Introduction to FDA's Division of Neurological and Physical Medicine Devices

AANS Abbreviated Slide Deck Coming Soon

AANS FDA Session 2018

- 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

Ablation Therapy

Cognitive Function following concussion

Prosthetic Arm

Medical Device For Migraine

Microcatheters for the neurovasculature

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.…"

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)

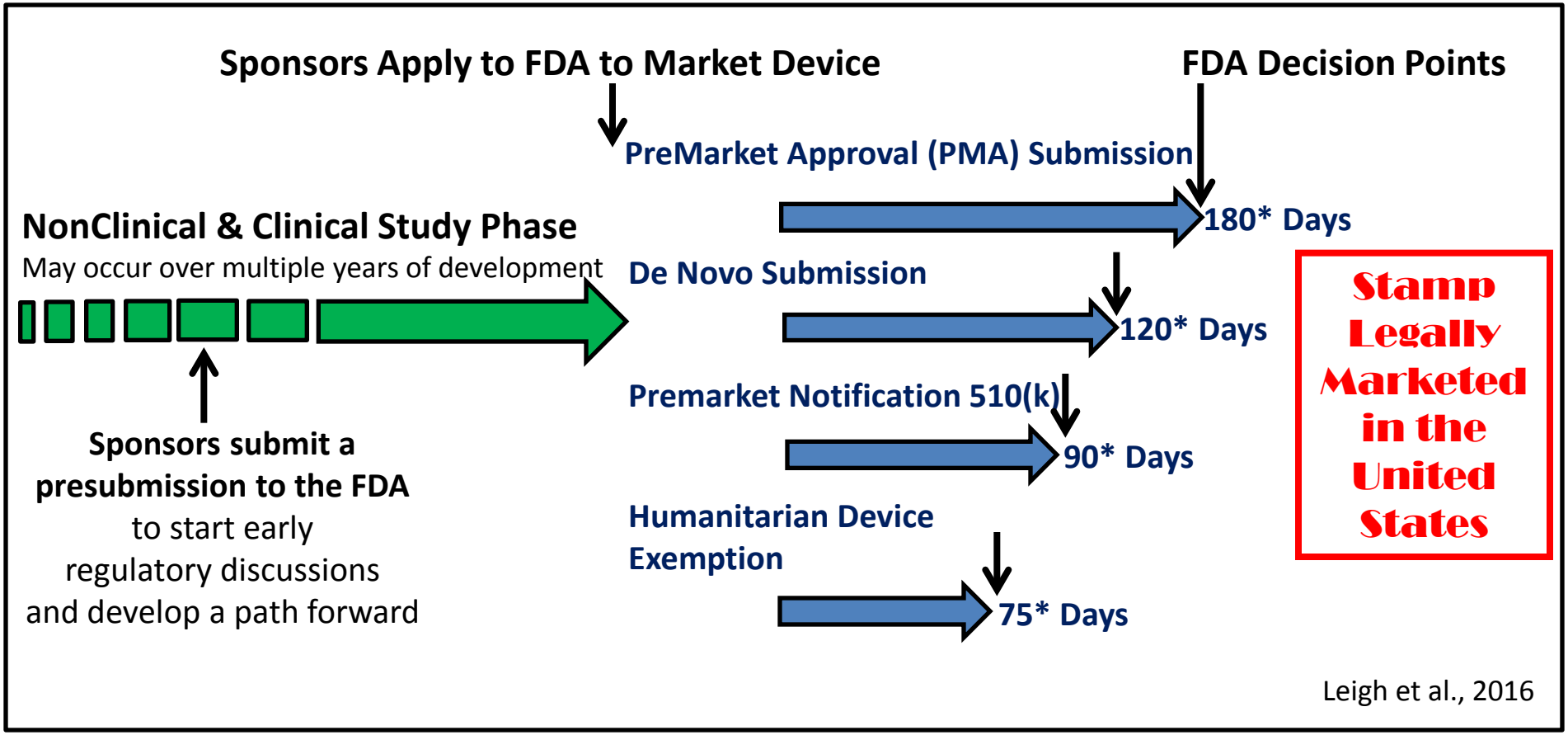
General Controls
- Electronic Establishment Registration
- Electronic Device Listing
- Quality Systems
- Labeling
- Medical Device Reporting (MDR)
- Premarket Notification [510(k)] (unless exempt)

