



Presidential Commission for the Study of Bioethical Issues

A FDA Staff Perspective on Neurotechnology

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Devices

Food and Drug Administration

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FDA's Mission

Wheelchairs

NEURO-

DIAGNOSTICS

Medical Devices

Pharmaceuticals

Drug Delivery Systems

Food

exoskeletons

Applications

Dietary

Neurological Devices

Products that

Supplements

Walkers

deep brain stimulation

give off
radiation

Spinal Cord Stimulators

In Vitro Diagnostics

Biologics

Neurosurgical Instruments

Tobacco Products

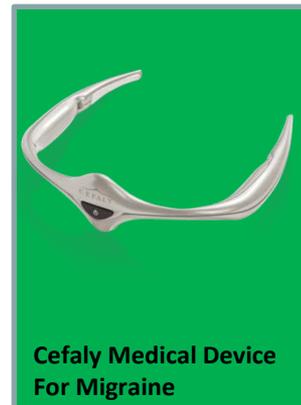
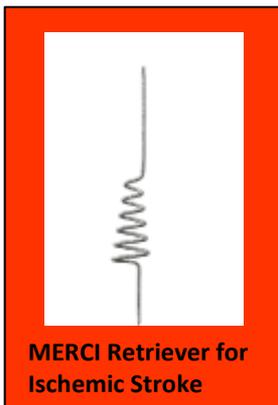
Cosmetics

Veterinary

Medicine

Brain Computer Interfaces

Experience in Moving Neurological Medical Devices From Bench to Market





Increasing Regulatory Transparency **for Developers and Innovators**

- Pre-Submission Guidance Document

<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM311176.pdf>

- IDEs for Early Feasibility Clinical Studies Guidance Document

<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM279103.pdf>

- Guidance Documents

<http://www.fda.gov/regulatoryinformation/guidances/>



Division of Neurological and Physical Medicine Devices

Neurostimulation Devices

Deep Brain Stimulators
Peripheral Nerve Stimulators
Spinal Cord Stimulators
Cranial Stimulators
Vagus Nerve Stimulators

Neurodiagnostic & Neurosurgical Devices

Surgical Instruments
Materials
Diagnostic Devices
Vascular Devices
Therapeutic Devices

Physical Medicine & Neurotherapeutic Devices

Brain Computer Interfaces
Functional Electrical
Stimulators
Exoskeletons
Wheelchairs
Walkers



What is a medical device?

An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article that

Diagnoses, cures, mitigates, treats or prevents a disease or condition, or

Affects the function or structure of the body, and

Does not achieve intended use through chemical action

Is not dependent upon being metabolized

Who makes medical devices?

- Generally: Any company or entrepreneurs who produces a medical device for sale in the US
 - » All manufactures must Register and List with the FDA

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/>

- » Includes small businesses and entrepreneurs
- » Regulatory consultants

A risk based approach for medical devices since 1976

Increasing Risk

Classification determines extent of regulatory control

(Risk Based)

Class I

- General Controls

Class II

- General controls
- Special controls

Class III

- General controls
- Premarket approval (PMA)

General Controls

- Electronic Establishment Registration
- Electronic Device Listing
- Quality Systems
- Labeling
- Medical Device Reporting (MDR)
- Premarket Notification [510(k)] (unless exempt)

Special Controls (addressing Risk)

- Guidelines (e.g., Glove Manual)
- Mandatory Performance Standard
- Performance testing, such as biocompatibility, engineering, animal, etc.
- Special Labeling



A Few Topics of Interest (When does FDA Regulate)

Direct to Consumer Devices



Division Priorities

Transparency

Predictability

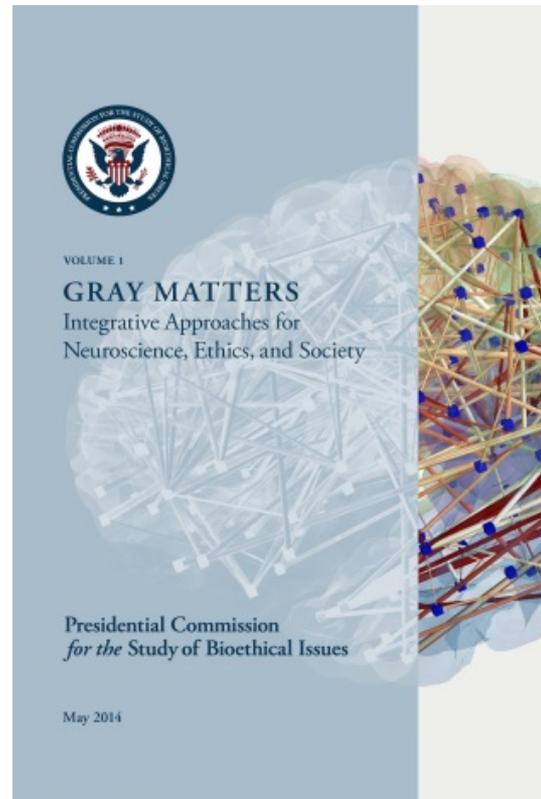
Efficiency

Coordination

Preparedness



Closing Thoughts



FDA Regulatory Review Resources

- FDA Home Page

<http://www.fda.gov/>

- CDRH Home Page

<http://www.fda.gov/MedicalDevices/>

- Division of Industry and Consumer Education (DICE) [Formerly Division of Small Manufacturers, International, and Consumer Assistance (DSMICA)] - *to ask general regulatory questions*

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ContactUs--DivisionofIndustryandConsumerEducation/default.htm>

- Overview of Device Regulation

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



Thank You

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