Exoskeleton Standards Technical Interchange Meeting (TIM): Medical Applications Section

Vivek Pinto, PhD
Chief
Physical Medicine and Rehabilitation Devices Branch (PMDB)
Division of Neurological and Physical Medicine Devices (DNPMD)
Office of Device Evaluation (ODE)
Center for Devices and Radiological Health (CDRH)
Food and Drug Administration (FDA)

Full Medical Agenda and Speakers

Time	Topic	Discussion	Speaker
Day 1	User Representative Introduction		Chris Tagatac Board of Directors for the Christopher Reeves Foundation
12:15 – 12:45 PM	FDA Introduction and Medical Exoskeleton Process Overviews	FDA Device Regulatory Introduction	Vivek Pinto, PhD
		Medical Exoskeletons	Devjani Saha, PhD
12:45 – 1:15 PM	Ongoing Related Standards Work	FDA Standard Recognition Process	Ian Broverman, MS
		JWG 36 Medical Robots for Rehabilitation	Eric Franca, PhD
1:15-2:40 PM	Unique Aspect Characterization, Open Discussion, & Generating Prioritization List	Open Discussion	All

FDA U.S. FOOD & DRUG ADMINISTRATION

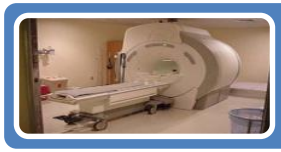
FDA


Center for Food Safety & Applied Nutrition


Center for Drug Evaluation & Research


Center for Biologics Evaluation & Research

Center for Tobacco Products


Center for Devices & Radiological Health

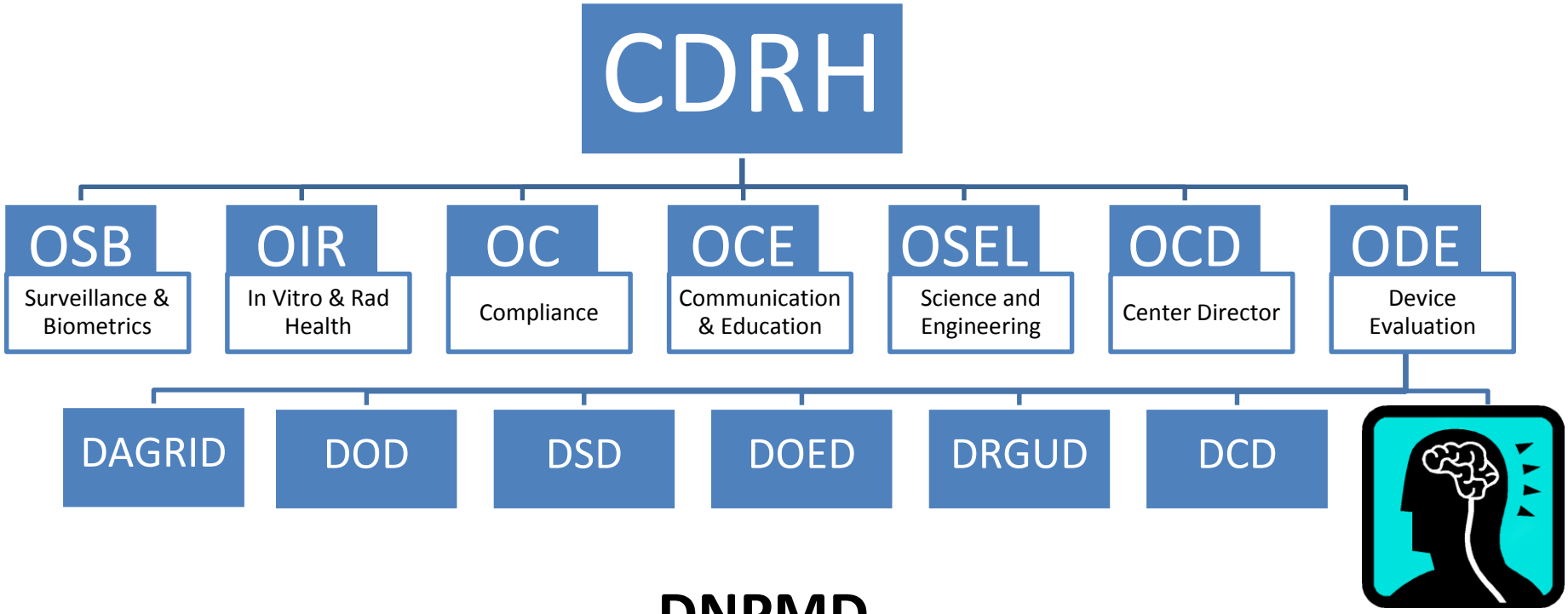

Center for Veterinary Medicine


National Center for Toxicological Research

Investing in Review-A New Division at FDA

Center for Devices and Radiological Health (CDRH) Organization

Pathway for Neurological and Physical Medicine Regulatory Submissions



DNPMD

Division of Neurological and Physical Medicine Devices

CDRH Vision

- 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.

Division of Neurological and Physical Medicine Devices

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

Experience in Moving Neurological and Physical Medicine 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