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

Classifications & Regulatory Pathways

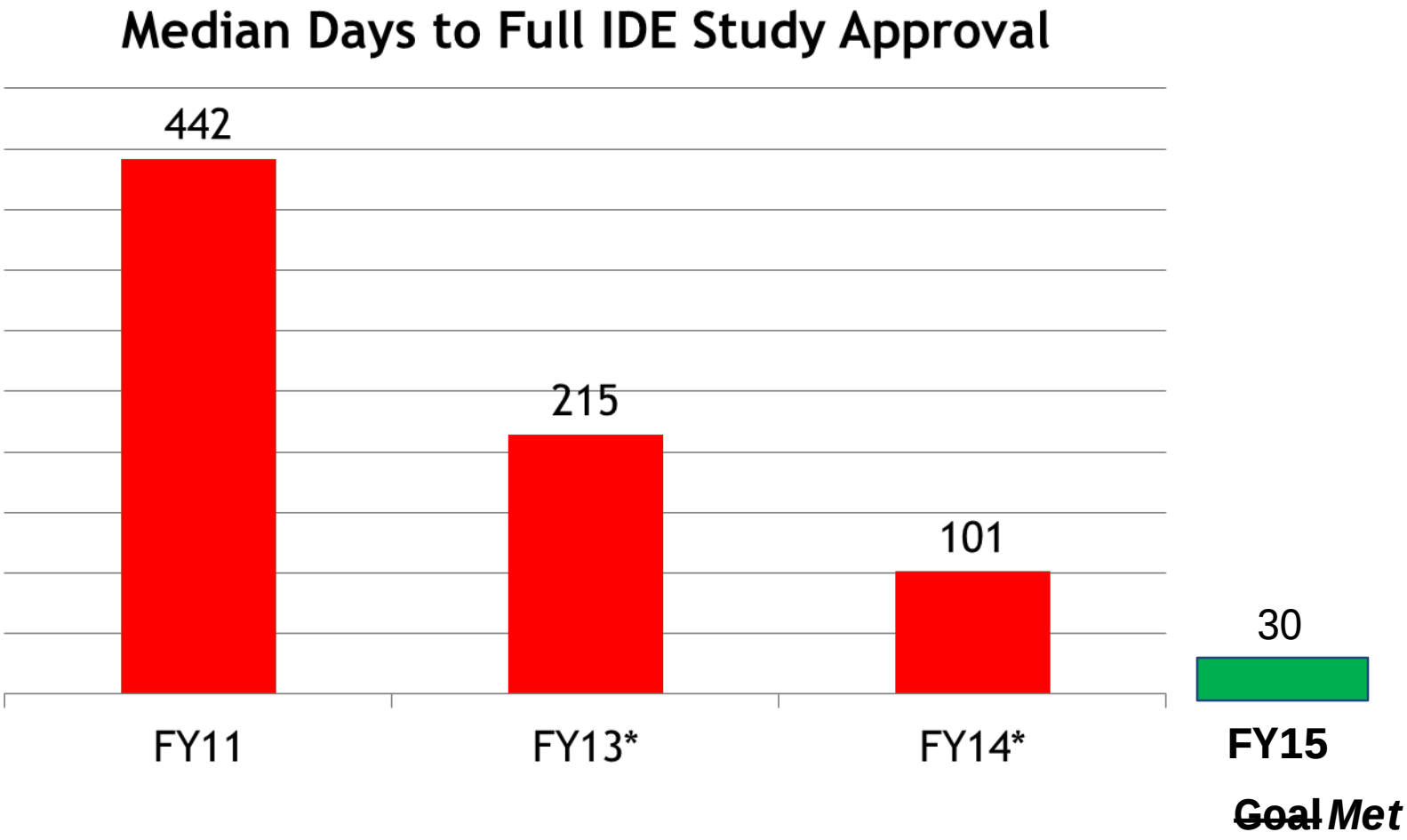
- Class III: generally PMA (Premarket Approval)
- Class II: 510(k) (premarket notification), if the intended use and technology are similar to something already classified
- De Novo: devices that aren't comparable enough to something on the market. This generates a new device classification regulation,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

Regulatory Pathways for Medical Devices



*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.

