Regulatory Perspectives on Non-Invasive Devices

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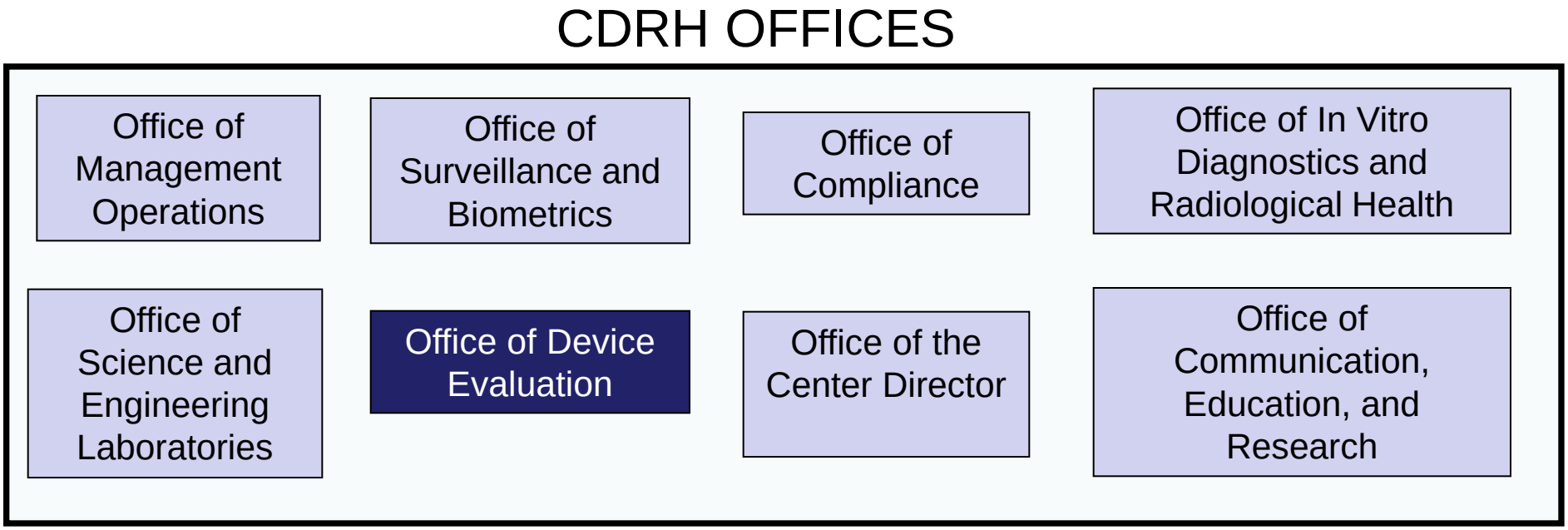
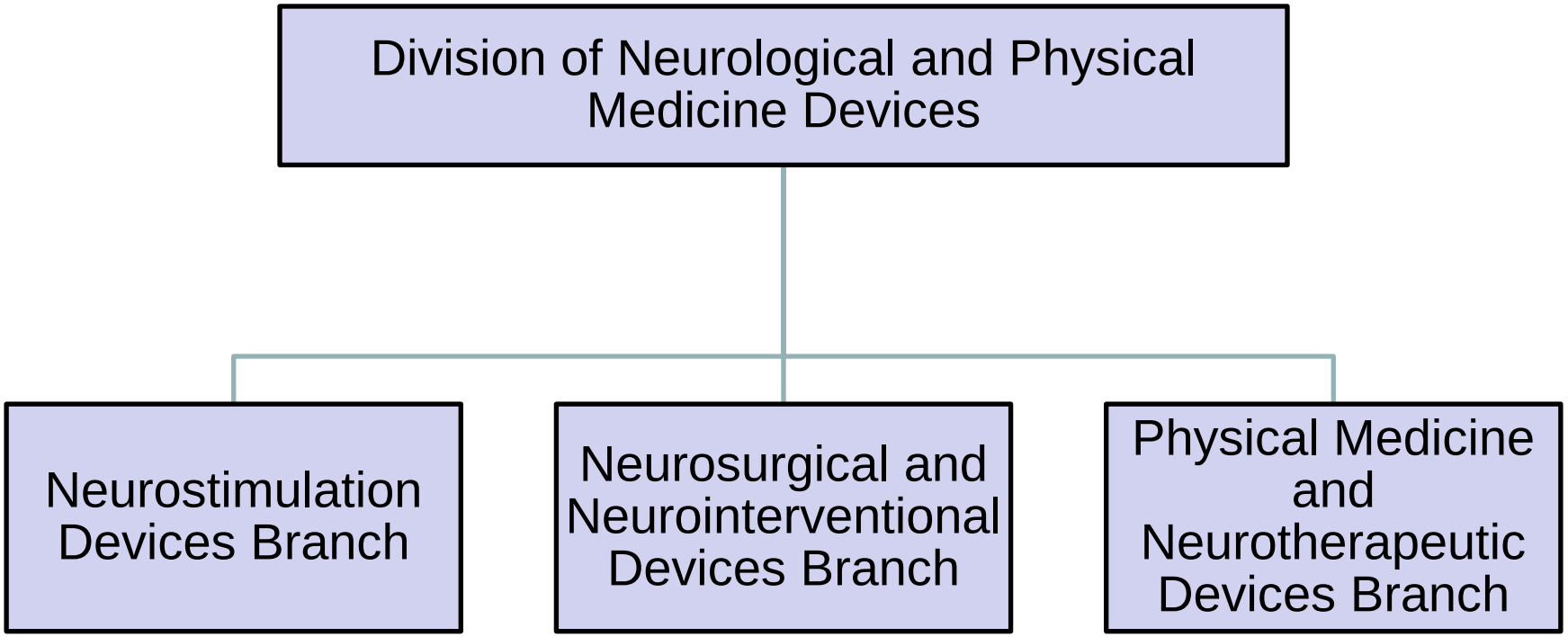
Outline

