



Food and Drug Administration
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June 26, 2014

Argo Medical Technologies, Inc.
John Hamilton
Vice President Regulatory/Clinical
33 Locke Drive
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Re: K131798
ReWalk™
Evaluation of Automatic Class III Designation – *De Novo* Request
Regulation Number: 21 CFR 890.3480
Regulation Name: Powered Exoskeleton
Regulatory Classification: Class II
Product Code: PHL
Dated: June 22, 2103
Received: June 24, 2013

Dear Mr. Hamilton:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your *de novo* request for classification of the ReWalk™, a prescription device under 21 CFR Part 801.109 that is indicated as follows:

The Argo ReWalk™ orthotically fits to the lower limbs and part of the upper body and is intended to enable individuals with spinal cord injury at levels T7 to L5 to perform ambulatory functions with supervision of a specially trained companion in accordance with the user assessment and training certification program. The device is also intended to enable individuals with spinal cord injury at levels T4 to T6 to perform ambulatory functions in rehabilitation institutions in accordance with the user assessment and training certification program. The ReWalk™ is not intended for sports or stair climbing.

FDA concludes that this device should be classified into class II. This order, therefore, classifies the ReWalk™, and substantially equivalent devices of this generic type, into class II under the generic name, Powered Exoskeleton.

FDA identifies this generic type of device as:

Powered Exoskeleton. 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.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This new law provides two options for *de novo* classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may, within 30 days of receiving notice of the NSE determination, request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** classifying the device type.

On June 24, 2013, FDA received your *de novo* requesting classification of the ReWalk™ into class II. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the ReWalk™ into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

After review of the information submitted in the *de novo* request, FDA has determined that the ReWalk™ indicated for the following:

The Argo ReWalk™ orthotically fits to the lower limbs and part of the upper body and is intended to enable individuals with spinal cord injury at levels T7to L5 to perform ambulatory functions with supervision of a specially trained companion in accordance with the user assessment and training certification program. The device is also intended to enable individuals with spinal cord injury at levels T4 to T6 to perform ambulatory functions in rehabilitation institutions in accordance with the user assessment and training certification program. The ReWalk™ is not intended for sports or stair climbing.

can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in Table 1.

Table 1 – Identified Risks to Health and Mitigation Measures

Identified Risk	Mitigation Measure
Instability, Falls, and Associated Injuries	Clinical Testing Training Software Verification, Validation, and Hazard Analysis Wireless Testing Electromagnetic Compatibility (EMC) and Electromagnetic Interference (EMI) Testing Electrical Safety Testing Design Characteristics

Identified Risk	Mitigation Measure
	Non-clinical Performance Testing Water/Particle Ingress Testing Durability Testing Battery Testing Labeling
Bruising, Skin Abrasion, Pressure Sores, Soft Tissue Injury	Clinical Testing Training Labeling
Diastolic hypertension and changes in blood pressure, and heart rate	Clinical Testing Training Labeling
Adverse Tissue Reaction	Biocompatibility Assessment
Premature Battery Failure	Battery Testing Labeling
Interference with Other Electrical Equipment/Devices	EMC/EMI testing Labeling
Burns, Electrical Shock	Electrical Safety testing Thermal testing Labeling
Device Malfunction resulting in Unanticipated Operation (e.g., Device Stoppage, Unintended Movement)	Clinical testing Non-clinical Performance Testing Training Software Verification, Validation, and Hazard Analysis Electrical Safety Testing Battery Testing Water/Particle Ingress Testing Wireless Testing EMC/EMI Testing Flammability Testing Labeling
Use Error	Clinical Testing Training Labeling

In combination with the general controls of the FD&C Act, the Powered Exoskeleton is subject to the following special controls:

- Elements of the device materials that may contact the patient must be demonstrated to be biocompatible.
- Appropriate analysis/testing must validate electronic compatibility/interference (EMC/EMI), electrical safety, thermal safety, mechanical safety, battery performance and safety, and wireless performance, if applicable.

- Appropriate software verification, validation, and hazard analysis must be performed.
- Design characteristics must ensure geometry and materials composition are consistent with intended use.
- Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. Performance testing must include:
 - Mechanical bench testing (including durability testing) to demonstrate that the device will withstand forces, conditions and environments encountered during use.
 - Simulated use testing (i.e. cyclic loading testing) to demonstrate performance of device commands and safeguard under worst case conditions and after durability testing.
 - Verification and validation of manual override controls are necessary, if present.
 - The accuracy of device features and safeguards.
 - Device functionality in terms of flame retardant materials, liquid/particle ingress prevention, sensor and actuator performance, and motor performance.
- Clinical testing must demonstrate safe and effective use and capture any adverse events observed during clinical use when used under the proposed conditions of use, which must include considerations for:
 - Level of supervision necessary
 - Environment of use (e.g., indoors and/or outdoors) including obstacles and terrain representative of the intended use environment
- A training program must be included with sufficient educational elements so that upon completion of training program, the clinician, user and companion can:
 - Identify the safe environments for device use
 - Use all safety features of device
 - Operate the device in simulated or actual use environments representative of indicated environments and use
- Labeling for the Physician and User must include the following:
 - appropriate instructions, warning, cautions, limitations, and information related to the necessary safeguards of the device, including warning against activities and environments that may put the user at greater risk.
 - specific instructions and the clinical training needed for the safe use of the device, which includes:
 - instructions on assembling the device in all available configurations,
 - instructions on fitting the patient,
 - instructions and explanations of all available programs and how to program the device,

- instructions and explanation of all controls, input, and outputs,
- instructions on all available modes or states of the device,
- instructions on all safety features of the device, and
- instructions for properly maintaining the device.
- information on the patient population for which the device has been demonstrated to have a reasonable assurance of safety and effectiveness.
- pertinent non-clinical testing information (e.g., EMC, battery longevity)
- a detailed summary of the clinical testing including:
 - Adverse events encountered under use conditions.
 - Summary of study outcomes and endpoints.
 - Information pertinent to use of the device including the conditions under which the device was studied [e.g., level of supervision or assistance, and environment of use (e.g., indoors and/or outdoors) including obstacles and terrain].

In addition, this is a prescription device and must comply with 21 CFR 801.109. Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the Powered Exoskeleton they intend to market prior to marketing the device and receive clearance to market from FDA.

Please be advised that FDA's decision to grant this *de novo* request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD & C Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the FD & C Act); 21 CFR 1000-1050.

A notice announcing this classification order will be published in the **Federal Register**. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the *de novo* request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

If you have any questions concerning this classification order, please contact Michael Hoffmann at 301-796-6476.

Sincerely yours,

Jonette R. Foy -S

Jonette Foy, Ph.D.
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