



Welcome to today's FDA/CDRH Webinar

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

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Conference Number: PW3106674



**REGULATORY OVERVIEW FOR
DEVELOPERS AND SPONSORS OF
NEUROLOGICAL DEVICES:**
An Introduction to the De Novo Pathway

**Wednesday, March 22, 2017
1:00PM-2:30PM**

What We'll Discuss Today

- Introduction to the Review of Neurological Devices under the De Novo Pathway
- Regulatory History of the De Novo Pathway
- Benefit Risk Analysis
- Case Study
- Expedited Access Pathway (EAP) Program
- Engaging with the FDA through the pre-submission process
- Closing Remarks



Introduction

Carlos Peña, PhD, MS

Director

Division of Neurological and Physical Medicine
Devices

Office of Device Evaluation

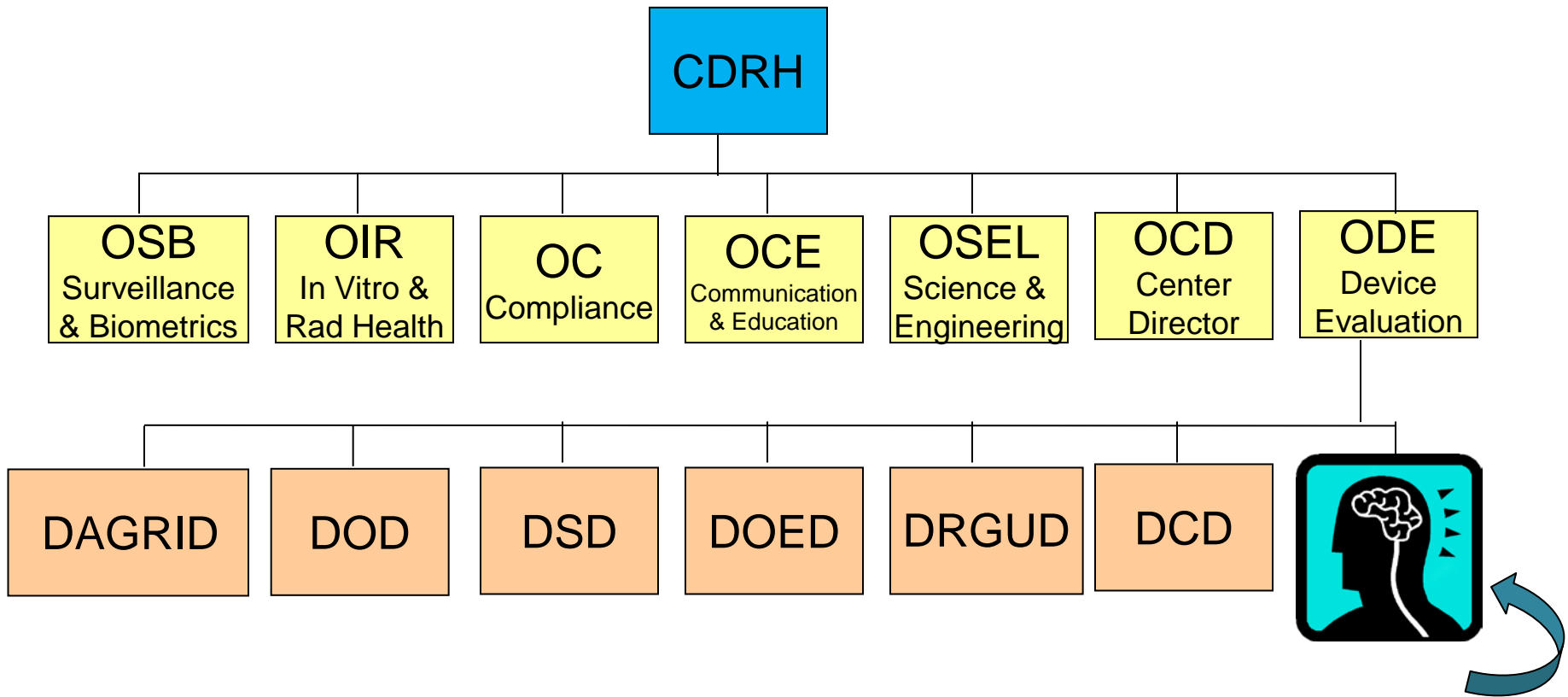
Center for Devices and Radiological Health



