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 (DNPMED)
Office of Device Evaluation (ODE)
Center for Devices and Radiological Health (CDRH)
Food and Drug Administration (FDA)
## Full Medical Agenda and Speakers

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

CDRH

OSB
Surveillance & Biometrics

OIR
In Vitro & Rad Health

OC
Compliance

OCE
Communication & Education

OSEL
Science and Engineering

OCD
Center Director

ODE
Device Evaluation

DAGRID

DOD

DSD

DOED

DRGUD

DCD

DNPMD
Division of Neurological and Physical Medicine Devices
• 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**

<table>
<thead>
<tr>
<th>Neurodiagnostic and Neurosurgical Devices</th>
<th>Neurointerventional Devices</th>
<th>Neurostimulation Devices Neurology Branch</th>
<th>Neurostimulation Devices Psychiatry Branch</th>
<th>Physical Medicine &amp; Rehabilitation Devices</th>
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<tbody>
<tr>
<td>• Cranial Materials &amp; Other Sealants</td>
<td>• Embolization Coils</td>
<td>• Stimulation Devices for Movement Disorders, Epilepsy, Alzheimer’s Disease, Headache, and Traumatic Brain Injury</td>
<td>• Stimulation Devices for Major Depression, Obsessive Compulsive Disorder, and Post Traumatic Stress Disorder</td>
<td>• Brain Computer Interfaces</td>
</tr>
<tr>
<td>• EEG &amp; Non-EEG Diagnostic Devices</td>
<td>• Flow Diverters</td>
<td>• Devices may include cortical stimulation devices and deep brain stimulation devices</td>
<td>• Devices may include cranial electrical stimulation devices, electroconvulsive therapy, and transcranial magnetic stimulation devices</td>
<td>• Diathermy</td>
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<tr>
<td>• Neurocognitive Diagnostic Devices</td>
<td>• Guidewires &amp; Catheters for the Neurovasculature</td>
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<td>• Functional Electrical Stimulators</td>
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<tr>
<td>• Surgical Instruments &amp; Tools for the Neurovasculature</td>
<td>• Neurothrombectomy Devices</td>
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<td>• Iontophoresis Devices</td>
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<tr>
<td>• Stereotactic Systems for the Neurovasculature</td>
<td>• Neurovascular &amp; Cerebral Interventional Devices</td>
<td></td>
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<td>• Massagers/Vibrators</td>
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<td></td>
<td>• Cerebrospinal Fluid Shunts</td>
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<td>• Orthoses, Exoskeletons</td>
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<td>• Powered Muscle Stimulators</td>
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<td>• Rehabilitation Equipment</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Wheelchairs, Walkers</td>
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</table>
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

- **Managers**
  - Branch, Division, Office, Center Agency

- **Regulatory Staff**
  - 510k, PMA, IDE

- **Team**
  - Biocompatibility
  - Clinician
  - Engineers
  - Human Factors
  - Scientists
  - Statistician
  - Sterilization
  - Veterinary

- **Lead Reviewer**

- **External Expertise**
  - Panel Meetings
  - Special Government Employees (SGE)
    - Academia
    - Industry
  - Intergovernmental Personnel Act (IPA)
    - Government laboratories
    - Other regulatory and funding agencies
  - Staff Exchange Programs

- **Sponsor**

- **External Expertise**
  - Panel Meetings
  - Special Government Employees (SGE)
    - Academia
    - Industry
  - Intergovernmental Personnel Act (IPA)
    - Government laboratories
    - Other regulatory and funding agencies
  - Staff Exchange Programs
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](http://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
Public Databases: *de novo* (DEN130034)


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

**Public Databases: Product Code PHL**


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**Product Classification**

- **Device Description:** Powered 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. An tilt sensor is mounted on the left side of the pelvic band. The ankle/foot band 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:** 890-3440
- **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
Public Databases: 510(k) Premarket Notification

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm
## Public Databases: Cleared 510(K)’s

**510(k) Premarket Notification**  
1 to 4 of 4 Results  
Product Code: PHL Decision Date To: 01/10/2017  
Results per Page: 10

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<tr>
<th>Device Name</th>
<th>Applicant</th>
<th>510(K) Number</th>
<th>Decision Date</th>
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<tr>
<td>Rewalk(TM)</td>
<td>Rewalk Robotics Inc.</td>
<td>K160987</td>
<td>07/22/2016</td>
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<tr>
<td>Ekso™ (Version 1.1) And Ekso Gt™ (Versio</td>
<td>Ekso Bionics, Inc.</td>
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<td>07/19/2016</td>
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<td>Ekso™ (Version 1.1) And Ekso Gt™ (Versio</td>
<td>Ekso Bionics, Inc.</td>
<td>K143690</td>
<td>04/01/2016</td>
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<tr>
<td>Indego</td>
<td>Parker Hannifin Corporation</td>
<td>K152416</td>
<td>02/26/2016</td>
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</table>
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 -
FDA Guidance Documents

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

• Significant Risk/Non-Significant Risk Guidance Document

• 513(g) Guidance Document – when to assess the appropriate device classification
documents/ucm209851.pdf

• The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]

• Draft: De Novo Classification Process (Evaluation of Automatic Class III Designation)
documents/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


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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