- Definition of a medical device is specified in section 201(h) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 321) *
- Section 201(h) states:
  - The term "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…."

*Federal Register Notice, 76 FR 8637 (Feb 15, 2011), Final Rule for MDDS

What makes a device a medical device?

- Usage and Risks
  - Clinical use may require different (sometimes higher) standards
  - How and where is the device used? (IFU)
  - How does the device work? (Technology)

- Example: Lego Mindstorm
    - *As a toy and teaching tool*
      - Optional, low risk
      - Minimal consequences
    - *Actuating a rehabilitation device*
      - At risk population
      - Health consequences for misuse or error

A Risk Based Approach for Medical Devices since 1976

Increasing Risk

Classification determines extent of regulatory control (Risk Based)

Class I
- General Controls

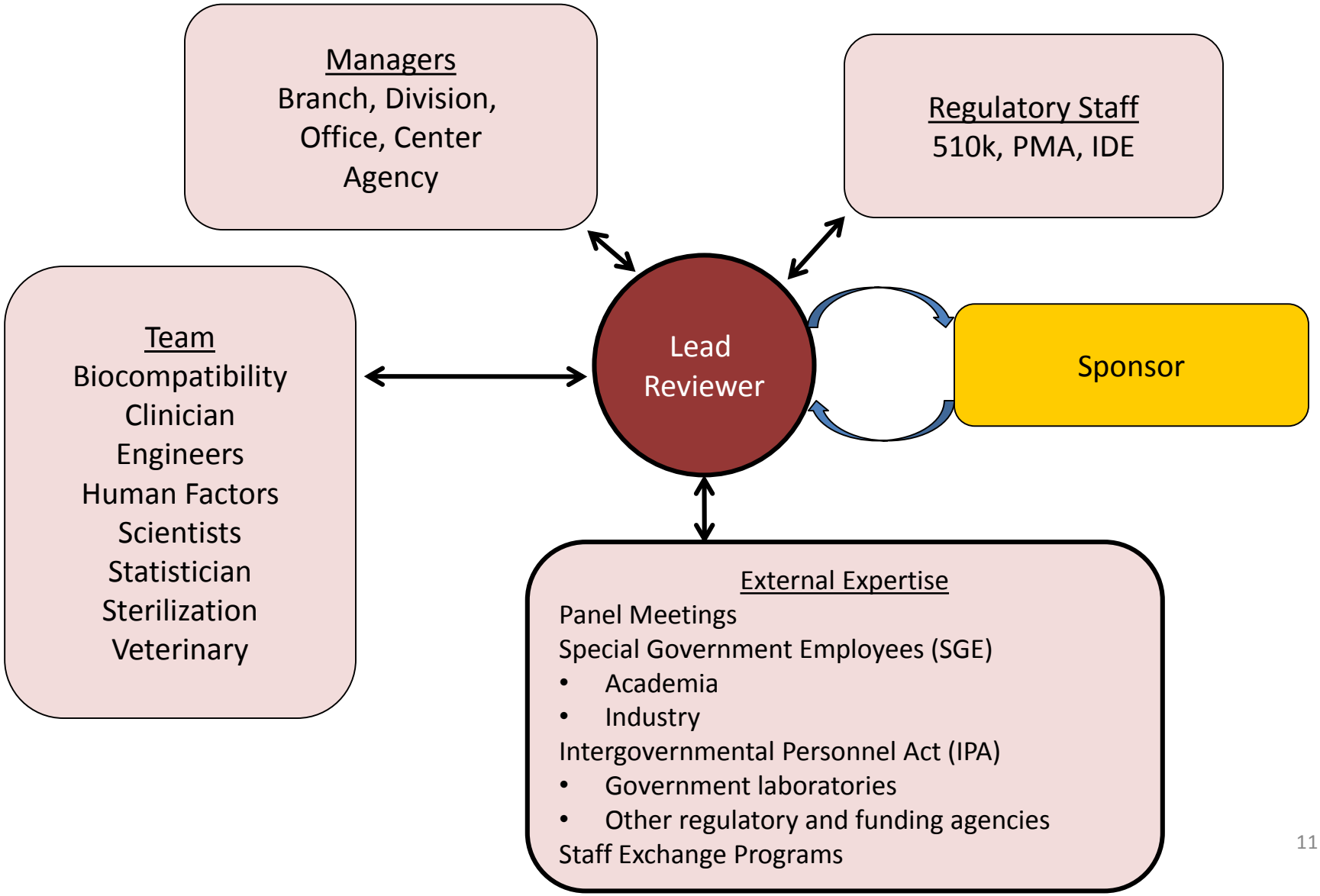
Class II
- General controls
- Performance data
- Special controls

