EVALUATION OF AUTOMATIC CLASS III DESIGNATION (DE NOVO) FOR
ARGO REWALK™

REGULATORY INFORMATION

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.

NEW REGULATION NUMBER: 21 CFR 890.3480

CLASSIFICATION: II

PRODUCT CODE: PHL

BACKGROUND

DEVICE NAME: REWALK™

SUBMISSION NUMBER: K131798

DATE OF DE NOVO REQUEST: JUNE 22, 2013

REQUESTOR CONTACT:
JOHN HAMILTON
ARGO TECHNOLOGIES
33 LOCKE DRIVE
MARLBOROUGH, MA 01752

REQUESTOR'S RECOMMENDED CLASSIFICATION: II

INDICATIONS FOR USE

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.

LIMITATIONS

ReWalk™ is indicated for Prescription Use.

Candidates for the device should have the following characteristics:

- Hands and shoulders can support crutches or a walker
- Healthy bone density
- Skeleton does not suffer from any fractures
- Able to stand using a device such as a standing frame
- In general good health
- Height is between 160 cm and 190 cm (5'3" -6'2")
- Weight does not exceed 100 kg (220 lbs)

The device has been contraindicated for use in sports or stair-climbing.

Warnings:

- Users must be trained to use the ReWalk™. Use of the device without training can result in serious injury.
- Improper adjustment of device size to suit the user could cause skeletal fractures and injury to the patient.
- Using the device on irregular surface could result in loss of balance and possible injury. Do not try to walk on sand, in stony areas, or on any surface that isn't appropriate for crutches. Do not use the device on a non ADA compliant ramp.
- Do not use the device if you are distracted or not paying careful attention to your operation of the system.
- The device is designed for use with crutches.
- Use the device on paved surfaces on dry, even surfaces.
- The device must be fitted over clothing to prevent skin abrasions. Where necessary, use the extra padding provided with the device.

DEVICE DESCRIPTION

The device is a wearable exoskeleton device (refer to Figure 2 below) that allows the user to enable ambulation over the course of the day (refer to Figure 1 below). The control of the device is achieved through a wrist-worn user-operated wireless communicator, tilt sensor and specific body movements.

The movement of the swing leg is controlled by a set of gears and DC motors at the knee and hip joints.

Figure 1: User in WALK mode

Components of the Exoskeleton	
Item	**Description**
1	Chest strap
2	Waist strap
3	Thigh straps
4	Upper knee straps
5	Lower knee straps
6	Ankle straps
7	Tilt sensor
8	Upper limb support
9	Lower limb support
10	Calf and shoe support

Figure 2: Components of the Exoskeleton

Hardware, Motor and Power Source:

The system consists of three major components: remote control communicator, exoskeleton and backpack.

1. Remote Control Communicator

   The remote control (RC) communicator (Figure 3) is a small wireless device that provides two-way communication between the user and the ReWalk™ unit. It provides control of selecting between modes and presents a visual indication of the status of the system, which includes the mode in which the device is operating (walking, standing, sitting, etc.). Communication between the communicator and the main computer is performed wireless at 2.4 GHz with a frequency hopping protocol.

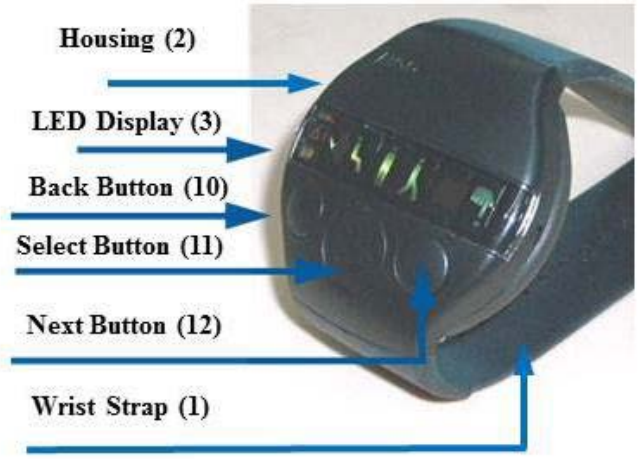

Figure 1-Remote Control communicator

The modes that are available for the remote control communicator are shown below in Table 1.

