Pediatric Neurological Devices

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Presented at ASENT
February 23, 2012

Medical Device Classification: Risk Based

Class I
General Controls

Class II
General controls
Special controls

Class III
Premarket approval (PMA)

Neurological Device Classifications
(Examples)

- **Class I**: Manual Surgical Instruments, Tuning Fork, Neurosurgical Chair
- **Class II**: Shunts, Cranial Orthoses, EEG, TENS, aneurysm clips
- **Class III**: Vagus Nerve Stimulation, Spinal Cord Stimulation, Deep Brain Stimulation, Stents

Main Regulatory Pathways to Market

- Premarket Notification (510(k))
- Premarket Approval Application (PMA)

Additional Regulatory Pathways

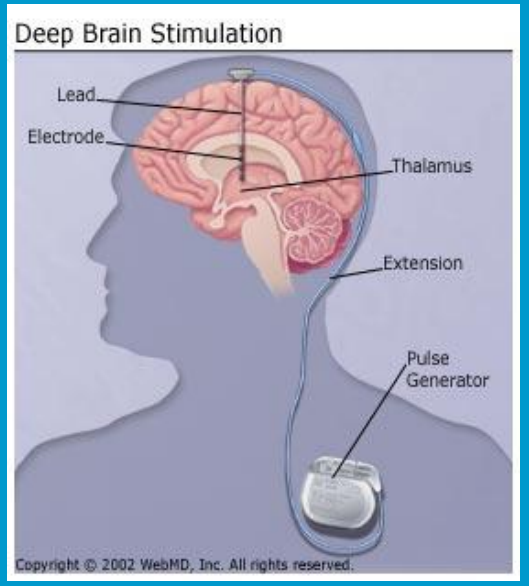
DeNovo

Device 'types' that cannot be determined to be SE through the 510(k) program, but we are able to appropriately develop special controls to mitigate the risks

http://www.medwow.com/med/cranialrthoses/unknown/infant/50718.model-spec

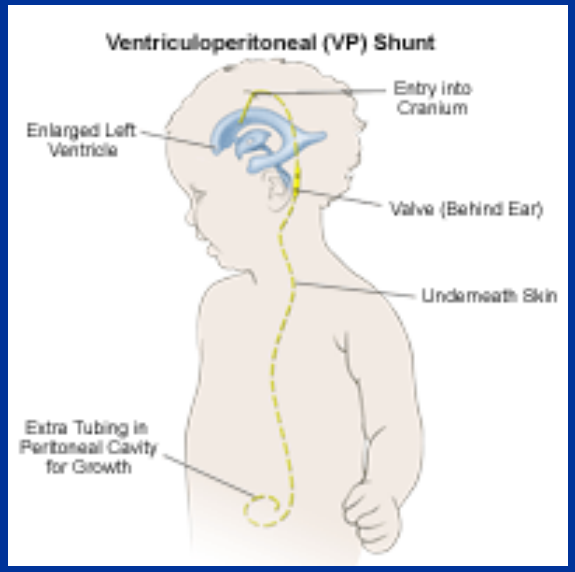
Humanitarian Use Device

Devices for orphan diseases intended to benefit patients in diagnosis and/or treatment of disease or condition affecting or manifested in fewer than 4,000 patients per year in the US.