Class III
- General controls
- Premarket approval (PMA)
- Scientific evidence to support safety and effectiveness

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

Roles in the Review Process



Classifications & Regulatory Pathways

- Class III: generally PMA (Premarket Approval)
- Class II: 510(k) (or 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

Physical Medicine Panel (21 CFR 890)

(Visit www.ecfr.gov → Title 21 Food and Drugs → Part 890)

Diagnostic, prosthetic, and therapeutic Physical Medicine

Diagnostic examples

- 21 CFR 890.1375 Diagnostic electromyograph
- 21 CFR 890.1925 Isokinetic testing and evaluation system

Prosthetic examples

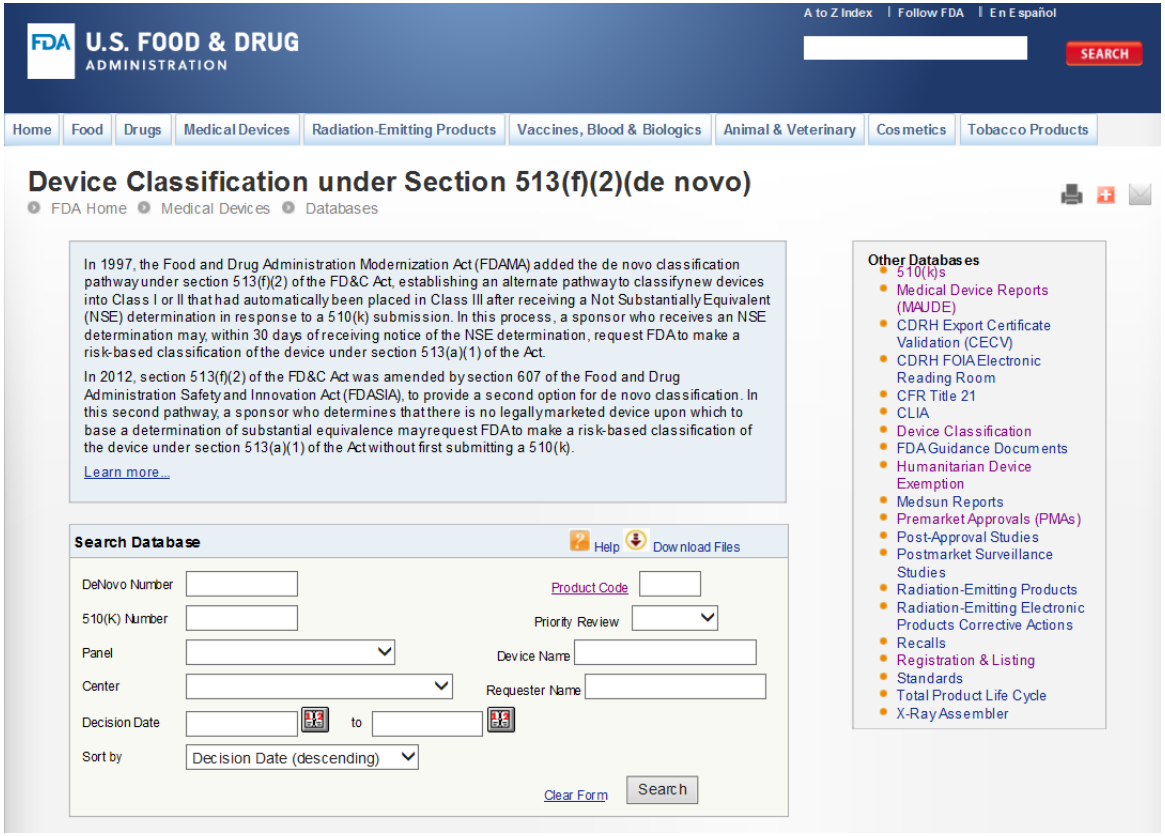
- 21 CFR 890.3480 Powered lower extremity exoskeleton
- 21 CFR 890.3860 Powered wheelchair

Therapeutic examples

- 21 CFR 890.5300 Ultrasound diathermy
- 21 CFR 890.5700 Cold pack

Public Databases: *de novo*

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/denovo.cfm



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Public Databases: *de novo (*DEN130034)

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/denovo.cfm?ID=DEN130034

New Search | Back To Search Results

Device Classification Name	Powered Exoskeleton
De Novo Number	DEN130034
510(K) Number	K131798
Device Name	REWALK
Requester	ARGO MEDICAL TECHNOLOGIES, INC. 33 Locke Dr. Suite 240 Marlborough, MA 01752
Contact	John V Hamilton
Regulation Number	890.3480
Classification Product Code	PHL
Date Received	06/17/2013
Decision Date	06/26/2014
Decision	Granted (DENG)
Classification Advisory Committee	Physical Medicine
Review Advisory Committee	Physical Medicine
Reclassification Order	Reclassification Order
FDA Review	Decision Summary
Type	Direct