SIT-TO-STAND	The user always dons the ReWalk™ in a chair. Once the user is wearing the ReWalk, rising from the chair to a standing position is required prior to starting the walking function. Once the user has initiated the chair rising function with the wrist communicator, the user has to wait 3 seconds before starting to rise from the chair.
STAND	The standing function serves several purposes, including that it is the transitional phase between sitting and walking. Moreover, when the user stops the walking motion, the unit defaults to this mode. Also, it allows the user to communicate and interact with other people in a face-to-face manner.
WALK	The main function of the ReWalk™ is to allow the user to ambulate. When the user tilts forward, the leg will swing forward with the crutches following. Once the leg reaches the end of the swing, the user will shift

	their weight to this leg and then when the tilt of the torso is sensed the opposite leg will swing forward.
STAND-TO-SIT	The stand to sit function is always performed from the standing position and must be done in front of an appropriately sized chair without arms. Sitting initiated during walking is prevented by the software and the communicator. Once the user is standing in front of a chair and has initiated the sitting function using the communicator, they have 3 seconds to prepare themselves to begin moving downwards.
MANUAL	This mode is only accessible from the sit mode and is used to control the thigh/calf segments without relying on the communication from the remote control. The buttons to control this function are located on the calf actuation units.
BYPASS	In the event that communication is lost between the communicator (remote control) and the main computer as a result of EMI interference or dropping the remote control, the system goes into bypass mode where the unit can be controlled using the buttons on the thigh actuation units.

Table 1:-Modes for the RC Communicator

2. Exoskeleton

The exoskeleton is comprised of 4 components:

a. articulating legs consisting of thigh and calf components
The legs consist of left and right segments that are secured to the thigh and calf and interconnect robotic joints located over the patient's hips and knees. The main structural component of each segment carries the load generated across the ReWalk™. Multiple attachment straps are mounted along the length of each leg. DC motors, gearing and electronics are located at each hip and knee joint to provide motion. Cabling for communication and power is contained within the leg unit.

b. *pelvic band*
The pelvic band support (refer to Figures 4 and 5) 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.

Figure 2-Pelvic Band (Rear View)

Figure 3-Pelvic Band (Side View)

c. *straps and padding*
Six straps hold the user in the exoskeleton at the following locations: chest, waist, thigh, upper knee, lower knee and calf straps. The rigid calf support provides a structure to hold the calves of the user in the system.

d. ankle/foot bed
The ankle/foot bed (Figure 6) holds the calves of the user to the system. The calf holders are connected to the foot beds, which are located within the shoes provided and fitted by the clinician for use with the ReWalk™.

Figure 4-Foot/ankle bed

3. Backpack

A lightweight backpack (Figure 7) is worn by the user using two padded shoulder straps. The backpack consists of a rigid outer shell and an inner compartmentalized shell with the power management and computer control system components. The main battery is a Lithium ion battery that is capable of allowing a user to walk continuously for more than 2 hours on a charge. Once the battery reaches a predetermined charge the power switches to the Lithium polymer battery which provides the users with at least an additional 15 minutes of continuous walking.

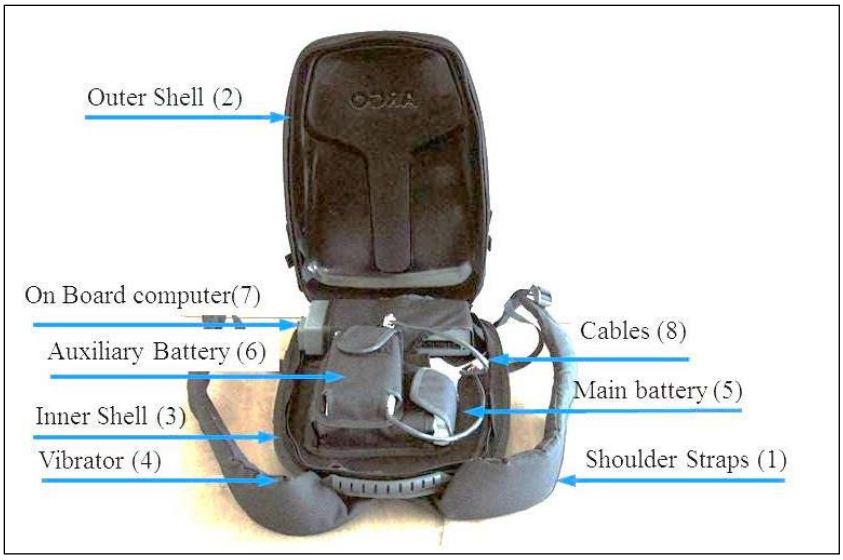

Figure 5-User worn-backpack

Additionally, bilateral standard forearm crutches are required while using the ReWalk™. The crutches provide a stable platform during standing and walking and are an integral part of the chair raising activity. A full-circle forearm cuff is utilized to ensure the crutch stays attached to the user's arm.

There are two models of the device that are offered, ReWalk™ –R (rehabilitation) and the ReWalk™ –P (personal). All functions of the two models are identical. Both models share the same drive mechanics, control software, power sources, electronics, and computers. The ReWalk™ -R will be supplied with a graphical user interface (GUI) to allow configuring of the systems by a trained clinician. The ReWalk™ -P will not be supplied with the GUI. The ReWalk™ –R will also be offered with five different pelvic band widths (29, 31, 33, 35, and 37 cm). The ReWalk™ –P will be offered with only one pelvic band width.

Custom fitting are performed by an ARGO-trained health care professional. The following dimensions can be adjusted: knee center to ankle joint, hip center to knee center and pelvic width. Additionally, a number of variables associated with patient gait, such as knee flexion, hip flexion, hip extension, maximum velocity, tilt angle and timeout time can be adjusted to accommodate user preferences, capabilities and experience level.