Investing in Review:

Neurological Device Division at the FDA

Center for Devices and Radiological Health (CDRH) Organization



Division of Neurological and Physical Medicine Devices



CDRH Vision

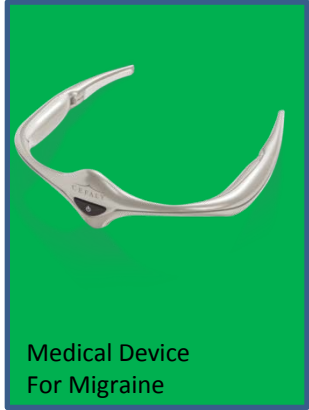
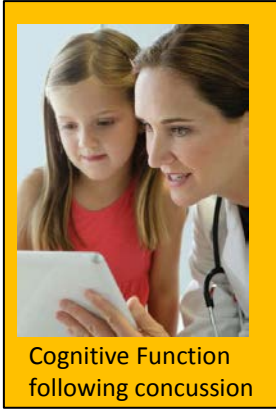
- Patients in the U.S. have access to high-quality, safe, and effective medical devices of public health importance first in the world.
- The U.S. is the world's leader in regulatory science, medical device innovation and manufacturing, and radiation-emitting product safety.
- U.S. post-market surveillance quickly identifies poorly performing devices, accurately characterizes real-world performance, and facilitates device approval or clearance.
- Devices are legally marketed in the U.S. and remain safe, effective, and of high-quality.
- Consumers, patients, their caregivers, and providers have access to understandable science-based information about medical devices and use this information to make health care decisions.

Medical Device Definition

Section 201(h) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 321) states, in part:

- “Device... means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is...”
- “...intended for use in the **diagnosis** of disease or other conditions, or in the **cure, mitigation, treatment, or prevention** of disease, in man...” or
- “...intended to affect the structure or any function of the body of man and which does not achieve any of its primary intended purposes through chemical action....”

Experience in Moving Neurological Medical Devices From **Bench to Market**



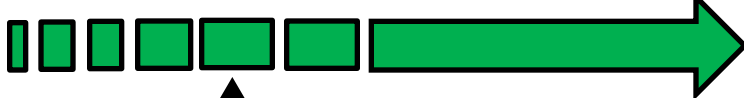
Regulatory Pathways for Medical Devices

Sponsors Apply to FDA to Market Device

FDA Decision Points

NonClinical & Clinical Study Phase

May occur over multiple years of development



Sponsors submit a presubmission to the FDA to start early regulatory discussions and develop a path forward

PreMarket Approval (PMA) Submission



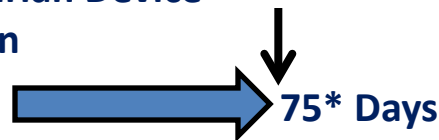
De Novo Submission



Premarket Notification 510(k)



Humanitarian Device Exemption



Stamp Legally Marketed in the United States

*Number of days noted is days the submission is under review by the FDA, not the total time that it may take to get the device technology to market or through the review process. In some cases, the review process may take longer depending upon the particular device, technology, indication for use, user, and risk of the device.

Classifications & Regulatory Pathways

- Class III: generally PMA (Premarket Approval)
- Class II: 510(k) (premarket notification), if the intended use and technology are similar to something already classified
- De Novo: devices that aren't comparable enough to something on the market. This generates a new device classification regulation, and will typically (but not always) be Class II
- Class I: Low risk, general controls are typically sufficient; generally exempt from 510(k)

Division of Neurological and Physical Medicine Devices

New Branch Organization

Neurodiagnostic and Neurosurgical Devices

- Cranial Materials & Other Sealants
- EEG & Non-EEG Diagnostic Devices
- Neurocognitive Diagnostic Devices
- Surgical Instruments & Tools for the Neurovasculature
- Stereotactic Systems for the Neurovasculature

Neurointerventional Devices

- Embolization Coils
- Flow Diverters
- Guidewires & Catheters for the Neurovasculature
- Neurothrombectomy Devices
- Neurovascular & Cerebral Interventional Devices
- Cerebrospinal Fluid Shunts

