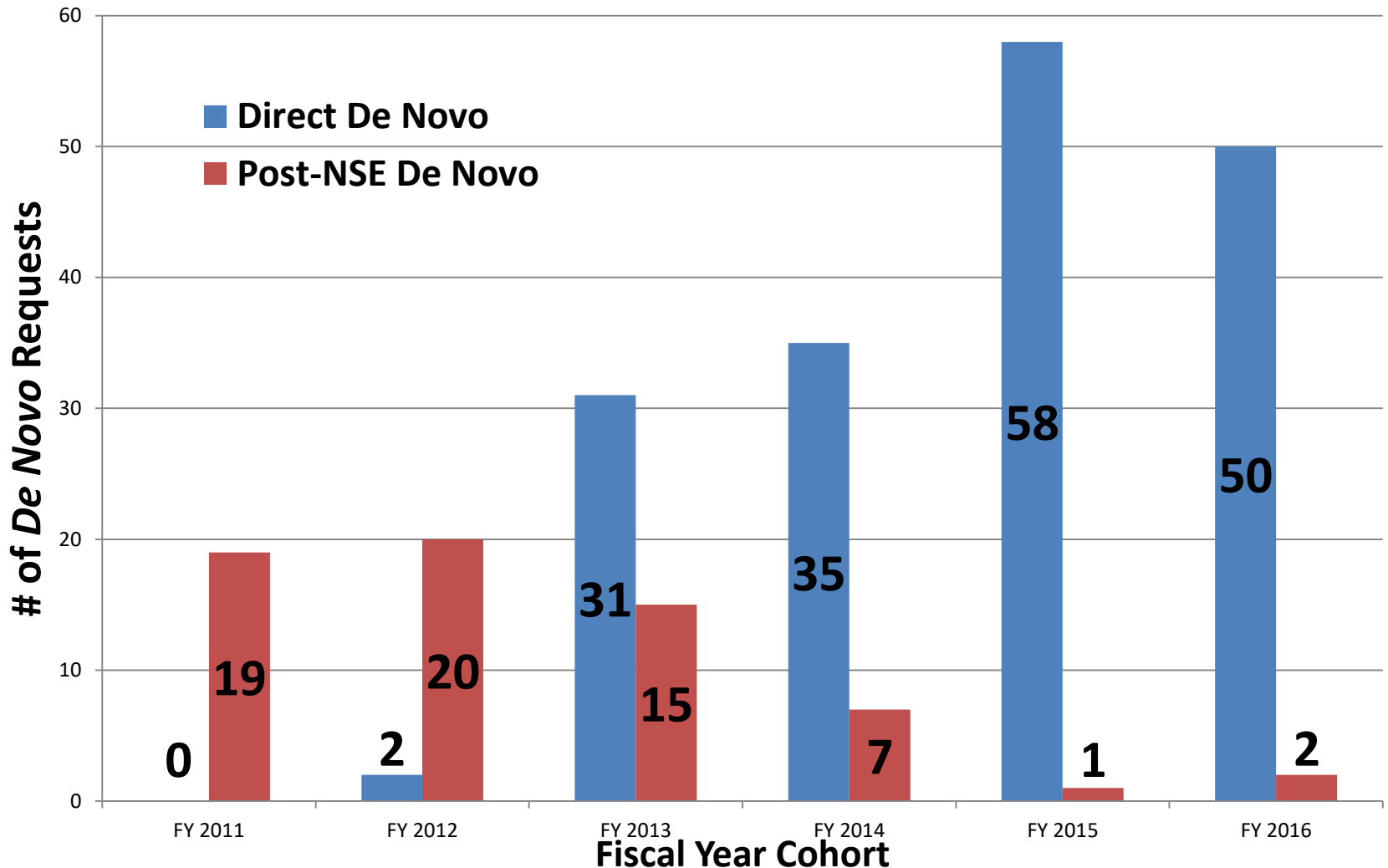
***Goal → Streamline review process***

# History and Background

- FDASIA created two (2) pathways:
  - Post-NSE *de novo* (original process)
  - Direct *de novo* (new process)