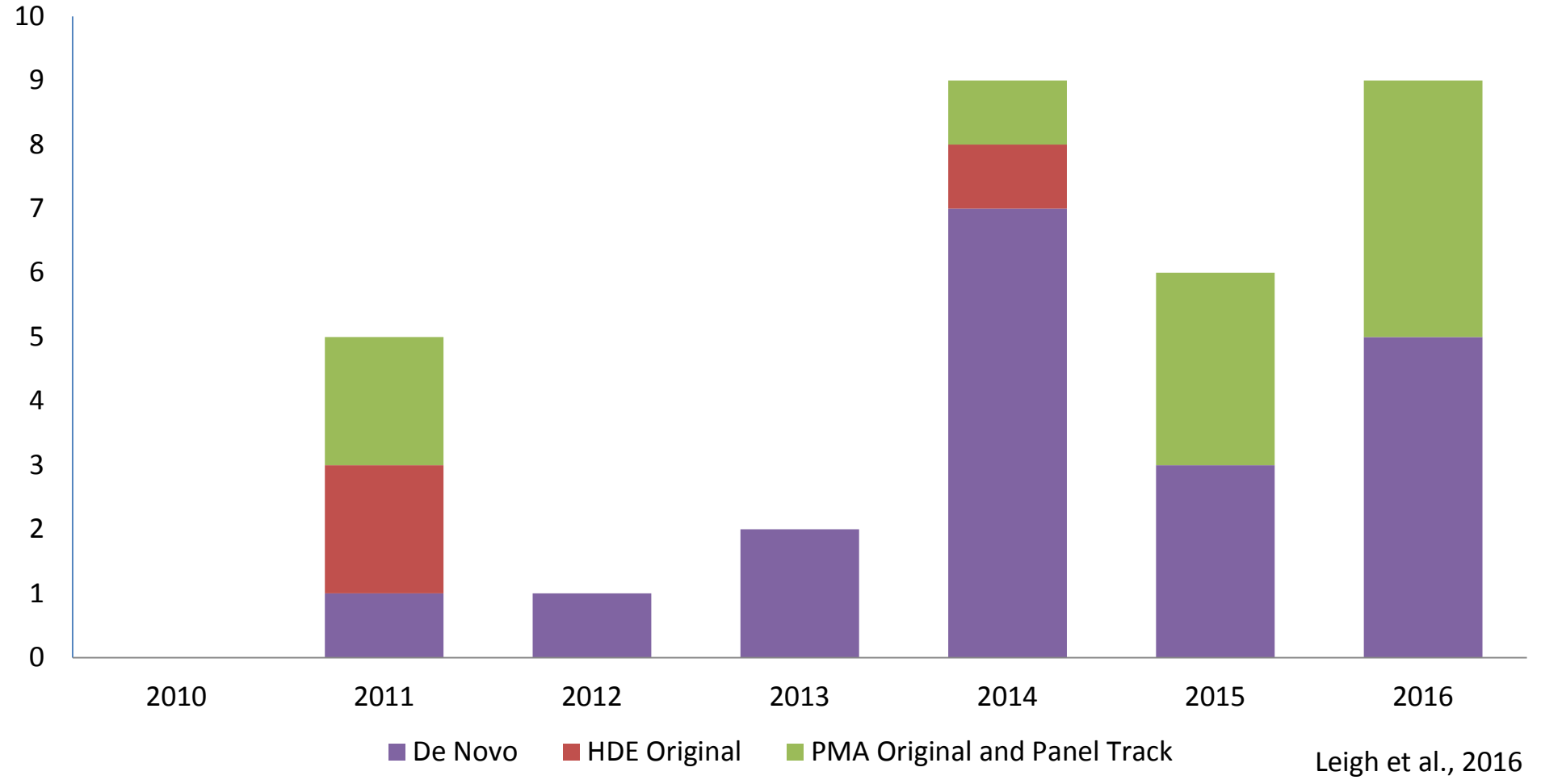
Reducing FDA Review Timelines



* Values calculated on 10/31/13 and 10/31/14 respectively

FDA U.S. FOOD & DRUG ADMINISTRATION

PMA Originals & Panel Tracks, Original HDEs, and De Novos FDA Activity



Leigh et al., 2016

Increasing Regulatory Transparency

NEW Targeted Guidance for Sponsors (and Developers & Innovators)

