A Regulatory Staff Perspective on
Neuroscience Trials of the Future & Medical Devices

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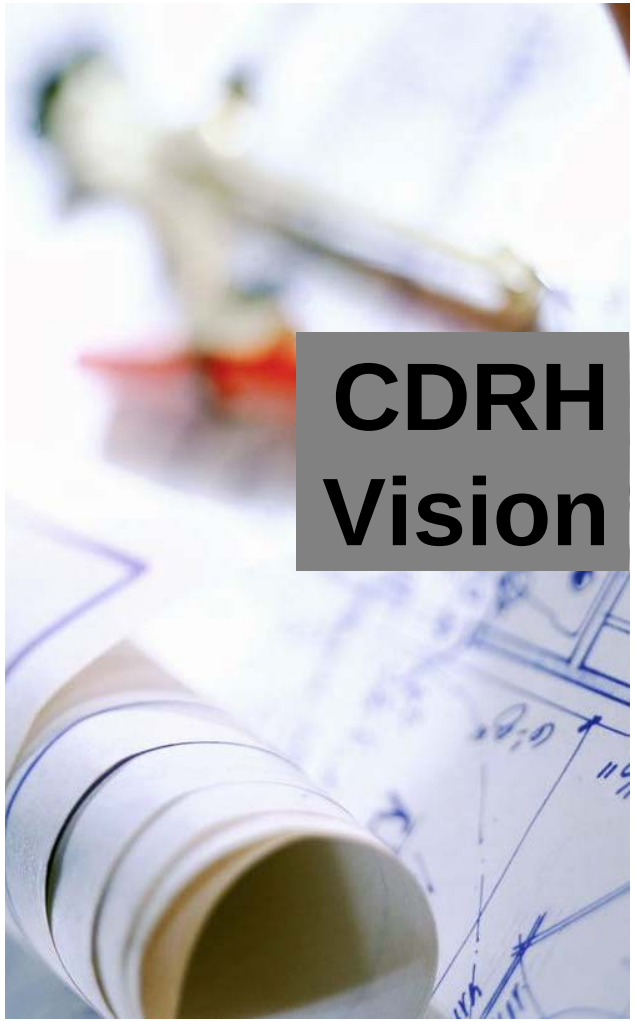


- **Patients in the U.S. have access to high-quality, safe, and effective medical devices of public health importance first in the world.**
- The U.S. is the world's leader in regulatory science, medical device innovation and manufacturing, and radiation-emitting product safety.
- U.S. post-market surveillance 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.

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

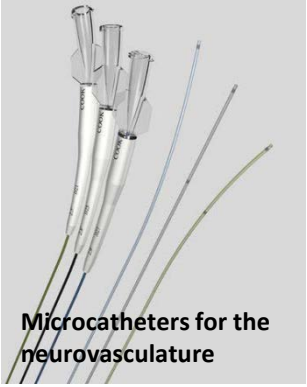
Clot Retriever for Ischemic Stroke

Epilepsy DBS

ADHD Neurodiagnostics

DEKA Prosthetic Arm

Cefaly Medical Device For Migraine



Microcatheters for the neurovasculature

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

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

Neurologic Device Trial Design
Points to Consider

- Balancing risks and benefits is important
- Outcome assessment measures:
  - » Validated measures
  - » Measures of functioning, psychological health, and level of disability
  - » Clearly defined parameters for what constitutes a clinically meaningful change
- Patient needs should be taken into account

Increasing Regulatory Transparency

NEW Targeted Guidance for Sponsors (+ Developers & Innovators)

- Pre-Submission Guidance Document
- IDEs for Early Feasibility Clinical Studies Guidance Document
- Design Considerations for Pivotal Clinical Investigations
- Expedited Access for Premarket Approval Medical Devices Intended for Unmet Medical Need for Life Threatening or Irreversibly Debilitating Diseases or Conditions
- Additional Guidance following…

Division of Neurological and Physical Medicine Devices

Organizational Structure

3 Branches

Neurostimulation Devices Branch

Cortical Stimulators
Deep Brain Stimulators
Peripheral Nerve Stimulators
Spinal Cord Stimulators
Vagus Nerve Stimulators
Other Cranial Stimulators
Cranial Electrotherapy Stimulators
Electroconvulsive Therapy
Transcranial Magnetic Stimulators
Transcutaneous Electrical Nerve Stimulators

Neurointerventional & Neurosurgical Devices Branch

Surgical Instruments & Tools
Cranial Materials & Other Sealants
Neurovascular and Cerebral Therapeutic Devices
Shunts
Stroke Treatments

Physical Medicine & Neurotherapeutic Devices Branch

Brain Computer Interfaces
Orthoses, Exoskeletons
Diathermy
Functional Electrical Stimulators
Iontophoresis Devices
Powered Muscle Stimulators
Massagers/Vibrators
Wheelchairs, Walkers
Patient Lifts

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"

(Document issued on February 18, 2014)

Closing Remarks

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