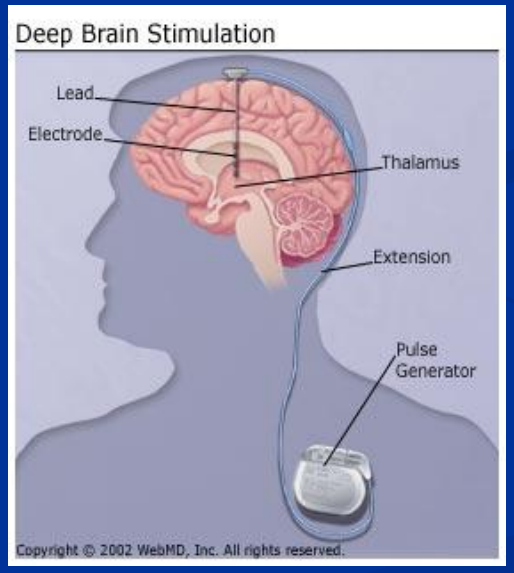


http://www.medicinenet.com/deep_brain_stimulation/article.htm

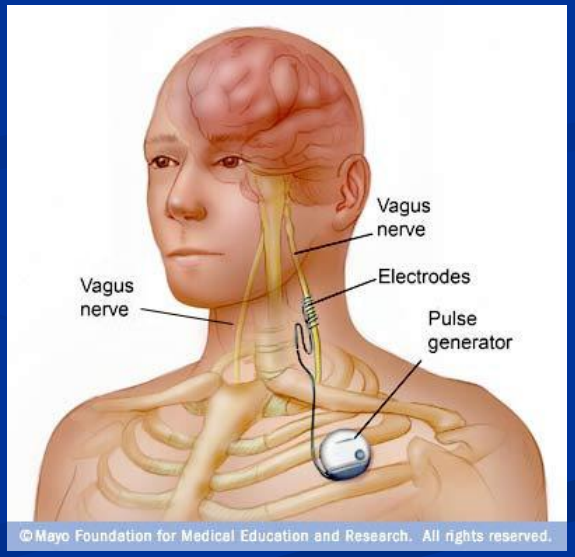
Considerations for Pediatric Neurological Devices



http://www.urmc.rochester.edu/encyclopedia/content.aspx?ContentTypeID=90&ContentID=P02367



http://www.medicinenet.com/deep_brain_stimulation/artide.htm



http://www.mayodinic.com/health/medical/IM00187

Children are NOT little adults!

One Size Does Not Fit All

Each Subpopulation is Different

CDRH Defined Pediatric Subpopulations

CDRH Pediatric Guidance† defines children ≤ 21 years

Neonate	Birth – 28 days
Infant	>28 days - 2 years
Child	>2 - 12 years
Adolescent	>12 - 21 years

†**"Premarket Assessment of Pediatric Medical Devices"** - Document issued on: May 14, 2004 http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089742.pdf

Other CDRH subgroups

- **Transitional Adolescent A: 18-21 years old *AND*** Special considerations are being given to this group, *different* from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)
- **Transitional Adolescent B:** 18-21 years old ***BUT*** No special considerations compared to adults ≥ 21 years old.

Pediatric Neurologic Devices Considerations

- Neurological disorders are often lifelong challenges
- Children are not generally the primary patient population to be treated for most complex medical devices
- Adult devices are often modified to accommodate pediatric populations
- Need to assess both how the device affects the child and how the child affects the device.

Pediatric Neurologic Devices Considerations

Brain Growth and Development

Very important consideration for devices interfacing with the brain!

- Brain is growing in volume
- Extensive brain development (e.g., myelination, synaptic density, pruning, etc.)
- Brain is developing functionally (cognitive, behavioral, emotional, etc.)

Pediatric Neurologic Devices Considerations

Physical Growth and Development

- Device Size: children's anatomy is generally smaller than adults
- Compatibility of device with growth
- Developmental milestones and maturity
- Hormonal and physiologic changes
- Psychosocial and behavioral factors

Pediatric Neurologic Devices Considerations

Surgical Considerations

- Timing of surgery with respect to growth, disease progression & natural history
- For implants:

  Need to replace implants and reoperation

  Device shifting or migrating due to growth
- Immunization status & susceptibility to infection
- Smaller circulating blood volume
- Anesthesia
- Special surgical techniques

Pediatric Neurologic Devices Considerations

Human Factors

- Age-appropriate usability (physical (e.g., strength, & dexterity) and intellectual differences)
- Device size
- Impact of activity (e.g., sports and rough housing)
- Portability
- Required level of device interaction
- Required level of adult supervision