***Almost all de novo's are now direct***

# De Novo Requests Received in CDRH



# Eligibility

# Eligibility

- **Must be a medical device**
  - (Section 201(h) of FD&C Act)
- **Must not fit into any existing classification regulation**
  - No predicate device (NSE)
  - Doesn't fit into existing Class III regulation
  - No approved PMA(s) for the same device type

# Eligibility

**What kinds of devices may be granted  
through *de novo*?**

# DEN150010 – DigniCap™



## DEN150010 – DigniCap™

- Indicated to reduce the likelihood of chemotherapy-induced alopecia (hair loss) in women with breast cancer
- Liquid coolant circulates through cap to reduce scalp temperature
- Scalp temperature is computer controlled and monitored

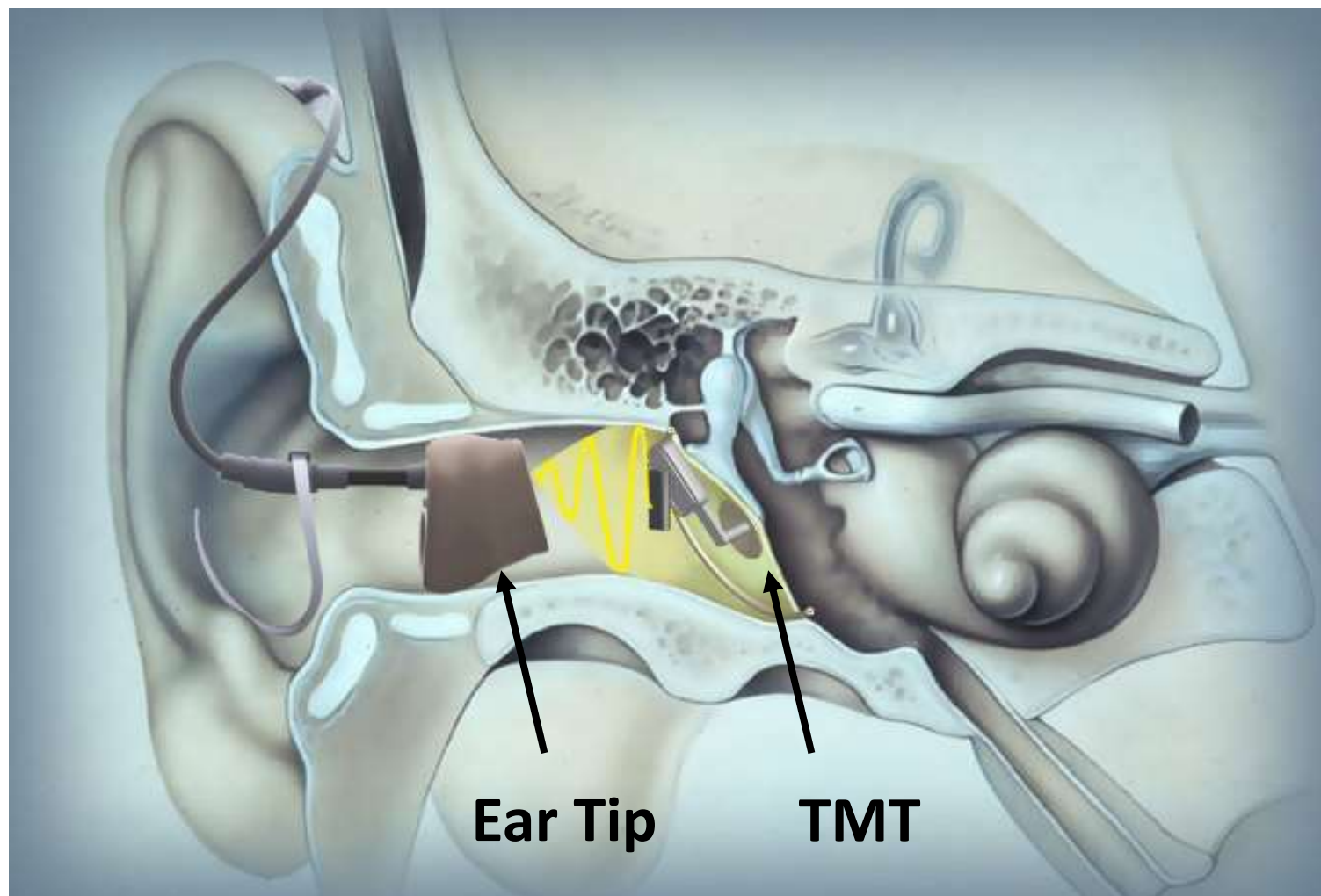
**No predicate devices... but eligible for *de novo*!**