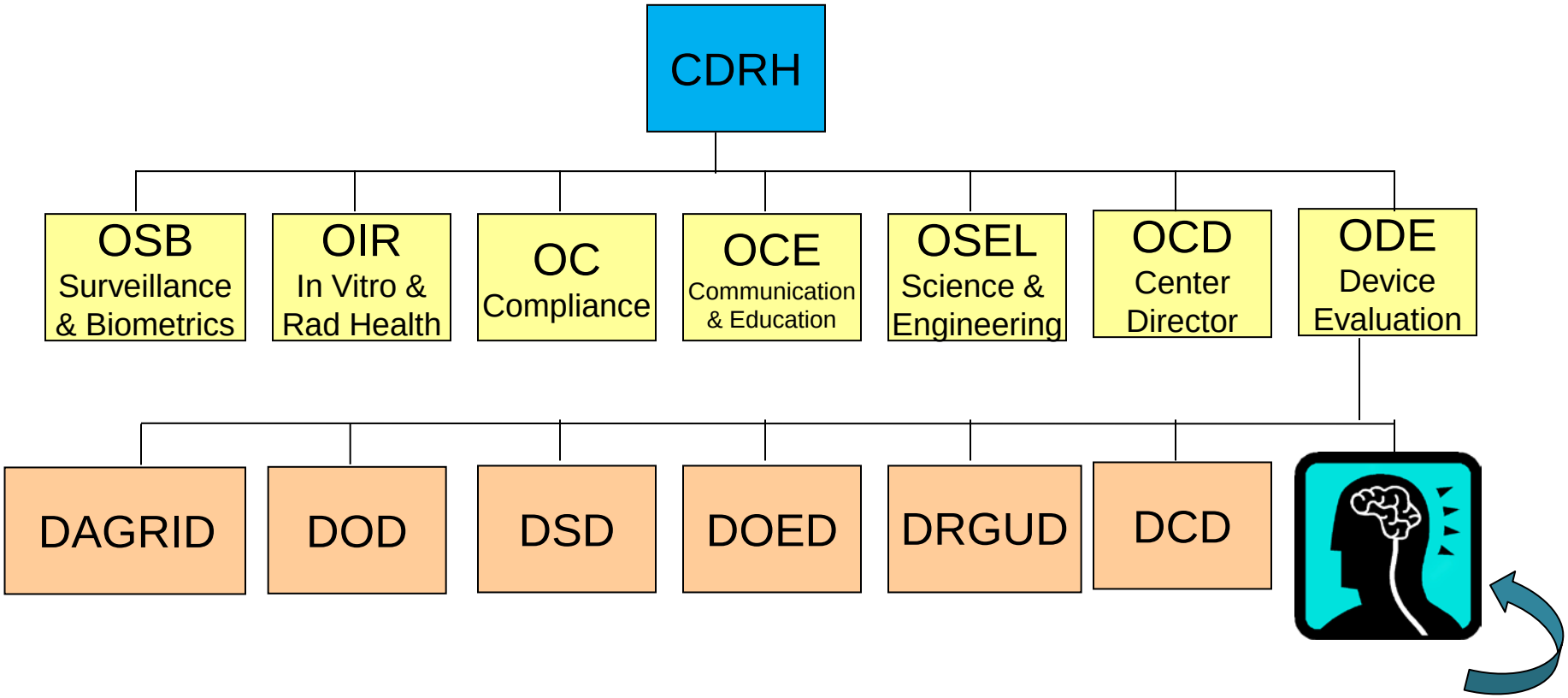
- Presubmission Guidance
- IDEs for Early Feasibility Clinical Studies Guidance Document
- Design Considerations for Pivotal Clinical Investigations
- Expedited Access for Premarket Approval Medical Devices Intended for Unmet Medical Need for Life Threatening or Irreversibly Debilitating Diseases or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

NEW FINAL Guidance - November, 2016

- **Clinical Considerations for IDEs for Neurological Devices Targeting Disease Progression and Clinical Outcomes**