- Organizational Overview
  - » CDRH, ODE
- Relevant Definitions
  - » Medical Device and Device Classifications
  - » “General Wellness”
- Submission Content
  - » Clinical Data, OTC Use
- Resources

Organizational Overview: CDRH



Organizational Overview: ODE/DNPMD



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

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

"General Wellness"

- **Draft** Guidance issued January 20, 2015 http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm429674.pdf (Comment period through the end of April)

- For low-risk general wellness products, CDRH does not intend to determine:

  - whether they are devices within the meaning of the FD&C Act or,

  - if they are devices, whether they comply with the premarket review and post-market regulatory requirements for devices"

"General Wellness"

- General wellness products present a very low risk to users' safety and are for:
  - » "An intended use that relates to a maintaining or encouraging a general state of health or a healthy activity, or
  - » "An intended use claim that associates the role of healthy lifestyle with helping to reduce the risk or impact of certain chronic diseases or conditions and where it is well understood and accepted that healthy lifestyle choices may play an important role in health outcomes for the disease or condition."
- "A product's inclusion under this guidance does not establish that it has been shown to be safe, effective, and not misbranded for its intended use."

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)

Important Note About Implants

- Device classification is not determined solely by whether something is an implant
  - » Class III: Novocure (P100034) is a non-invasive device that applies low electric fields to the head to treat recurrent glioblastoma multiforme (GBM).
  - » Class II: The leads and can for RF-coupled spinal cord stimulation devices (for pain relief) are fully implanted.
- While non-invasive devices are generally not Class III, this will not always be true

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

Interaction with Other Regulatory Bodies / OUS (Outside the U.S.) Data

- Generally focuses on Agency initiatives, specific activities (e.g., nanotechnolgy), Standards
- Submissions specific reviews within FDA only
- OUS data can be used to support clearance or approval (21 CFR 814.15)
  - » If you plan to use OUS data to support approval, please discuss your approach with us.

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.

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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