Neurostimulation Devices Neurology Branch

- Stimulation Devices for Movement Disorders, Epilepsy, Alzheimer’s Disease, Headache, and Traumatic Brain Injury
- Devices may include cortical stimulation devices and deep brain stimulation devices

Neurostimulation Devices Psychiatry Branch

- Stimulation Devices for Major Depression, Obsessive Compulsive Disorder, and Post Traumatic Stress Disorder
- Devices may include cranial electrical stimulation devices, electroconvulsive therapy, and transcranial magnetic stimulation devices

Physical Medicine & Rehabilitation Devices

- Brain Computer Interfaces
- Diathermy
- Functional Electrical Stimulators
- Iontophoresis Devices
- Massagers/Vibrators
- Orthoses, Exoskeletons
- Powered Muscle Stimulators
- Rehabilitation Equipment
- Wheelchairs, Walkers



De Novo Policy and Regulatory History

Michael Hoffmann, MS
Regulatory Deputy Director
Division of Neurological and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

What is a De Novo?

A classification process:

- Using a risk-based strategy
- For new, novel devices automatically classified into Class III
- Request for classification into Class I or II

What is a De Novo? Cont...

A classification process:

- An application sent by the medical device Sponsor to the FDA
- If granted:
 - Establishes new “device type” along with classification, regulation, necessary controls and product code
 - Device is eligible to serve as a predicate for new medical devices, where appropriate (via the 510K process)



FD&C Act – Modified in 1997

Food and Drug Modernization Act (FDAMA)

Section 513(f)(2): established De Novo classification process

- Also known as “Evaluation of Automatic Class III Designation”
- Provided regulatory authority for the FDA to classify devices that were automatically classified into Class III per Section (f)(1) (new devices)
- To Class I or II using criteria of Section 513(a)(1)(A-B)

Excludes devices which fit into an existing classification regulation.

De Novo Process, 1997

Steps:

- Sponsor submits premarket notification (510(k))
- The FDA issues “not substantially equivalent” (NSE) decision due to lack of viable predicate, new intended use, or different technological questions
- Sponsor submits De Novo request within 30 days
- The FDA decides whether to classify device from Class III to Class I or II with new classification regulation

FD&C Act – Further Modified in 2012 Food and Drug Administration Safety and Innovation Act (FDASIA)

Section 513(f)(2) – De Novo provision

What changed:

- Submission of a 510(k) prior to De Novo no longer required
- Timeframe for review set at 120 FDA days
- Goal: Streamline and increase efficiency in process

FD&C Act – Further Modified in 2012 Food and Drug Administration Safety and Innovation Act (FDASIA)

Section 513(f)(2) – De Novo provision

FDASIA allows two pathways:

- Post-NSE De Novo (original process)
- Direct De Novo (revised process)
- Almost all De Novos are direct
- Intent and decision-making threshold for De Novo unchanged

Suggested Information

- **Regulatory History**

- Prior submissions to the FDA for same device
- Prior 510(k)s and related NSE decisions
- Investigational Device Exemptions (IDEs)
- Pre-submissions (Pre-Subs)
- Previously withdrawn/declined De Novos

Suggested Information

- **Device Information and Summary**
 - Device name
 - Device description
 - Intended use/indications for use statement
 - Technological characteristics
- **Device Labeling (directions for use)**

Suggested Information

- **Classification Summary**
 - Review of FDA classification regulations, product codes, and approved PMAs
 - In other words, confirmation that this is a “new device”
- **Recommended Classification**
 - Class (i.e., either Class I or II)
 - Justification for recommended classification and controls

Suggested Information

- **Proposed Special Controls**
 - Applicable to Class II devices ONLY

- **Supportive Evidence**
 - Methods, data, results
 - Testing to include: non-clinical, animal, clinical, where appropriate
 - Correlation between evidence and classification recommendation

Suggested Information

- **Summary of Probable Benefits**
- **Summary of Known/Probable Risks to Health**
- **Risk and Mitigation Information**
 - Discussion of each risk, mitigation measure, and evidence
- **Benefit-Risk Considerations**
 - Discuss how benefits, with recommended general/special controls, outweigh risks

Benefit Risk Determinations

Leigh Anderson
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Center for Devices and Radiological Health

Guidance for Industry and Food and Drug Administration Staff

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

Document issued on August 24, 2016.