Pediatric Neurologic Devices Considerations

Human Factors

- Presence of complicating conditions
- Use environment (e.g., home or school)
- Rehabilitation time

Biocompatibility

Need to consider long-term consequences of exposure (especially if a chronic implanted device)

Pediatric Neurologic Devices Considerations

Patient Labeling

- Ensure instructions for use are clear and age appropriate if to be used by the child
- Consider the different pediatric subpopulations and any associated considerations
- Indicate any differences in safety and effectiveness among subpopulations.
- Clearly indicate any activity constraints

Examples of Approved/Cleared Pediatric Neurologic Devices

Deep Brain Stimulation

(HDE Approved)

Medtronic Activa® Dystonia Therapy:

For unilateral or bilateral stimulation of the internal globus pallidus (GPi) or the subthalamic nucleus (STN) to aid in the management of chronic, intractable (drug refractory) primary dystonia, including generalized and/or segmental dystonia, hemidystonia, and cervical dystonia (torticollis) in **patients 7 years of age or above**.

(http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cftopic/pma/pma.cfm?num=H020007)

Deep Brain Stimulation (HDE)

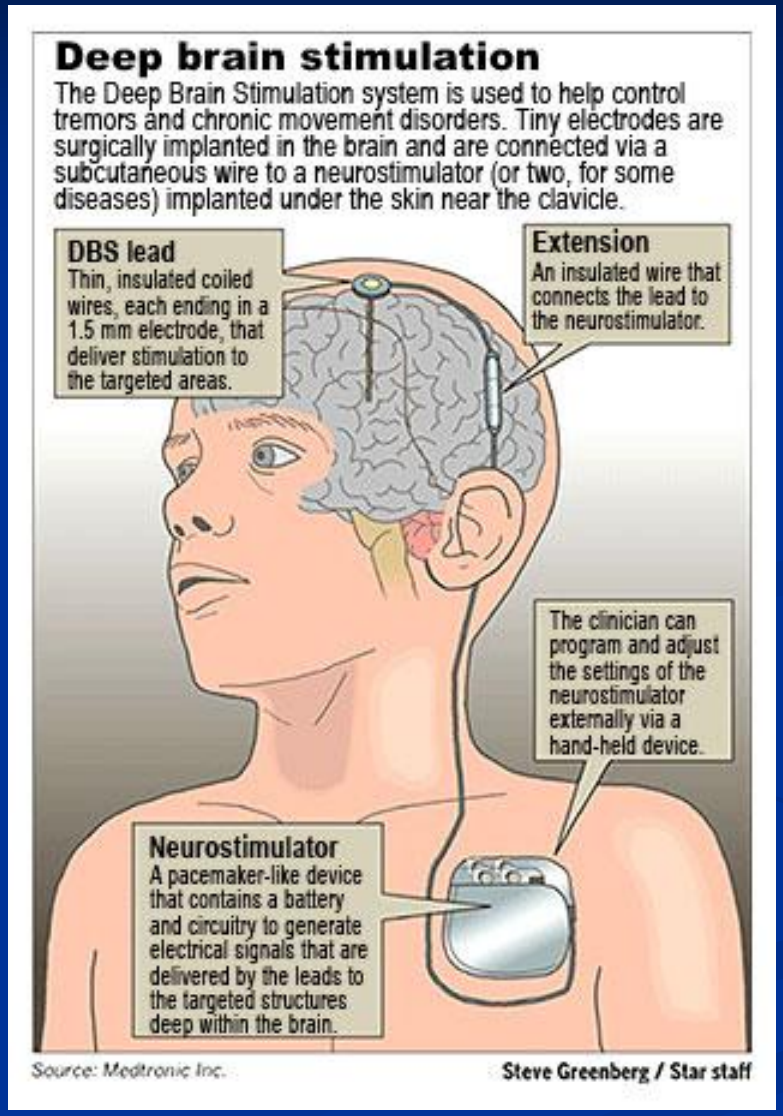


Image taken from: http://www.torticollis.org/treament-deep-brain-stimulation.html