Investing in Review:
Neurological Device Division at the FDA

Center for Devices and Radiological Health (CDRH) Organization



Division of Neurological and Physical Medicine Devices

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New Branch Organization

Neurodiagnostic and Neurosurgical Devices	Neurointerventional Devices	Neurostimulation Devices Neurology Branch	Neurostimulation Devices Psychiatry Branch	Physical Medicine & Rehabilitation Devices
•Cranial Materials & Other Sealants •EEG & Non-EEG Diagnostic Devices •Neurocognitive Diagnostic Devices •Surgical Instruments & Tools for the Neurovasculature •Stereotactic Systems for the Neurovasculature	•Embolization Coils •Flow Diverters •Guidewires & Catheters for the Neurovasculature •Neurothrombectomy Devices •Neurovascular & Cerebral Interventional Devices •Cerebrospinal Fluid Shunts	•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	•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	•Brain Computer Interfaces •Diathermy •Functional Electrical Stimulators •Iontophoresis Devices •Massagers/Vibrators •Orthoses, Exoskeletons •Powered Muscle Stimulators •Rehabilitation Equipment •Wheelchairs, Walkers

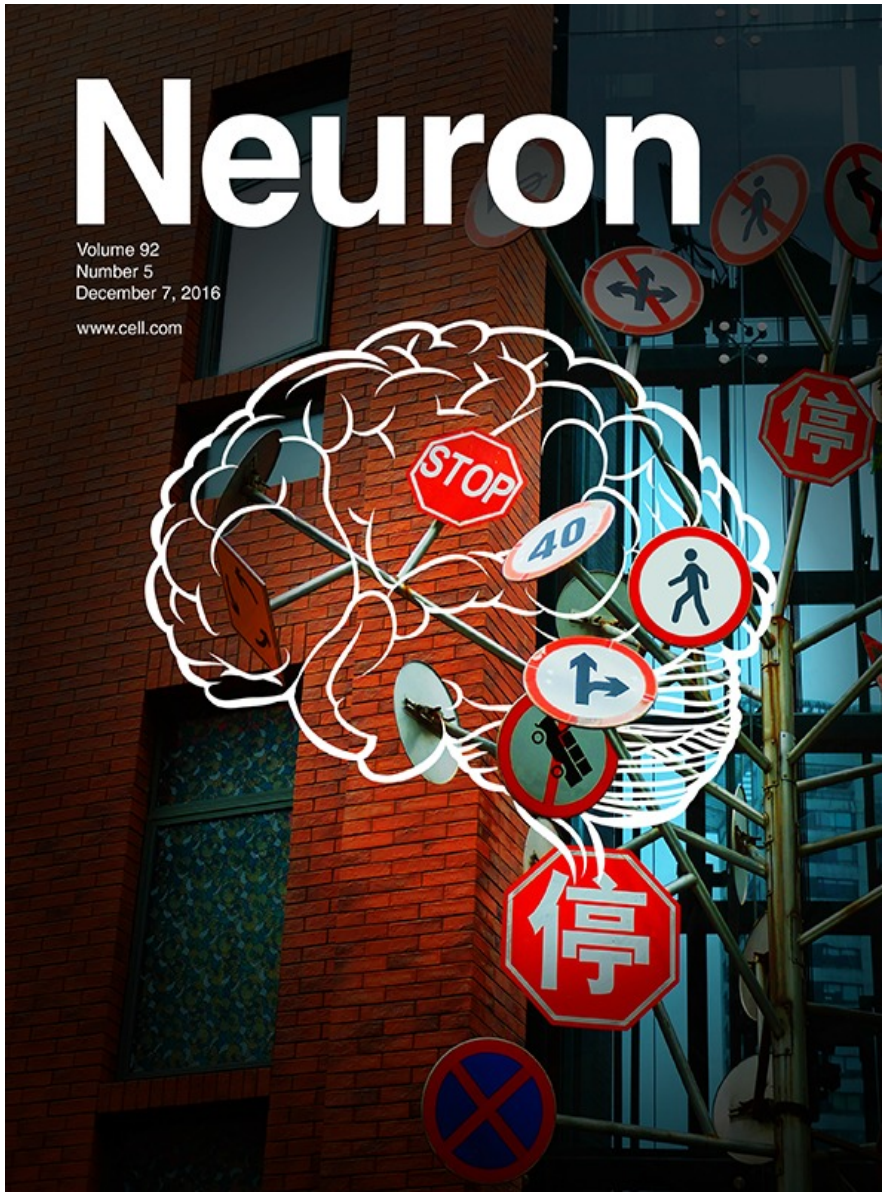
Pre-Submissions

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)



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

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