The draft of this document was issued on August 15, 2011.

As of October 23, 2016, this document supersedes
“Factors to Consider When Making Benefit-Risk
Determinations in Medical Device Premarket Approvals
and De Novo Classifications” dated March 28, 2012.

<http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm517504.pdf>

Benefit-Risk Determinations

- Balance considerations of **probable benefits** and **probable risks** as part of determination of a **reasonable assurance of safety and effectiveness** for the device for its intended use
- Both clinical and non-clinical data can play a role in benefit-risk determinations
- Probable risks and probable benefits supported by valid scientific evidence

Benefit-Risk Determinations

- A **reasonable assurance of safety** occurs when “it can be determined, based upon valid scientific evidence, that the probable benefits ... outweigh any probable risks,” and can be demonstrated by establishing “the absence of unreasonable risk of illness or injury associated with the use of the device for its intended uses and conditions of use.” (21 CFR 860.7(d)(1)).
- A **reasonable assurance of effectiveness** occurs when “it can be determined, based upon valid scientific evidence ... the use of the device for its intended uses ... will provide clinically significant results.” (21 CFR 860.7(e)(1)). The evidence of which is demonstrated principally through “well-controlled investigations” (see 21 CFR 860.7(e)(2)), as defined in 21 CFR 860.7(f).

Benefit-Risk Determinations

- **Valid scientific evidence:** “evidence from well-controlled investigations, partially controlled studies, studies and objective trials without matched controls, well-documented case histories conducted by qualified experts, and reports of significant human experience with a marketed device, from which it can fairly and responsibly be concluded by qualified experts that there is reasonable assurance of the safety and effectiveness of a device under its conditions of use.” (21 CFR 860.7(c)(2)).

Benefit-Risk: Factors the FDA Considers

Benefits	Risks
<p>Extent of the probable benefit(s):</p> <ul style="list-style-type: none"> • Type of benefit(s) • Magnitude of the benefit(s) • Probability of the patient experiencing one or more benefit(s) • Duration of effect(s) 	<p>Extent of the probable risk(s)/harm(s):</p> <ul style="list-style-type: none"> • Severity, types, number and rates of harmful events associated with the use of the device <ul style="list-style-type: none"> - Device related serious adverse events - Device related non-serious adverse events - Procedure related complications • Probability of a harmful event • Duration of harmful events • Risk from false-positive or false-negative results for diagnostics

Benefit Considerations

Factors	Questions to Consider?
Type of benefit	<ul style="list-style-type: none"> • What primary endpoints, key secondary or surrogate endpoints were evaluated? • What value do patients place on the benefit?
Magnitude of the benefit(s)	<ul style="list-style-type: none"> • What was the magnitude of each treatment effect (based on primary, secondary or surrogate endpoints)? • How did the benefit rank on the scale used to measure benefit?
Probability of the patient experiencing one or more benefit(s)	<ul style="list-style-type: none"> • Was the study able to predict which patients will experience a benefit? • What is the probability that a patient for whom the device is intended will experience a benefit? • How did the benefits evaluated vary across sub-populations? • Was there a variation in public health benefit for different populations? • Even if the benefit is in a small portion of the population, do those patients who would experience the benefit value it?
Duration of effect(s)	<ul style="list-style-type: none"> • Could the duration, if relevant, of each treatment effect, including primary and secondary endpoints be determined? If so, what was it? • Is the duration of the benefit achieved of value to patients?

Risk Considerations

Factors	Questions to Consider?
Severity, types, number and rates of harmful events	<ul style="list-style-type: none"> • What are the device related serious adverse events? • What are the device related non-serious adverse events? • What are other procedure related complications?
Probability of a harmful event	<ul style="list-style-type: none"> • What percent of the intended patient population would expect to experience a harmful event? • What is the incidence of each harmful event in the study population? • How much uncertainty is in that estimate? • How does the incidence of harmful events vary by sub-population (if applicable)? • Are patients willing to accept the probable risk of the harmful event, given the probable benefits of the device?
Duration of harmful events	<ul style="list-style-type: none"> • How long does the harmful event last? • Is the harmful event reversible? • What type of intervention is required to address the harmful event?
Risks from false-positive or false-negative results for diagnostics	<ul style="list-style-type: none"> • What are consequences of a false-positive, or false-negative? • Is this the only means of diagnosing the problem, or is it part of an overall diagnostic plan?

