



# **Housekeeping and Logistics**



# Regulatory Perspectives on External Electromagnetic Neurostimulation Devices Intended to Improve Normal Cognitive Function in Healthy Individuals

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# Outline

- Organizational Overview
  - » CDRH, ODE
- Relevant Definitions
  - » Medical Device and Device Classifications
- Submission Content
  - » Clinical data, OTC use
- Resources



# Organizational Overview: CDRH

## CDRH OFFICES

Office of  
Management  
Operations

Office of  
Surveillance and  
Biometrics

Office of  
Compliance

Office of In Vitro  
Diagnostics and  
Radiological Health

Office of  
Science and  
Engineering  
Laboratories

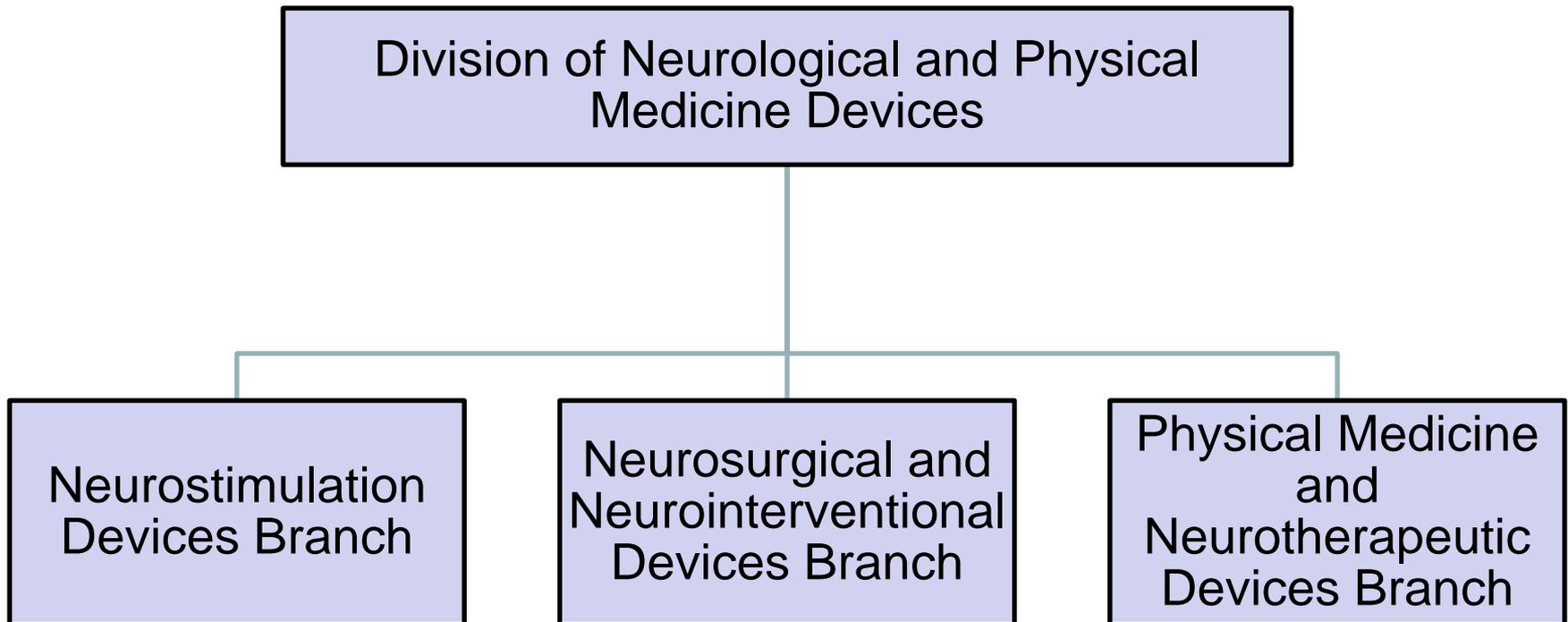
Office of Device  
Evaluation

Office of the  
Center Director

Office of  
Communication,  
Education, and  
Research



# Organizational Overview: ODE/DNPMD





## **Today's Topic:**

**External Electromagnetic  
Neurostimulation Devices Intended  
to Improve Normal Cognitive  
Function in Healthy Individuals**

# What Does This Mean?

- **Non-invasive:** does not penetrate or pierce either the skin or mucous membranes of the body
- **Electromagnetic:** some form of stimulation that is not mechanical, visible light, etc.
- **Neurostimulation:** applied to the head



# How Do We Best Define:

- “Improve Normal Cognitive Function”?
- “Healthy Individuals”?