## DEN150010 – DigniCap™

- Probable benefits outweigh probable risks
- Sufficient information to determine general + special controls mitigate risks
- Created new classification regulation
  - *Scalp cooling system to reduce the likelihood of chemotherapy-induced alopecia*
  - 21 CFR 878.4360; Class II
  - Product code PMC
- Authorized to legally market

# DEN150002 – EarLens™



## DEN150002 – EarLens™

- Indicated for persons 18+ years old with mild to severe sensorineural hearing impairment who can benefit from amplification
- Converts audio signals into light (Class I laser)
- Light then converted to sound through direct mechanical stimulation of the eardrum
- No predicate devices

# DEN150002 – EarLens™ Contact Hearing Device (CHD)

- Probable benefits outweigh probable risks
- Sufficient information to determine general + special controls mitigate risks
- Created new classification regulation
  - *Tympanic membrane contact hearing aid*
  - 21 CFR 874.3315; Class II
  - Product code PLK
- Authorized to legally market

## *De Novo* vs. PMA

	<i>De Novo</i>	PMA
User fee	No	Yes
FDA Review time (calendar days)	120 days	180 days - no panel 320 days - with panel
Manufacturing review	No	Yes
Premarket inspection	No	Yes
Device modifications	510(k)	PMA Supplement
Annual reporting	No	Yes

# ***De Novo* Content**

## ***De Novo Content***

**Highly recommend submitting  
a Pre-Submission!**

- Introduce your device
- Discuss eligibility
- Obtain feedback on performance testing
- Obtain feedback on clinical study design

# *De Novo* Content

- **Administrative information**
  - Applicant/contact name
  - Address
  - Contact information (phone, fax, email)
- **Regulatory history**
  - Previous 510(k)
  - Any Pre-Sub feedback



# *De Novo* Content

- **Device description**
  - Trade name
  - Technological characteristics
  - System components/accessories
- **Intended use/indications for use**
- **Device labeling**

# *De Novo* Content

- **Classification summary (eligibility)**
  - Describe search for legally marketed devices of potentially the same type
  - List possible regulations, approved PMAs, or product codes
  - Explain why your device does not fit into any of the above

# *De Novo* Content

- **Proposed classification (Class I or II)**
- **Supportive evidence**
  - All test methods (protocols) and data
  - Include non-clinical, animal, and clinical data, where appropriate
  - Discuss correlation between evidence and proposed classification

## *De Novo* Content

- **Risks to health associated with device**
- **Measures to mitigate risks to health**
  - Includes general and/or special controls
  - Provide evidence to support each mitigation
- **Proposed special controls (Class II)**
- **Assessment of benefits and risks**

# ***De Novo* Review Process**

# ***De Novo* Review Process**

## **Classification Process**

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

## *De Novo* Review Process

- Goal → Review in 120 FDA days
- Two review cycles (~60 days each)
- Can request Additional Information
- Final decision: **grant** or **decline**

# ***De Novo* Review Process**

**Initial review**



**Substantive review**



**Internal Office-level briefing**



**Issue letter**



# ***De Novo* Review Process – Decline**

- **Reasons to decline:**
  - Not a medical device
  - Fits into existing classification regulation
  - Appropriate predicates are available
  - Approved PMAs for same device type
  - Benefits do not outweigh risks
  - Insufficient information to determine level of control needed to mitigate risks

## ***De Novo* Review Process – Grant**

- Risks to health + mitigation measures
  - General controls only = Class I
  - General controls + special controls = Class II
- Benefits outweigh risks
- Above provide reasonable assurance of safety and effectiveness