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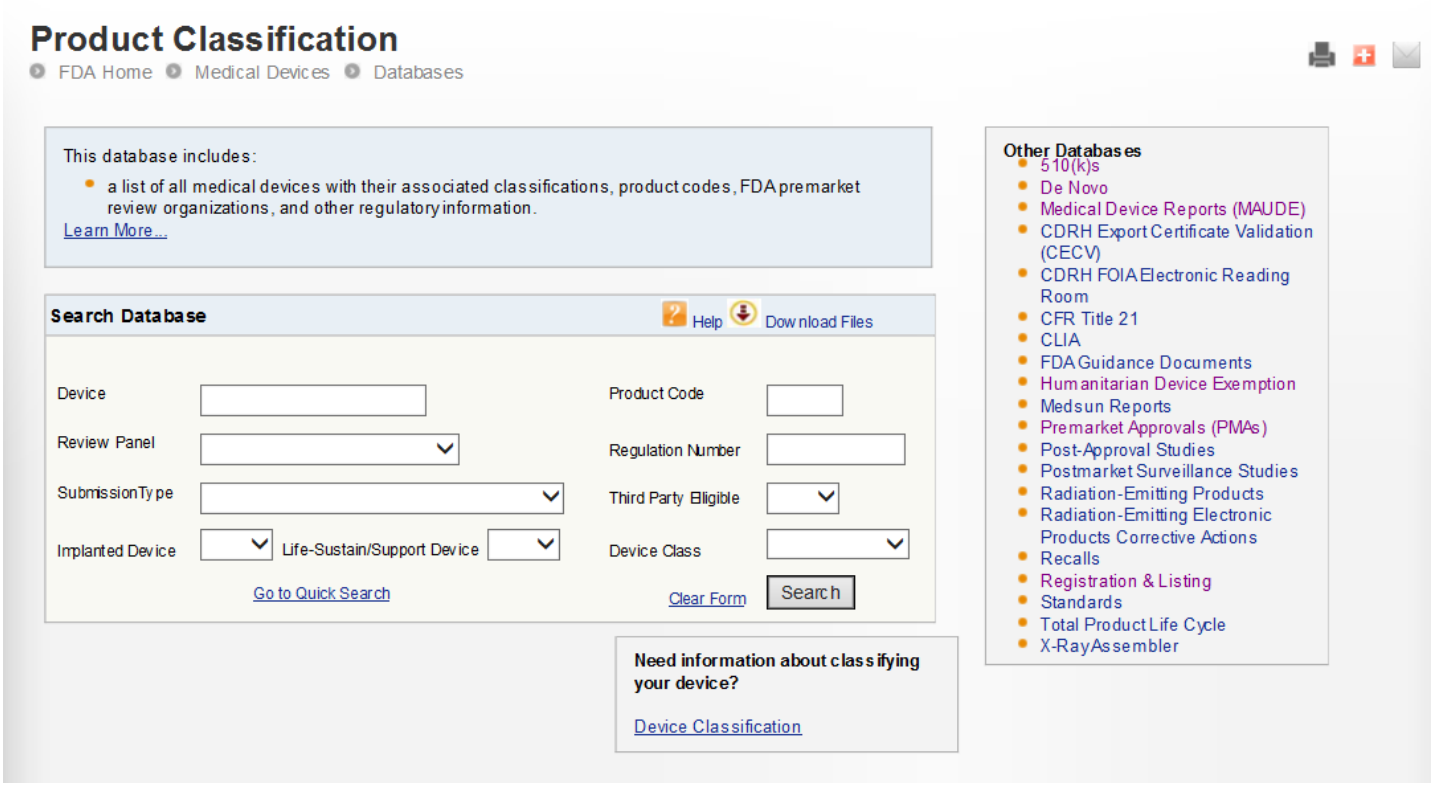
Public Databases: Product Classification

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm



Public Databases: Product Code PHL

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=3598

Product Classification

FDA Home › Medical Devices › Databases

New Search | Back To Search Results

Device	Powered Exoskeleton
Regulation Description	Powered lower extremity exoskeleton.
Definition	A powered exoskeleton is a prescription device that is composed of an external, powered, motorized orthosis used for medical purposes that is placed over a person's paralyzed or weakened limbs for the purpose of providing ambulation.
Physical State	The device is a wearable exoskeleton device that allows the user to enable ambulation over the course of the day. The control of the device is achieved through a wrist-worn user-operated wireless communicator, tilt sensor and specific body movements
Technical Method	The movement of the swing leg is controlled by a seat of gears and DC motors at the knee and hip joints. Minimizing energy expenditure with gait approximation is critical for maximizing battery life between charges.
Target Area	The device legs consist of left and right interconnect hip and knee segments. Multiple attachment straps are mounted along the length of each leg. The pelvic band support provides a structure to join the two legs together and the pelvic strap helps hold the user firmly in the system. A tilt sensor is mounted on the left side of the pelvic band. The ankle/foot bed holds the calves of the user to the system.
Regulation Medical Specialty	Physical Medicine
Review Panel	Neurology
Product Code	PHL
Premarket Review	Office of Device Evaluation (ODE) Division of Neurological and Physical Medicine Devices (DNPMD) Physical Medicine and Rehabilitation Devices Branch (PMDB)
Submission Type	510(k)
Regulation Number	890.3480
Device Class	2
Total Product Life Cycle (TPLC)	TPLC Product Code Report
GMP Exempt?	No
Implanted Device?	No
Life-Sustain/Support Device?	No
Third Party Review	Not Third Party Eligible