DBS for Dystonia
Pediatric Risks

- Brain growth and development
- Lead strain/fracture due to normal growth
- Lead migration due to increasing head size
- Interference between bilateral neurostimulators
- Use of general vs. local anesthesia
- Activity levels of children (e.g., sports)

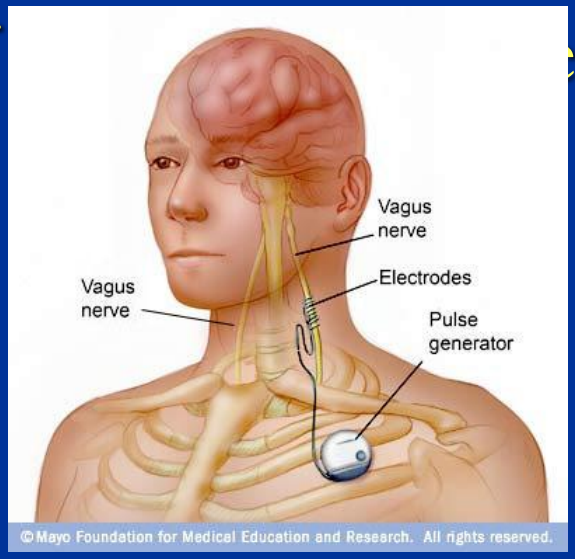
DBS for Dystonia
Pediatric Risk Mitigations

- Limit age range to ≥ 7 years
- Warning that device should only be implanted in children whose brain growth is 90% complete
- Evaluate the extension for sufficient strain relief at regular post-op intervals
- Instructions that in cases of lead tip migration due to growth reprogramming may be effective
- Recommendations for alternate placement of neurostimulators (e.g., abdomen & chest)
- Labeling warning to avoid games, sports, and other pasttimes where damage to system components are likely to occur (e.g., soccer, football, rugby)

Pediatric Neuro PMA Approved Devices

(examples)

- Cyberonics NeuroCybernetic Prostheses (NCP) for Partial Onset Seizures (≥ 12 years) (P970003)
- Natus Medical CoolCare System for treatment of [illegible]onates) (P040025)



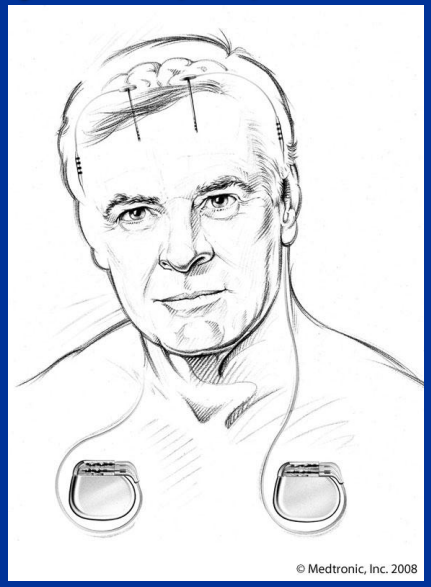
http://www.mayodinic.com/health/medical/IM00187

http://www.jlgh.org/Past-Issues/Volume-6--Issue-3/Hypothermia-for-Neuroprotection-in-the-Newborn.aspx

Pediatric Neuro HDE Approved Devices

(examples)

- Medtronic Activa Dystonia Therapy (≥ 7 years) (H020007)
- Elana Surgical Kit$_{HUD}$ for creating arteriotomies (> 13 years) (H080005)