The device has both hardware and software safety and emergency features built in. The system performs a self-test and will disable and prevent use if any of the components are not functioning or communicating properly. If the main computer fails during a routine operation, there is a redundant control of the exoskeleton left to switch over to manual mode. There is both a limit in the software and fixed mechanical stops that prevent excessive joint flexion/extension. There is also a "graceful sitting" or "graceful collapse" feature on the device for either loss of balance or power. In the event of a major system failure, such as complete loss of power, the weight of the patient causes the ReWalk unit to enter into a graceful collapse, i.e., the body's weight rotates the inner rotor of the motor and moves the exoskeleton joints into a slowly achieved collapsed sitting position. The magnetic field within the motor provides resistance to the rotor's rotation that slows the collapse of the ReWalk™.

Lithium Ion/Polymer batteries:
The electrical power to the ReWalk™ consists of two redundant battery systems. These battery systems are unique to the device. The batteries are supplied with the system and not intended to be serviced or replaced by the user. The voltage is 28.8V DC with 30 A peak current and 10 A continuous current. The main battery is a Lithium ion battery that allows the user to walk continuously for more than 2 hours on a charge. The secondary is a Lithium polymer battery that allows at least an additional 15 minutes of continuous walking. The user is alerted when the charge of the battery is low by a short vibration (buzz) repeated every 10 seconds. The user is encouraged to charge the batteries overnight. The charger for the ReWalk™ was tested separately per appropriate EMC/EMI standards and warnings are provided to the user not to use the device while charging.

Fault Safety
The device has the following safety systems:

- System Fault at Power Up
  The system does a self-check at start up and disables the system until the problem is corrected.

- Main computer failure
  The system will default over to manual control. The manual buttons are used to position the legs into a sitting position so the user can remove the device.

- Incorrect operational mode selection
  The device cannot enter certain operational modes from select modes, e.g., the user cannot enter “walk” mode from “sit mode” directly.

- Excessive joint flexion/extension angles
  There is a limit in the software that limits the movement and a fixed mechanical stop that prevents excessive movements. Hip flexion is limited between -34 and 104 degrees relative to the torso sagittal plane. The knee flexion is limited to 2 degrees extension and 112 degree flexion. The torque is limited to 125Nm (max).

- Loss of balance while rising from a chair
  If the threshold angle during “sit to stand” mode exceeds a certain amount, the device returns to “sit” mode (graceful sitting).

- Misstep or obstacle
  If the user contacts an obstacle with one of the limbs, the movement restriction generates excess torque. A torque (Current) threshold limit and alert is issued by the buzzer and vibrator and the leg moves back to a standing position. The torque limit can be adjusted in the software to a value below the upper limit, if desired.

- Complete loss of power

If the device enters a major system failure, the unit enters into a "graceful collapse", where the exoskeleton rotates "slowly" (via motor resistance) into a collapsed sitting position.

- Loss of communication between remote and main computer
  The system can enter a bypass mode where the device can be controlled with buttons on the hip actuation unit.

SUMMARY OF NONCLINICAL/BENCH STUDIES

The sponsor conducted a series of bench testing to demonstrate that the ReWalk™ System would perform as anticipated. Non-clinical testing included the following: endurance testing of the device from sit-to-stand mode and cyclic walking, structural analysis of the frame, battery testing, electrical safety testing, electromagnetic compatibility and interference (EMC/EMI) testing, flammability testing and software testing as summarized in Table 2 below.

Electrical Safety	IEC 60601-1: 2005
Electromagnetic Compatibility	IEC 60601-1-2: 2007
Battery testing	EMC/EMI certificate
Worst Case Loading of Knee Joint	Sponsor study PT-10-06
Worst Case Loading of Hip Joint	Sponsor study PT-10-07
Structural Analysis of Frame	FEA analysis
Flammability	ISO 7176-16: 2012
Software Testing	Verification, validation & hazards analysis

Table 2: Table of Non-Clinical/Bench Tests

A. ELECTRICAL TESTING

1. ELECTRICAL SAFETY

The device was tested per IEC 60601-1: 2005 (3rd edition) and IEC 60601-1-2: 2007. The device was in conformance with the standard and passed applicable sub-clauses.

2. ELECTROMAGNETIC COMPATIBILITY (EMC)

Testing was performed to address EMC concerns for this device which is intended to be used in a wide variety of use environments (institutional and non-institutional). The device was tested per IEC 60601-1-2: 2007. The device was evaluated per the IEC 60601-1-2 criteria, and the device was tested at higher levels for non-institutional use: specifically electrostatic discharge at (b)(4) TS/CCI air discharge, power frequency magnetic field at (b)(4) TS/CCI and radiated RF at (b)(4) TS/CCI

EMC labeling, as necessary to claim compliance with IEC 60601-1-2, has been included in the User manuals. This includes tests at higher test levels than the recommended hospital environment.