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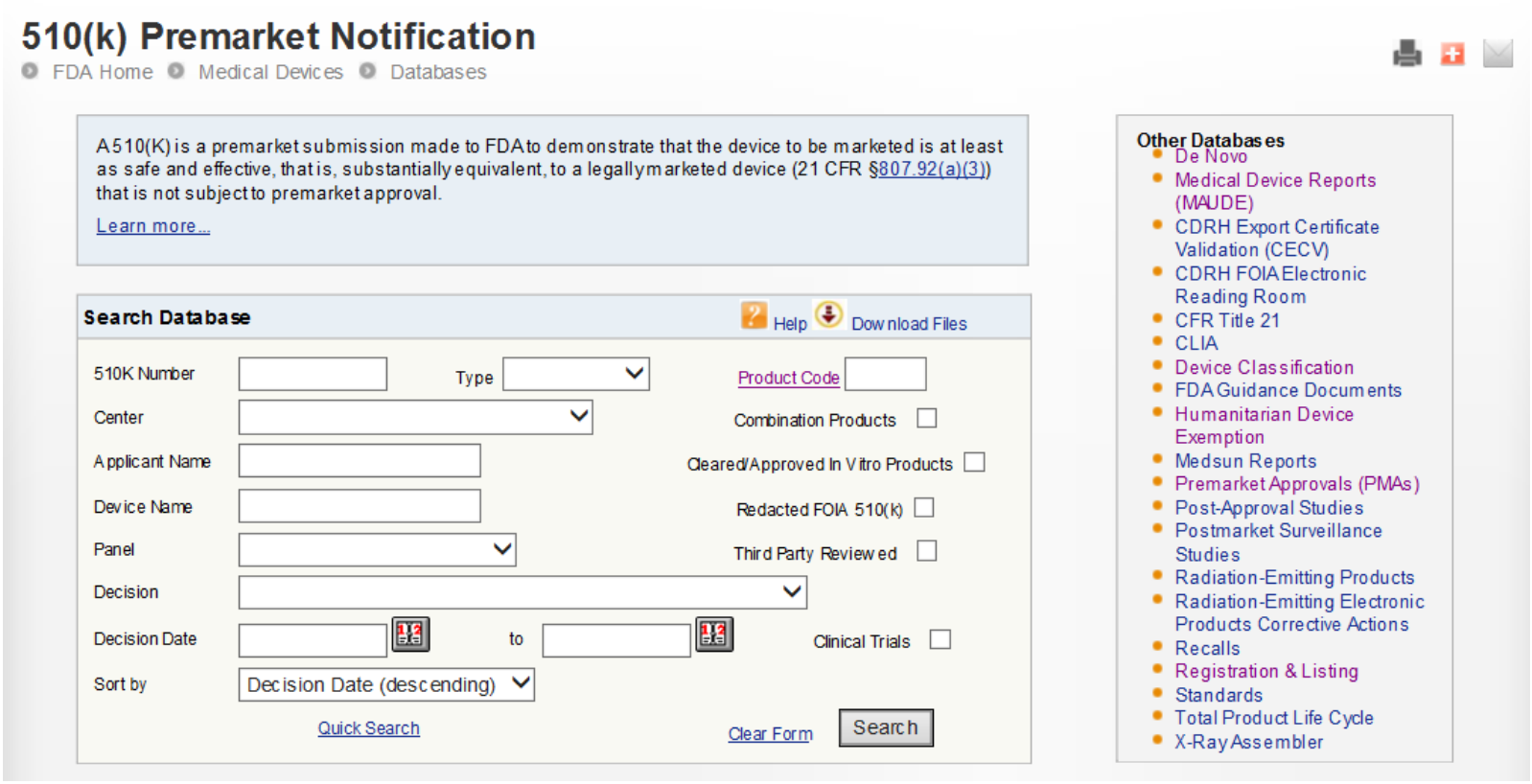
Public Databases: 510(k) Premarket Notification