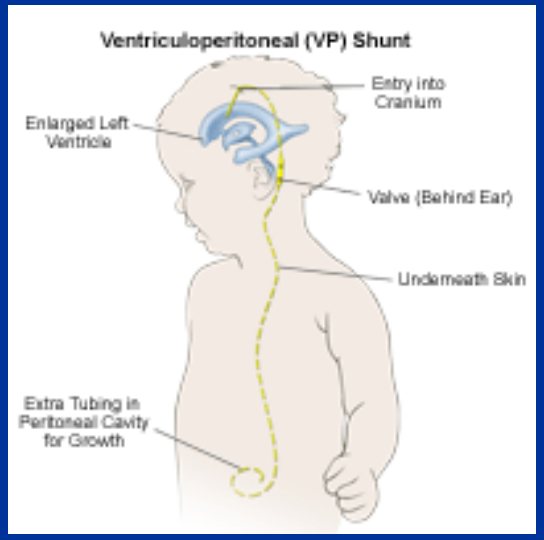
http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm082535.htm

http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm248604.htm

Pediatric Neuro 510(k) Cleared Devices

(examples)

- Hydrocephalus Shunt
- EEG
- Cranial Orthosis (originally a DeNovo)



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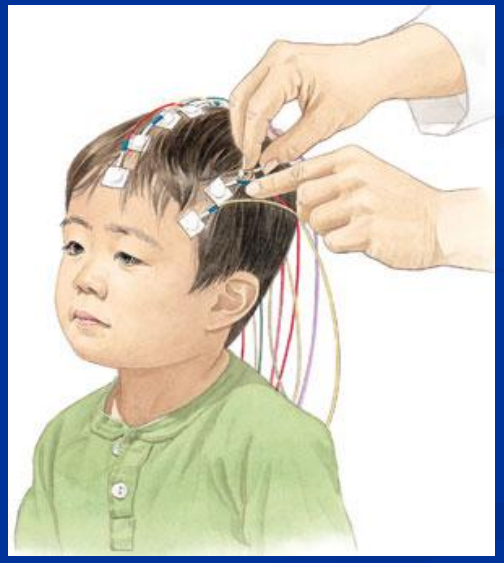

http://www.kidzmedical.com/images/eegjpg

http://www.hanger.com/orthotics/services/plagiocephaly/Pages/DailyLifeandCare.aspx

"Children's Active Lifestyles"

"It has been quite a while since I have had a [hydrocephalus shunt] revision…There was a period in time when I had five or six in a row, just back to back. The main reason for that [was that] I was racing wheelchair competitively, at the national level, for a while…The shunt really couldn't keep up with the strenuous activity. It couldn't drain the fluid off my brain fast enough….Eventually, we found a valve that would drain the fluid quick enough."

Ben Harper

Quote taken from "Safe Medical Devices for Children", Institute of Medicine (2006)

Pediatric Neurologic Devices Considerations

Post-Market

- It is important to look at post-market use of pediatric neurological devices to evaluate longer term effects and how children's active lifestyles may affect failure rates and device longevity, especially in implanted devices.
- Children with implanted and/or long-term devices should be evaluated at intervals to ensure they are meeting developmental milestones.

CDRH ASK Children Study

Assess Specific Kinds of CHILDREN Challenges for Neurologic Devices STUDY

- Collect self reported data directly from children with neuroprosthetic devices to identify human factors, safety, usability, and adverse events important for future products, including the identification of early postmarket challenges
- Devices being studied for **on-label** use include: DBS for dystonia, VNS for seizures, shunts, VOCARE bladder stimulator, and cochlear implants
- Four Investigational Sites
- http://www.askchildrenstudy.org

Relevant Publications

- **"Premarket Assessment of Pediatric Medical Devices"** - Document issued on: May 14, 2004 http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089742.pdf
- Peña C, Bowsher K, Samuels-Reid J, **"FDA Approved Neurological Devices Intended for Infants, Children, and Adolescents",** *Neurology*, 63(7): 1163-7, 2004 Oct 12.
- Samuels-Reid J, Cope JU, Morrison AE, **"Device Safety and effectiveness in the pediatric population: a US FDA perspective",** *Expert Rev Med Devices* 6(2), 131-135 (2009)
- **"Safe Medical Devices for Children",** Institute of Medicine (2006)

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