3. **BATTERY TESTING**

Battery testing was conducted to show the device is sufficiently able to detect when the battery is low on capacity. Low battery testing demonstrated adequate detection of a low battery. The battery is in a low battery state when it has ~15 minutes of life left. The device has an alarm to advise the user the device is low on power.

B. DURABILITY TESTING

PT-10-06 Worst-Case Loading of Knee Joint (Sit-To-Stand)

To assess the ability of the ReWalk™ to meet the intended working life of 5 years, the device was cyclically tested for 73,000 cycles under a worst-case load of 100 kg. This was determined through the assumption that the device would undergo ~20 chair rising and sitting motions per day for 5 years (36,500 cycles) with a safety factor of 2.

Two devices were tested and each completed the 73,000 cycles without any structural failures of the device. There were failures of the device becoming "stuck" in an inoperable state; however, this was deemed acceptable by providing the user appropriate instructions in the labeling in how to recover when the device is "stuck."

PT-10-07 Worst-Case Loading of Hip Joint (Gait)

To ensure that the ReWalk™ will be capable of meeting the system specifications for the intended 5-year working life, additional bench tests evaluated cyclical testing of the hip joints using a "gait" cycle. It is assumed that the device will undergo 1 million gait cycles per year. The sponsor conducted an "accelerated" testing cycle that corresponded to 6 million gait cycles (safety factor of 1.8). This accelerated testing cycle used a load greater than the maximum load recommended for daily use to represent a worst case scenario. A combination of tension bands and aluminum blocks were attached to the legs to create a 7 Amp (A) load on the electric hip motors.

Two devices were tested and each completed over 1,000,000 cycles at the higher current to represent a greater number of cycles without a mechanical failure. Any device failures regarding the initial battery set-up during the test were adequately addressed by the sponsor.

Structural Analysis

A finite element structural analysis of the ReWalk™ exoskeleton to provide validation that the mechanical components, when subjected to the repeated loads of daily use, would not fracture, deform, or fail in such a way as to render the device dangerous to the user was provided.

For purposes of this analysis, the sponsor configured the system to the largest size possible: widest pelvic section (370mm), longest thigh section (480mm), and longest calf section (470mm) to represent a worst case scenario. The materials modeled are: cast aluminum, tempered aluminum, and tempered steel. The sponsor has provided adequate analysis to show that the frame would not fracture, deform, or fail after repeated loads of daily use.

C. THERMAL TESTING

The sponsor provided testing of the fabric materials for the backstrap material, which is closest to the battery and tested it per ISO 7176-16: 2012.

The sponsor also provided information showing that the user's skin would not receive excessive heat from the DC motors. Temperature limits are below that specified in IEC 60601-1:2005. That is acceptable.

D. SOFTWARE

The software/firmware was reviewed according to the "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices," dated May 11, 2005.

The device software consisted of proprietary software. The software was reviewed and the provided documentation was found adequate and consistent with a "MODERATE" level of concern (as defined in the referenced FDA guidance document).

All software was appropriately validated.

E. BIOCOMPATIBILITY/MATERIALS

The components that are in direct skin contact are identified in Table 3. The sponsor noted that the padding would not come into contact with the patient's skin as it is intended to be worn over clothing. Additionally, the patient contacting materials in the ReWalk™ are well characterized in prosthetic applications and an assessment was deemed adequate to ensure sufficient biocompatibility to minimize any potential risk to the patient.

Component	Description
Communication Strap	(b)(4) TS/CCI
Communication Housing	(b)(4) TS/CCI plastic

Table 3: Materials of patient contact

F. SHELF LIFE/STERILITY

Neither the device nor any of the components are provided sterile, which is acceptable for the ReWalk™. The device is intended only for external use and the User Manual includes appropriate cleaning instructions for the device.

ReWalk™ does not have a stated shelf life, which based upon the nature of the device components is acceptable.

The sponsor stated a service life of five years is to be expected based on the cyclic testing of the device in sit-to-stand mode and for cyclic walking.

G. PERFORMANCE TESTING – BENCH

- Abuse testing (consolidation of shock and impact testing) was included (and done according to several sections of IEC 60601-1-11 2010 and IEC 60601-1:2005 Sec. 15.3).
- IP22 testing was documented and done according to the requirements of IEC 60529.

All results demonstrated acceptable performance.

H. MAGNETIC RESONANCE (MR) COMPATIBILITY

The ReWalk™ device system has not been tested for MR compatibility. The following has been included as part of the labeling for ReWalk™

"The Argo ReWalk™ should be removed before entering an MR scan room or having an MR scan. The Argo ReWalk™ has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of Argo ReWalk™ in the MR environment is unknown. Scanning a patient who has this device may result in patient injury. Contact with or being in proximity to an MR scanner may cause the exoskeleton to move or lead to electric shocks and may result in patient injury."

The mitigations and measures identified above are appropriate for the ReWalk™.