Benefit-Risk: Additional Factors

- **Uncertainty**
- Patient-centric assessments and patient-reported outcomes (PROs)
- Characterization of the disease
- Patient perspectives
- Availability of alternative treatments or diagnostics
- Risk mitigation
- Post-market data
- Novel technology addressing unmet medical need

De Novo Hypothetical Case Study

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Office of Device Evaluation
Center for Devices and Radiological Health

Hypothetical Case Study

“Using the De Novo Process to Classify and Bring to Market an Innovative, Low-to-Moderate Risk Device”

<https://www.fda.gov/downloads/Training/CourseMaterialsforEducators/NationalMedicalDeviceCurriculum/UCM437250.pdf>

CDRH Learn: FDA Case Study – March, 2015

Step 1

Define Technology and Intended Use

“DailyStim” Device

- **Technology:**
Transcranial Magnetic Stimulator (TMS) - Portable, AC powered, externally delivers directed brief duration, pulsed, magnetic fields to induce electric currents in specific brain regions.
- **Intended Use:**
Adjunctive therapy to aid in reducing the symptoms of advanced levodopa-responsive Parkinson’s disease that are not adequately controlled with medication.

Step 2

Is the DailyStim a medical device?

[201(h) of the FD&C Act (21 U.S.C. 321)]

- “...an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is...”
- “...intended for use in the **diagnosis** of disease or other conditions, or in the **cure, mitigation, treatment, or prevention** of disease, in man...” or
- “...intended to affect the structure or any function of the body of man and which does not achieve any of its primary intended purposes through chemical action....”

Step 3

Are there similar devices already being legally marketed?

- Is there a predicate Class II or Class I device?
- Is there a similar Class III PMA device?

FDA website “Classify Your Medical Device”:

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/default.htm>

[FDA Home](#)³ [Medical Devices](#)⁴ [Databases](#)⁵

Product Classification

This database includes:

- a list of all medical devices with their associated classifications, product codes, FDA premarket review organizations, and other regulatory information.

[Learn More...](#)⁶

Search Database

 [Help](#)⁷  [Download Files](#)¹⁰

Device	<input type="text" value="transcranial"/>	Product Code	<input type="text"/>
Review Panel	<input type="text" value=""/>	Regulation Number	<input type="text"/>
SubmissionType	<input type="text" value=""/>	Third Party Eligible	<input type="text" value=""/>
Implanted Device	<input type="text" value=""/> Life-Sustain/Support Device <input type="text" value=""/>	Device Class	<input type="text" value=""/>
Go to Quick Search ¹¹		Clear Form	<input type="button" value="Search"/>

Need information about classifying your device?

[Device Classification](#)³²

Other Databases

- [510\(k\)s](#)¹²
- [De Novo](#)¹³
- [Medical Device Reports \(MAUDE\)](#)¹⁴
- [CDRH Export Certificate Validation \(CECV\)](#)¹⁵
- [CDRH FOIA Electronic Reading Room](#)¹⁶
- [CFR Title 21](#)¹⁷
- [CLIA](#)¹⁸
- [FDA Guidance Documents](#)¹⁹
- [Humanitarian Device Exemption](#)²⁰
- [Medsun Reports](#)²¹
- [Premarket Approvals \(PMAs\)](#)²²
- [Post-Approval Studies](#)²³
- [Postmarket Surveillance Studies](#)²⁴
- [Radiation-Emitting Products](#)²⁵
- [Radiation-Emitting Electronic Products Corrective Actions](#)²⁶
- [Recalls](#)²⁷
- [Registration & Listing](#)²⁸
- [Standards](#)²⁹
- [Total Product Life Cycle](#)³⁰
- [X-Ray Assembler](#)³¹



Product Code	Device	Regulation Number	Device Class
OBP	Transcranial Magnetic Stimulator	882.5805	2
OKP	Transcranial Magnetic Stimulator For The Treatment...	882.5808	2