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm



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Public Databases: Cleared 510(K)'s

510(k) Premarket Notification

FDA Home ▸ Medical Devices ▸ Databases

1 to 4 of 4 Results
ProductCode: *PHL* **Decision Date To:**
01/10/2017

Results per Page 10

New Search | Export to Excel | Download Files | More About 510(k)

Device Name	Applicant	510(K) Number	Decision Date
Rewalk(Tm)	Rewalk Robotics Inc.	K160987	07/22/2016
Ekso™ (Version 1.1) And Ekso Gt™ (Versio	Ekso Bionics, Inc.	K161443	07/19/2016
Ekso™ (Version 1.1) And Ekso Gt™ (Versio	Ekso Bionics, Inc.	K143690	04/01/2016
Indego	Parker Hannifin Corporation	K152416	02/26/2016

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Powered lower extremity exoskeleton

21 CFR 890.3480 Powered lower extremity exoskeleton

- (a) *Identification.* A powered lower extremity exoskeleton is a prescription device that is composed of an external, powered, motorized orthosis that is placed over a person's paralyzed or weakened limbs for medical purposes.
- (b) *Classification.* Class II (special controls). The special controls for this device are:
  - » List of 7 Special Controls (with parts) to provide a reasonable assurance of safety and effectiveness

- Dr. Saha will elaborate in her presentation

Assistive Devices for the Upper Extremity

- At this time we've cleared assistive devices wrapped around the upper extremity of stroke patients undergoing rehabilitation for muscle re-education, and maintaining or increasing range of motion.

- Devices can involve different control mechanisms (i.e., myoelectric)

- Consider submitting a 513(g) if you want our feedback on what regulation your device would be classified.

Indications for Use vs. Intended Use

- ***Indications for use –*** *The disease or condition the device will diagnose, treat, prevent, cure or mitigate, including a description of the patient population for which the device is intended.*

- ***Intended use –*** *The general purpose of the device or its function. The intended use of a device encompasses the indications for use.*

New Indications for Use are cleared through the 510(k) Notification whereas new intended use is granted/approved through a *de novo* application or premarket approval

How to determine whether a different indications for use presents a new intended use - http://www.fda.gov/downloads/MedicalDevices/.../UCM284443.pdf

FDA Guidance Documents

FDA Guidance Documents

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

- Significant Risk/Non-Significant Risk Guidance Document
  - http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126418.pdf
- 513(g) Guidance Document – when to assess the appropriate device classification
  - http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm209851.pdf
- The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]
  - http://www.fda.gov/downloads/MedicalDevices/.../UCM284443.pdf
- Draft: De Novo Classification Process (Evaluation of Automatic Class III Designation
  - http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm273903.pdf

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)