SUMMARY OF CLINICAL INFORMATION

A. STUDY 1: PERFORMANCE EVALUATION OF REWALK RECIPROCATING GAIT ORTHOSIS (PILOT STUDY)

1. Design: open label, non-comparative, non-randomized trial.

2. Population: Subjects with a complete motor (ASIA Scale A-B) cervical (C7-C8) or thoracic (T1-T12) spinal cord injury (SCI) that were between 18 and 55 years of age, at least 6 months post injury, using a Reciprocating Gait Orthosis (RGO) or Knee Ankle Foot Orthosis (KAFO) or standing device regularly, height between 160 to 190 cm (5'3" to 6'3"), with a weight less than 100kg (220lbs) were eligible for enrollment. Subjects were excluded for: neurological injuries other than SCI, severe concurrent medical diseases, severe spasticity (Ashworth ≥4), unstable spine, unhealed fractures, heterotopic ossification, significant contractures, and psychiatric or cognitive situations that may interfere with the study.

3. Methods: Subjects who met screening criteria were trained using the ReWalk™ device for approximately 24, 60 - 90 minute sessions over the course of approximately 8 weeks. The target training interval was 3 times per week. When training was completed, the subjects underwent a performance evaluation that consisted of a 6 minute test walk, a 10

meter test walk, and a stand-to-sit test. The subject's pulse and blood pressure were measured at the beginning and end of each session. In addition, evaluation of Ashworth scale, Visual Analog Scale (VAS) pain, VAS fatigue, and skin and joint integrity were performed at the beginning and end of each session. The primary outcome measures were the 10 meter walk test (10MWT) and the 6 minute walk test (6MWT). The secondary outcome measure reported was the Ashworth scale. No statistical analysis was performed and no calculation of sample size was completed.

4. Results: A total of 7 subjects were enrolled in the study. Six subjects completed the 6MWT and 10MWT. For the 6MWT, subjects were able to ambulate a distance of 10 to 79 meters. For the 10MWT, subjects completed 10 meters in a time that ranged from 40 to 163 seconds. Four of the six subjects had no change in average Ashworth scale and 2 subjects had a decrease in average Ashworth scale. Two subjects sustained one hematoma each. One subject sustained 5 skin lesions, 2 subjects sustained 4 skin lesions for a total of 13 skin lesions in 3 of the six subjects. No falls were reported.

5. Additional Observational Data:
   Table 4 below shows the number of times each subject ambulated on smooth surfaces, carpet, and concrete.

Subject	Smooth surface	Carpet	Concrete
1001	3	0	15
1002	3	0	21
1003	3	0	10
1004	3	0	21
1005	3	0	5
1006	0	0	1
1007	2	0	1
1008	3	0	4

Table 4: Number of times ambulated on each surface

B. STUDY 2: PERFORMANCE EVALUATION OF REWALK RECIPROCATING GAIT ORTHOSIS (MULTI-CENTER STUDY)

1. Design: Open, non-comparative, non-randomized trial at 2 sites, Moss Rehab and Centro Villa Beretta

2. Population: Subjects with a complete motor (ASIA Scale A-B) cervical (C7-C8) or thoracic (T1-T12) SCI that were between 18 and 55 years of age, at least 6 months post injury, using a Reciprocating Gait Orthosis (RGO) or Knee Ankle Foot Orthosis (KAFO) or standing device regularly, height between 160 to 190 cm (5'3" to 6'3"), with a weight less than 100kg (220lbs) were eligible for enrollment. Subjects were excluded for: neurological injuries other than SCI, severe concurrent medical diseases, severe spasticity (Ashworth ≥4), unstable spine, unhealed fractures, heterotopic ossification, significant contractures, and psychiatric or cognitive situations that may interfere with the trial.

3. Methods: Subjects who met screening criteria were trained using the ReWalk™ device for approximately 16 - 24, 60 – 90 minute sessions over the course of approximately 8 weeks. The target training interval was 3 times per week. When training was completed, the subjects underwent a performance evaluation that consisted of a 6 MWT, a 10MWT, and a stand-to-sit test. The subject's pulse and blood pressure were measured at the beginning and end of each session. In addition, evaluation of Ashworth scale, VAS pain, VAS fatigue, and skin and joint integrity were performed at the beginning and end of each session. The primary outcome measures were the 10MWT and the 6MWT. The secondary outcome measure reported was the Ashworth scale. No statistical analysis was performed and no calculation of sample size was completed.