# Definition of a Medical Device

- According to Section 201(h) of the Food, Drug, and Cosmetic Act, devices are things that are
  - » “...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....”

# What About Non-Therapeutic and Non-Diagnostic products?

- If your product is non-therapeutic and non-diagnostic, it may still “affect the structure or function of the body,” and we may regulate it as a medical device.
  - » Example: Powered Muscle Stimulators for Muscle Conditioning. “Unlike the classified powered muscle stimulator devices intended for use in physical medicine and rehabilitation, this device is not intended for use in patients with medical conditions and is intended only for muscle conditioning purposes.”  
(<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=4808>)
  - » Whether or not we will regulate something in this situation will depend on numerous factors
- If you have questions about whether your product is a medical device, you can talk to the Device Determination Group:  
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/ucm051521.htm>



# Device Classifications (21 CFR 806.3)

- Based on the level of regulatory control needed to provide a reasonable assurance of safety and effectiveness
  - » Class I: subject to only the general controls authorized by the FD&C Act (e.g., toothbrushes)
  - » Class II: general controls alone are insufficient to provide reasonable assurance of its safety and effectiveness, and there is sufficient information to establish special controls (e.g., transcranial magnetic stimulation)
  - » Class III: general controls alone are insufficient, and not enough information to establish special controls (e.g., deep brain stimulation)

# Determining Device Classification

- Do any of the following apply?
  - » “Life-supporting or life sustaining”
  - » “For a use which is of substantial importance in preventing impairment of human health”
  - » “Presents a potential unreasonable risk of illness or injury”
  
- Do you have enough information to write special controls that will provide a “reasonable assurance of safety and effectiveness”?

# Regulatory Submissions

- Class III: generally PMA (Premarket Approval)
- Class II: 510(k) (or 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 regulation, and will typically (but not always) be Class II

# When is Clinical Data Needed?

- PMA: always needed
- De novo: typically needed, but not always
- 510(k): generally not needed

You can request feedback on any protocols through the pre-submission process, preferably before starting the study

## Over the Counter (OTC) Use

- Typically needs human factors/usability testing
  - » Can someone self-select as an appropriate user?
  - » Can they use the device properly?
- Not all devices may be appropriate for OTC use

# Benefit Risk Considerations

- Factors to Consider When Making Benefit-Risk Determinations in Medical Device Premarket Approvals and De Novo Classifications (<http://www.fda.gov/RegulatoryInformation/Guidances/ucm267829.htm>)
- What are the probable benefits? Type, magnitude, duration, etc.
- What are the probable risks? Type, severity, probability, duration, etc.
- Additional Factors, such as:
  - » Uncertainty
  - » Patient tolerance for risk and perspective on benefit
  - » Alternatives
  - » Etc.

# Don't be Afraid to Ask for Feedback Early!

- 513(g): “requests for information regarding the class in which a device has been classified or the requirements applicable to a device.”
  - » “Here’s my product; what is it and what type of submission does it need?”
- Pre-submission: “Here’s what we want to do in terms of (pre-)clinical testing; what do you think?”
- We’re here to help you navigate the process



# FDA Resources

- Device Advice:  
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>
- Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with FDA Staff:  
<http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm311176.pdf>
- FDA and Industry Procedures for Section 513(g) Requests for Information under the Federal Food, Drug, and Cosmetic Act:  
<http://www.fda.gov/RegulatoryInformation/Guidances/ucm209841.htm>
- Medical Device Databases:  
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm>



# Contact Information

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