Point of Contact for General Submission Questions

DICE

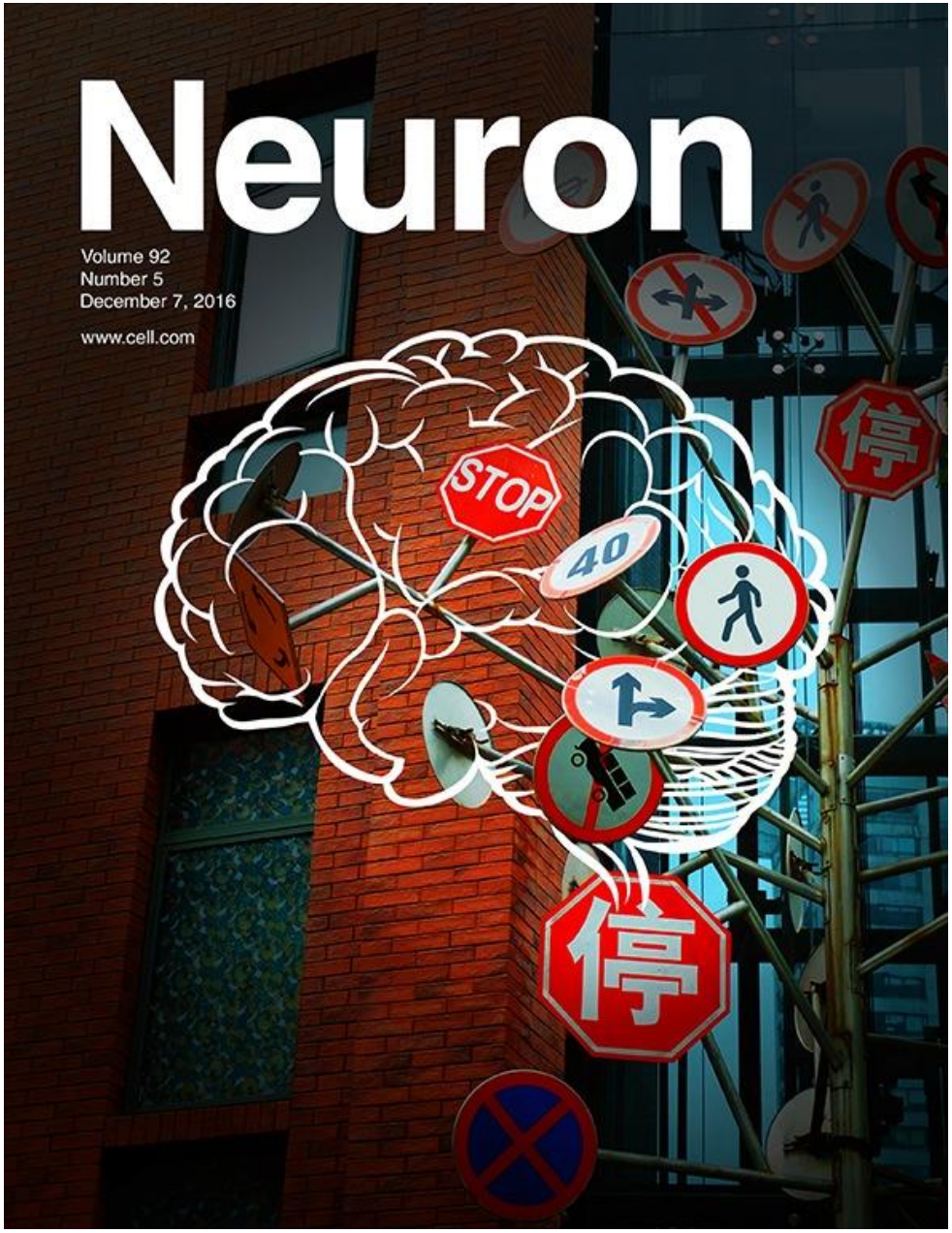
Division of Industry and Consumer Education

EMAIL : DICE@fda.hhs.gov

Phone: 1(800) 638-2041 or (301) 796-7100

Press 1 to speak to the Consumer Team

Press 2 to speak to the Industry Team



NeuroView

FDA Regulation of Neurological and Physical Medicine Devices: Access to Safe and Effective Neurotechnologies for All Americans

Anderson L, Antkowiak P, Asefa A, Ballard A, Bansal T, Bello A, Berne B, Bowsher K, Blumenkopf B, Broverman I, Bydon M, Chao K, Como P, Cork K, Costello A, De Laurentis K, DeMarco A, Dean H, Doucet J, Dworak B, Epperson L, Franca E, Ghassemian N, Ghosh C, Govindarajan A, Gupta J, Gutowski S, Herrmann R, Hoffmann M, Heetderks W, Hsu S, Kaufman D, Keegan E, Kittlesen G, Khuu K, Lee H, Lo L, Marcus I, Marjenin T, Mathews B, Misra S, Pinto V, Ramos V, Raben S, Russell A, Saha D, Seog J, Shenouda C, Smith M, Tang X, Wachrathit K, Waterhouse J, Williams D, Zheng X, Peña C.

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

Medical Device Premarket Review Contact Information

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