4. Results: Of 24 subjects, results for 20 subjects were provided for the 6MWT. The subjects ambulated from 0 meters to 100+ meters in 6 minutes. For the 10MWT, 22 subjects ambulated 10 meters in 10 seconds to 100+ seconds. Of 24 subjects, the results for 13 subjects were provided for the Ashworth Spasticity scale; 8 subjects had no change in average Ashworth Scale, 1 subject had an increase in average Ashworth Scale, and 4 subjects had a decrease in average Ashworth Scale. Of 24 subjects, results for 20 subjects were provided for the 6MWT. The subjects ambulated from 0 to 100+ meters in 6 minutes. For the 10MWT, 22 subjects ambulated 10 meters in 10 to 100+ seconds. Of 24 subjects the results for 13 subjects were provided for the Ashworth Spasticity scale; 8 subjects had no change in average Ashworth Scale, 1 subject had an increase in average Ashworth Scale, and 4 subjects had a decrease in average Ashworth Scale. There were six incidents of skin tears in 5 subjects, three incidents of bruising in 2 subjects, one subject sustained 1 incident of a blister, and one subject sustained lower extremity edema. No falls were reported.

   Figure 8 below shows ten meter time and six minute distances for the recorded thoracic injury levels.

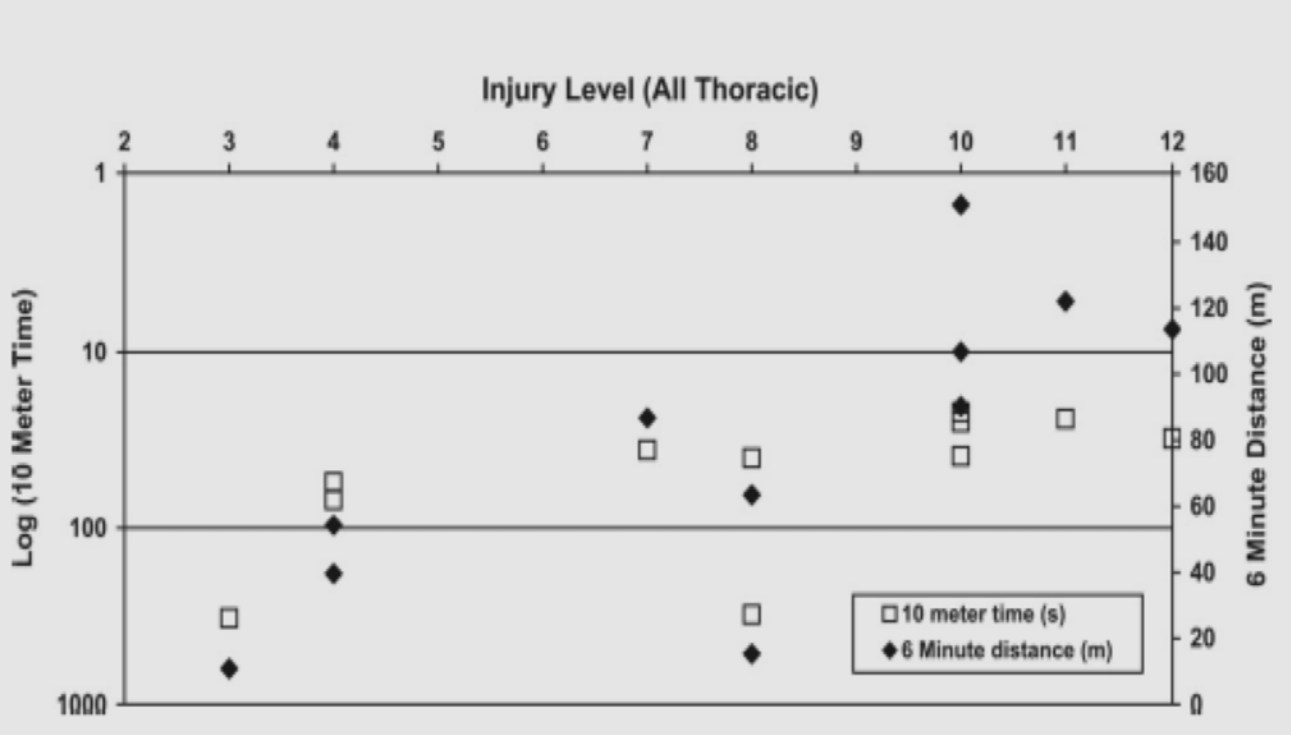

Figure 6: Velocity and distance performance by level of injury (Moss Rehab)

5. Additional Observational Data:
   Table 5 below shows the number of times each subject ambulated on smooth tile, rough tile, ceramic tile, carpet, concrete/asphalt, bricks, grass, ramp up, ramp down, curb cutout up, and curb cutout down.