Device Classification Name	Transcranial Magnetic Stimulator For The Treatment Of Migraine Headache ²²
De Novo Number	DEN130022
510(K) Number	K130556
Device Name	NEURALIEVE CERENA TRANSCRANIAL MAGNETIC STIMULATOR
Requester	ENEURA THERAPEUTICS 2690 Pheasant Road Orono, MN 55331
Contact	Larry Getlin
Regulation Number	882.5808 ²³
Classification Product Code	OKP ²⁴
Date Received	03/05/2013
Decision Date	12/13/2013
Decision	Granted (DENG)
Classification Advisory Committee	Neurology
Review Advisory Committee	Neurology
Reclassification Order	Reclassification Order ²⁵
FDA Review Type	Decision Summary ²⁶ Direct

Is a Non-Invasive Stimulation Device an Appropriate Predicate Device?

- Decision 1: Is there a legally marketed similar device?
- Decision 2: Does the DailyStim have the same intended use?
- Decision 3: Does the DailyStim have the same technological characteristics?
- Decision 4: Do the different technological characteristics raise different questions of safety and effectiveness?

*Also see Fig. 1 of FDA Case Study or 510(k) Guidance Document: “The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notification [510(k)]”

Is DailyStim Similar to the Invasive Devices?

- Intended Use: Similar
- Technology: Is there a key difference?

Yes, the DailyStim applies stimulation externally as compared to implanted devices

Step 4

Assess the risk of the device?

Can general controls or a combination of general and special controls ensure a reasonable assurance of safety and effectiveness?

Step 5

Obtain FDA Feedback?

[Optional and recommended]

- Section 513(g) of the FD&C Act [21 U.S.C. 360c(g)]
- Pre-submission (informal feedback on specific questions)

Neither of these submissions represent final FDA decisions.



Step 6

Submit the De Novo to the FDA

- The FDA performs its own classification review
- FDA Substantive Review

What happens after a De Novo is granted?

- New device is legally marketed - Subject to post-market requirements applicable to that device and class (including general controls, special controls as applicable)
- New device establishes new classification regulation – The FDA publishes order in the Federal Register which results in codification of the device’s identification, classification and applicable requirements (including general and special controls)
- New device is eligible to serve as a predicate device
- The FDA generates decision summary that is publicly available on the CDRH website

Expedited Access Pathway “EAP Program”

LCDR Avena Russell, MS
Assistant Director of Program Operations
Division of Neurological and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

What is the Expedited Access Pathway?

- A voluntary program
- Program participation is at the request of the sponsor through the pre-submission process
- Eligibility is for certain medical devices
- Must meet defined criteria
- Subject to premarket approval application (PMAs), De Novo requests and 510K submissions

EAP Program Eligibility Criteria

1. Provide for more effective treatment or diagnosis of life-threatening or irreversibly-debilitating human disease or conditions.

EAP Program Eligibility Criteria, cont.

2. The device meets at least one of the following criteria:

- Represent breakthrough technologies;
- No approved or cleared alternatives exist;
- Offer clinically meaningful advantages over existing approved or cleared alternatives, including the potential, when compared to existing approved alternatives, to reduce or eliminate the need for hospitalization, improve patient quality of life, facilitate patients' ability to manage their own care (such as through self-directed personal assistance), or establish long-term clinical efficiencies; or
- The availability of which is in the best interest of patients.



EAP Program Eligibility Criteria, cont.

3. Submission of a draft data development plan is no longer required for EAP designation, but is optional for sponsors who have received designation.

Features of the Expedited Access Pathway

- Sponsor will receive a grant, deny or additional information requested letter within 30 days; a final decision of grant or deny will be made within 60 days.
 - An EAP designation offers the following:
 - Increased interactive review
 - Senior management involvement
 - Case manager
 - Priority review

PRE-SUBMISSION BEST PRACTICES

Patrick Antkowiak

Biomedical Engineer

Neurodiagnostic and Neurosurgical Devices Branch
Division of Neurological and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Pre-Submission Guidance

- “Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff”:

<http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm311176.pdf>

- The guidance covers multiple types of interactions, but this webinar focuses on the “Pre-Submission”

Timeframe for Review

- Per the guidance, the FDA strives to hold a meeting (if requested) within 75-90 days of acknowledged receipt
 - If you request a meeting, we will provide written feedback about 3 days in advance of the scheduled date of the meeting
- Feedback is typically provided 75-90 days after receipt of a submission
- If a meeting is requested, they typically last approximately 1 hour and should be planned accordingly

Why Engage As Early As You Can?

