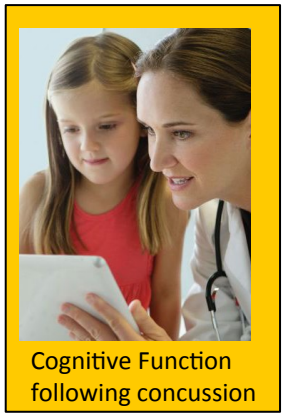
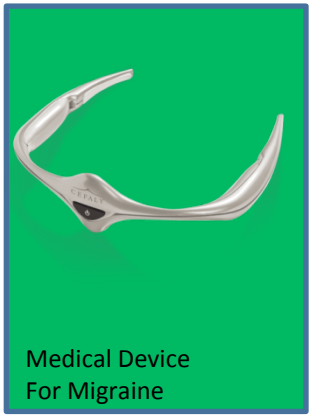
Experience in Moving Neurological Medical Devices From **Bench to Market**


Cognitive Function following concussion


Ablation Therapy

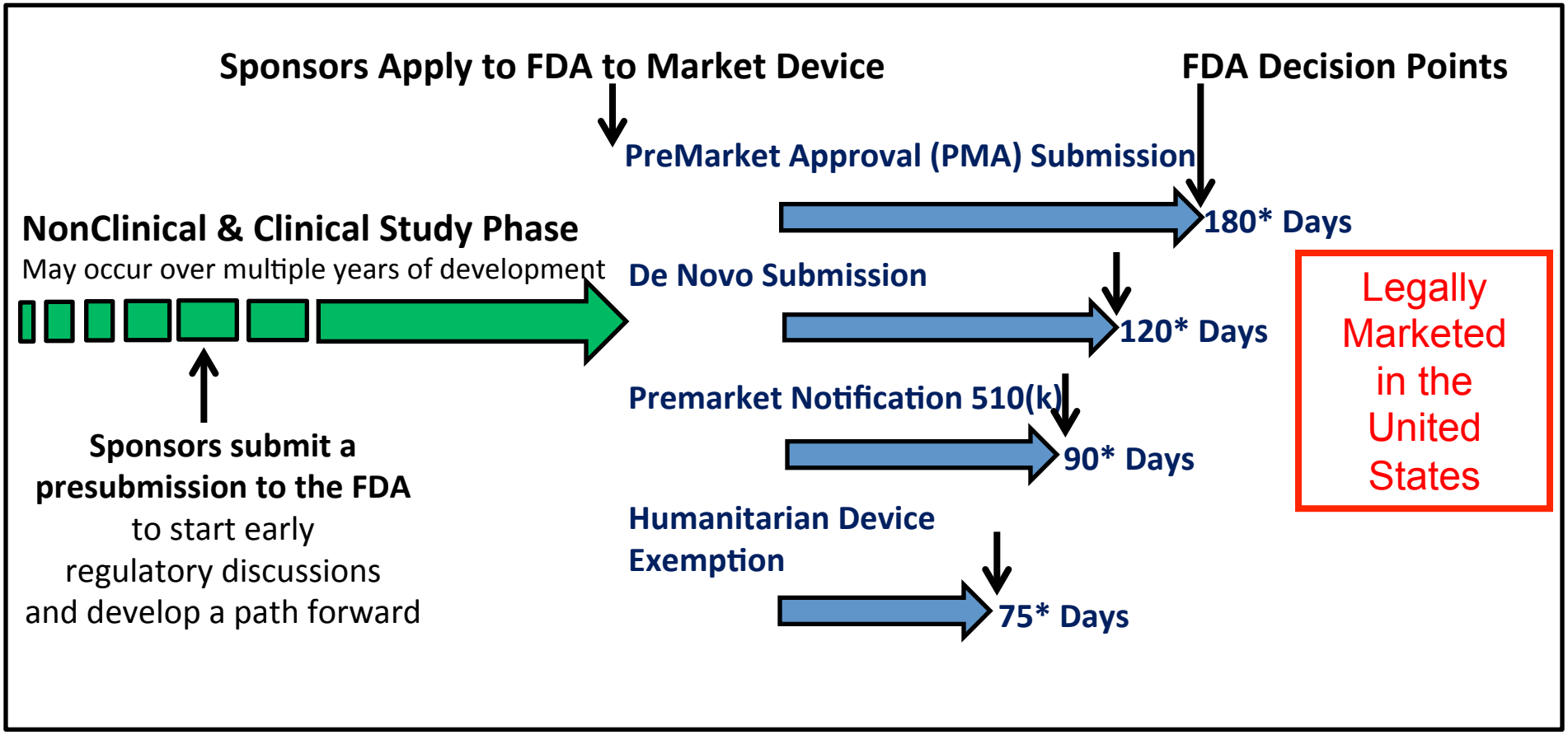

Clot Retriever for Ischemic Stroke


Prosthetic Arm


Medical Device For Migraine


Microcatheters for the neurovasculature

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.

A Few Medical Device Regulatory Concepts

- Device classification is based on risk
- **Weigh benefit vs. risk** to determine safety and effectiveness
- Use **valid scientific evidence**
- Provide "**reasonable assurance**" of safety and effectiveness
- Consider **least burdensome** means
- Assess based on the **indication for use**

Mobile Medical Apps Guidance (2015)

- Mobile Medical Applications: Guidance for Industry and Food and Drug Administration Staff
- Purpose:
  - Provide clarity and predictability for manufacturers of mobile medical apps
  - Provide information on FDA's current thinking

https://www.fda.gov/downloads/MedicalDevices/.../UCM263366.pdf

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General Wellness Guidance (2016)

- Finalized July 2016
  http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm429674.pdf

- Purpose-Provide draft guidance on general wellness products that present a very low risk to users' safety and are for: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."

Benefit Risk Considerations (2016)

- Factors to Consider When Making Benefit-Risk Determinations in Medical Device Premarket Approvals and De Novo Classifications (https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm506679.pdf)

- 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.

21 Century Cures Act – Codifies FDA Policies

The new law amended the definition of "device" in the Food, Drug and Cosmetic Act to exclude certain software functions intended...

- *(A) for administrative support;*
- *(B) for maintaining or encouraging a healthy lifestyle;*
- *(C) to serve as a electronic patient records;*
- *(D) for transferring, storing, converting formats, or displaying clinical laboratory test or other device data and results and certain other related information; and*
- *(E) to provide recommendations to health care professionals for clinical decisions, where the user can independently review the basis of the recommendation.*

The Pre-Submission Program

Guidance Issued February 18, 2014

An opportunity to obtain FDA feedback prior to clinical study or marketing submission

Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff

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Biofeedback device

Neurodiagnostics♪

FDA

External functional neurostimulator

Depth Electrode

Thermal system for insomnia

Concussion cognitive assessment device

Cortical Electrode

Cognitive devices

Electroencephalogram (EEG)

Near Infrared Brain

Brain injury interpretive EEG

Hematoma Detector

Neurological Devices

Transcutaneous electrical nerve stimulator for headache

Neurotherapeutic Devices

Neuropsychiatric EEG Assessment Aid

Computerized Cognitive Assessment

Cranial Electrotherapy stimulator

Repetitive TMS

Physiological Signal Amplifier

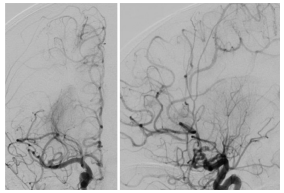
Alpha Monitor

Transcutaneous electrical nerve stimulator for pain relief

It's About the Patients







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