Subject	Smooth tile	Rough tile	Ceramic tile	Carpet	Concrete/ asphalt	Bricks	Grass	Ramp up	Ramp down	Curb cutout up	Curb cutout down
2001	33	0	0	0	0	0	0	0	0	0	0
2002	19	0	0	0	0	0	0	0	0	0	0
2003	15	0	0	0	0	0	0	0	0	0	0
2004	14	0	0	0	0	0	0	0	0	0	0
2005	24	0	0	0	0	0	0	0	0	0	0
2006	22	0	0	0	0	0	0	0	0	0	0
2007	9	0	0	0	0	0	0	0	0	0	0
2008	21	0	0	0	0	0	0	0	0	0	0
2009	21	0	0	0	0	0	0	0	0	0	0
2010	23	0	0	4	4	0	4	4	4	4	4
2011	20	0	0	0	0	0	0	0	0	0	0
2012	23	0	0	1	1	0	1	1	1	1	1
2013	24	0	0	8	8	0	8	8	8	8	8
2014	15	0	0	0	0	0	0	0	0	0	0
2015	24	0	0	10	10	0	10	0	0	0	0
3001	21	3	0	0	0	0	0	0	0	0	0
3002	Did	Not	qualify								
3003	22	1	0	0	0	0	0	0	0	0	0
3004	Did	Not	qualify								
3005	22	0	1	0		0	0	0	0	0	0
3006	26	1	1	3	0	0	0	1	1	0	0
3007	11	0	0	0	0	0	0	0	0	0	0
3008	9	0	0	1	0	0	0	0	0	0	0
3009	20	0	0	0	0	0	0	0	0	0	0
3010	Did	Not	qualify								
3011	2	0	0	0	0	0	0	0	0	0	0
3012	11	0	0	0	0	0	0	0	0	0	0
3013	18	0	0	0	0	0	0	0	0	0	
3014	11	0	0	2	1	1	0	1	1	0	0
3015	No	Data	provided								
3016	Did	Not	Qualify								
3017	No	Data	provided								

Table 5: Number of times each subject ambulated on each surface

C. Study 3: Exoskeletal-Assisted Walking for Persons with Motor-Complete Paraplegia[1]

1. Design: Single group, pre/post intervention pilot study performed to determine the number of sessions and level assistance needed to perform standing, walking, and stair climbing skills in the exoskeleton ReWalk™. Note – stair climbing is not a feature of the ReWalk™ device in the United States.

2. Population: A convenience sample of motor-complete paraplegia (T1- T12) subjects between 18 and 65 years of age with greater than 6 months elapsed since their initial SCI, who were between 160 and 190 cm in height, weighed <100 kg, and had the ability to provide their own consent, were included. Potential participants were excluded if they had any of the following: Diagnosis of another neurological injury or disease other than SCI, had a lower extremity fracture in the past 2 years, a knee (femoral neck or proximal tibia) bone mineral density (BMD) <0.70 gm/cm2, a hip T-score <-3.0, severe spasms defined as an Ashworth score of 4.0, flexion contractures limited to 35º at the hip and 20º at the knee, diagnosis of severe lower extremity heterotopic ossification limiting range of motion in the hip or knee joints, atherosclerosis, congestive heart failure, history of myocardial infarction, hypertension (systolic >140 and diastolic >90 mmHg blood pressure), trunk or lower extremity pressure ulcer, pregnant or lactating females, and/or had a severe concurrent medical disease, illness, systemic or peripheral infection, psychopathology, or other condition that the study physician, in his or her clinical judgment, considered to be exclusionary to safely participate. Of the 12 potential participants screened, 5 were excluded: 2 for low BMD, 1 for a medical condition and 2 were not able to participate due to their work schedules.

3. Methods: The study group participated in 3 sessions per week of 1 to 2 hours per session for an average of 45 +/- 20 sessions. The subjects were fitted for the device and then progressed through functional skills starting with sit-to-stand, standing balance, stand-to-sit, and finally to stepping and walking. The primary functional skills were the 10 10MWT, the 6MWT, and walking pivot turns. The secondary functional skills were arresting gait on command, maneuvering to a wall rest, walking on carpet, navigating a push button electric door, navigating a revolving door, outdoor ambulation, and stairs. Linear regression was used to determine the relationship between best distance or velocity walked and duration and level of injury

4. Results: The subjects ambulated from 50.5 to 166 meters in 6 minutes. For the 10MWT, 7 subjects ambulated 10 meters in 20 to 62 seconds. Three of the seven subjects sustained mild skin abrasions and two of the seven subjects sustained moderate skin abrasions. No falls were reported. Table 6 below shows ten meter time and six minute distances for the recorded thoracic injury levels and contains the level of assistance

[1] Spungen, A., Asselin, P., Fineberg, D., Kornfield, S., & Harel, N. (2013). Exoskeletal-assisted walking for persons with motor-complete paraplegia. *Force Sustainment: Rehabilitation, Regeneraton and Prosthetics for Re-integration to duty*. Meeting Proceedings STO-MP-HFM-228, Paper 6. Neuilly-sur-Seine, France:STO. Available from: http://www.cso nato.int/Pubs/rdp.asp?RDP=STO-MP-HFM-228

needed to accomplish the functional skill listed. Stair climbing and curbs are not features of the device in the United States. Additional retrospective data from this study was provided in a separate master file, which was also reviewed to support this *de novo*.