- Pre-submission interactions allow potential issues to be identified earlier, and we can work through them with you as appropriate
 - Particularly useful if there are concerns related to novel technology, testing, or the need for a clinical study
- If needed, you can submit a supplement to get additional feedback

Common Issues: eCopy

- Make sure you comply with the eCopy guidance
 - <http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm313794.pdf>
- Your submission will NOT be officially logged in, the review clock will not start until FDA received a valid eCopy
- Questions: cdRH-eCopyinfo@fda.hhs.gov

Submission Contents

- Cover Letter
- Background information, which can include:
 - Device description
 - Intended Use
 - Bench/animal testing protocols
 - Clinical study protocols
- Specific Questions
- Submission should NOT contain data

Submission Contents

- Additional information for Pre-Submissions regarding potential future De Novo submissions
 - Proposed Class (I or II)
 - Discussion of relevant existing regulations
 - Risk analysis
 - Proposed special controls

Common Issues: Not Enough Information Provided Upfront

- We recommend you first identify the proposed intended use and key aspects of the device design before submission
- Lack of Device Description information, especially for devices we have not previously reviewed under 510(k), may hinder meaningful discussion
- We encounter similar issues across other submission types

How This Impacts the Review Process

Without enough information to understand the device, CDRH ends up asking a lot of questions. Providing complete responses to our questions takes time, and extends the overall length of the review.

What You Can Do

- Remember, **YOU** as the applicant know the most about your device technology, not the FDA
- The more you can explain your thought processes when submitting a pre-submission, the more we can focus on the substance and give you better feedback

Understand the Existing Landscape

- Search for and review applicable guidance documents and standards (if there are any), such as:
 - Biocompatibility, if your device is patient contacting (ISO 10993)
 - “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices”
- Explain the relationship of what you’re proposing compared to what’s been done for similar devices

Best Practices: Background Information

- It's OK to err on the side of including what you think may be more information than we would need
 - Make sure it's organized and easy to follow
- If you cite literature articles, please provide copies in the submission
- There is such a thing as too much information. We don't need:
 - Circuit diagrams
 - Lines of software code
 - A copy of your entire grant

Best Practices: Background Information

- Avoid assumptions:
 - Unless there is an applicable guidance, standard, or other regulatory precedent you can cite, identify the most appropriate approach for **YOUR** needs and justify it
 - Example: not every animal study needs to use a non-human primate model. Some other model and protocol may be better suited to your particular situation

Common Issue: “Specific” Questions

- Not providing your own proposal for us to review:
 - “What animal model should we use?”
 - “What should our clinical control group be?”
- Wanting the FDA to review data:
 - “Does the FDA have any comments on the nonclinical test results?”

Best Practices: Specific Questions

- The questions should build on the background information you have provided
 - Good question: “What concerns do you have with our proposed animal model?”
 - Good question: “Is the selected control group in our proposed clinical trial appropriate?”

Best Practices: Specific Questions for a De Novo

- “Based on the information provided (device description, intended use, predicate analysis), does FDA agree that my device is eligible for a De Novo submission?”
- “Does FDA believe that there are risks, other than the ones we have identified, that must be mitigated?”
- “Are there other special controls that should be considered to provide a reasonable assurance of safety and effectiveness?”

Closing Remarks

Pre-Submissions

WHAT: an opportunity to obtain **FDA feedback** prior to IDE or marketing submission

Guidance Document

“Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff”

(Issued February 18, 2014)

Neuron

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www.cell.com

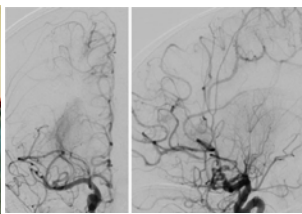


NeuroView FDA Regulation of Neurological and Physical Medicine Devices: Access to Safe and Effective Neurotechnologies for All Americans

Neuron. 2016 Dec 7;92(5):943-948. doi:
10.1016/j.neuron.2016.10.036.

**NEW FDA website for
Neurological Devices:**
<http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/NeurologicalDevices/default.htm>

It's About the Patients



Questions?

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 the Heading: How to Study and Market Your Device

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.