**Agency has final authority**

# *De Novo* Review Process – Grant

## Risk/Mitigation Table

Identified Risk	Mitigation Measure
Infection	<ul style="list-style-type: none"><li>• Cleaning Validation</li><li>• Labeling</li></ul>
Adverse Tissue Reaction	<ul style="list-style-type: none"><li>• Biocompatibility Testing</li></ul>
Skin Overheating / Burn	<ul style="list-style-type: none"><li>• Clinical Performance Testing</li><li>• Non-clinical Performance Testing</li><li>• Software Verification, Validation &amp; Hazards Analysis</li><li>• Labeling</li></ul>
Electromagnetic Interference / Electrical Shock	<ul style="list-style-type: none"><li>• Electromagnetic Compatibility Testing</li><li>• Electrical Safety Testing</li><li>• Labeling</li></ul>
Worsening Aesthetic Outcomes	<ul style="list-style-type: none"><li>• Clinical Performance Testing</li></ul>

# *De Novo* Review Process – Grant

- **Special Controls**

- Legally required for all devices
- Written into the new classification regulation
- Each special control maps back to R/M table
- **Your device MUST meet all identified special controls before it may be granted**

# ***De Novo* Review Process – Grant**

- **Special Controls (examples)**

1. Non-clinical performance data must demonstrate that the device meets all design specifications and performance requirements. The following performance characteristics must be tested: over-heating, power accuracy radiofrequency, pulse cycle, waveform, pulse duration, and device characterization parameters.
2. The patient-contacting components of the device must be demonstrated to be biocompatible.
3. Performance data must be provided to demonstrate the electromagnetic compatibility (EMC) and electrical safety of the device.

# ***De Novo* Review Process – Grant**

- **Regulation**

- Name of regulation (name of device type)
- Identification
  - Intended use
  - Technological characteristics
- Regulation number (e.g., 21 CFR 878.XXXX)

# *De Novo* Review Process – Grant

- **Regulation (example)**
  - **Number:** 21 CFR 878.4420
  - **Name:** *Electrosurgical device for over-the-counter (OTC) aesthetic use*
  - **Identification:** *An electrosurgical device for over-the-counter (OTC) aesthetic use is a device using radiofrequency energy to produce localized heating within tissues for OTC non-invasive aesthetic use.*

# ***De Novo* Review Process – Grant**

**After** a *de novo* is granted

- 1. New device may be legally marketed**
  - Subject to applicable requirements
- 2. New device may be used as a predicate device (follows 510(k) process)**
- 3. New classification regulation created**



# ***De Novo Review Process – Grant***

**After** a *de novo* is granted

- FDA send and publishes granting order
- FDA publishes decision summary (Transparency Summary)
- FDA publishes notice in Federal Register



# ***De Novo Review Process – Grant***

## ***De Novo Transparency Web Page***

**[www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHTransparency/ucm232269.htm](http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHTransparency/ucm232269.htm)**

## ***De Novo Searchable Database***

**[www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/denovo.cfm](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/denovo.cfm)**

# **Upcoming Program Changes**

# Upcoming Program Changes

## Medical Device User Fee Amendments 2017 (MDUFA IV)

- **Additional FDA resources for *de novo***
- **Anticipated performance goals**
  - 70% of requests reviewed in 150 days (by end of FY2022)

**Negotiations in progress...**

# Summary

- *De novo* is a classification procedure that allows novel, innovative devices to be legally marketed.
- A granted *de novo* creates a new classification regulation (new device type) and authorizes marketing of your device.
- The content of your *de novo* request will determine if sufficient information exists to classify your device into Class I or Class II.
- Use the Pre-submission process and public domain information to develop your *de novo* request.

# Questions

Please complete the session survey:

[surveymonkey.com/r/DEV-D1S6](https://surveymonkey.com/r/DEV-D1S6)

# Call to Action

- The *de novo* pathway may be a way to get novel and innovative medical devices onto the market faster.
- Decide whether your device is suitable for this program and take advantage of it!