SID#	Standing Skills		Walking Skills		Total number of sessions
	Sessions	Level of Assist	Sessions	Level of Assist	
1	1 to 2	Mod assist	5 to 10*	Mod assist	70 (20*)
2	1 to 2	CCG/NA	10 to 15	CCG/NA	25
3	1	Min assist	5 to 10	CCG/NA	64
4	1	Min assist	<5	CCG/NA	43
5	1	Min assist	10 to 15	CCG/NA	49
6	1 to 2	Min assist	10 to 15	Min assist	15
7	1 to 2	Mod assist	10 to 15	Mod assist	38

Table 1: Number of sessions and Level of Assist[2]

Abbreviations/definitions: SID# = study identification number. Mod assist = moderate assistance; trainer has both hands on subject at all times and assists with balance but not weight bearing. CCG/NA=close contact guard/no assistance; trainer is not touching subject but is there to lend hand if needed. Min Assist=minimal assistance; trainer has one hand on subject for balance. Standing skills: sit-to-stand, double and single arm crutch standing balance, weight shifts, and standing pivot turns. Walking skills: walk 10 meters and pivot turns in both directions. Stair skills: ascend and descend 5 steps.
*Represents the number of sessions after start up and staff learning curve for the first subject to complete the skills.

TRAINING

Training is a critical and required component of appropriate utilization and progression to higher degrees of proficiency for ReWalk™ usage. Patients and their caregivers must undergo training developed by the manufacturer to learn and demonstrate proper use of the ReWalk™ device. The sponsor has proposed the following training program, which is a tier-based system (Table 7), with the following skills identified for beginner, advanced and companion skills (Tables 8 & 9, 12 & 13). Prior to moving to another level of proficiency, the ReWalk™ User needs to demonstrate sufficient proficiency utilizing a scoring metric as summarized in Tables 10 & 11.

[2] Spungen, A., Asselin, P., Fineberg, D., Kornfield, S., & Harel, N. (2013). Exoskeletal-assisted walking for persons with motor-complete paraplegia. *Force Sustainment: Rehabilitation, Regeneraton and Prosthetics for Re-integration to duty*. Meeting Proceedings STO-MP-HFM-228, Paper 6. Neuilly-sur-Seine, France:STO. Available from: http://www.cso nato.int/Pubs/rdp.asp?RDP=STO-MP-HFM-228

It should also be noted that the ReWalk™ is currently indicated for usage only with supervision of a specially trained companion in accordance with the user assessment and training certification program.

Tiers	Rehabilitation		Rehabilitation Inside/Outside		Home and two blocks		Limited Community ambulation
Location	Institutional (use) inside only	Level 1 Certification test	Institution (inside and outside)	Level 2 Certification test	Interior Structure use / Institutional use and defined external use	Level 3 Certification test	Community Ambulation
Supervision	Therapist or trainer		Therapist or trainer		Companion or (Therapist or Trainer)		Companion
Training	Learn Basic skills training		Refine Basic skills and learn advanced skills		Refine advanced skills		Complete
Companion (Buddy) Training*	Companion learns skills		Companion skills demonstrated; no further training		N/A		N/A
Post Market Registry	Yes		Yes		Yes		Yes

Table 7: Proposed training tiers

Skills	Score	Comments
Independent manual joint adjustment		
Rises from chair unassisted		
Stand		
Walk		
Walking speed – 0.15 m/s		
Turns		
Left		
Right		
Reverse direction		
Threshold		

Stopping		
Sit in chair unassisted		
Safety features		
Graceful collapse		
By pass mode		
General knowledge of equipment		

Table 8: Basic Skills Evaluation Form

Ambulatory Environment	Skill	Surface	Score	Comments
Community	10 M walk – 0.4 M/s	Concrete / Asphalt		
		Dry, even Surface		
		Mild Irregular / slope		
	6 Minute walk 110 M min	Concrete / Asphalt		
		Mild Irregular / slope		
	Ramp	Interior		
		Concrete		
Interior	Close Quarter maneuvering	Interior		
	Elevator	Interior		
	Electric Door	Interior		

Table 9: Advanced Skills Evaluation Form

Score	Score[1]	What this means
Pass	5 or greater	Task completed with supervision, or independently
Pass with difficulty	4	Minimal Assist required
Fail	< 4	Task incomplete or unsafe

Table 10: Scoring options for individual skills [1].Scoring performed using FIM scoring criteria

Score	Description
Independent	
7	Complete Independence
6	Modified Independence (patient requires use of a device, but no physical assistance)
Modified Dependence	
5	Supervision or Setup (user can perform task without any assistance, companion only provides close contact assistance
4	Minimal Contact Assistance (patient can perform 75% or more of task)
3	Moderate Assistance (patient can perform 50% to 74% of task)
Complete Dependence	

2	Maximal Assistance (patient can perform 25% to 49% of tasks)
1	Total assistance (patient can perform less than 25% of the task or requires more than one person to
0 Activity does not occur	

Table 11: FIM Scoring Criteria – for ReWalk device

Topics	Skills	Score	Comments
Knowledge of device	Functions		
	Troubleshooting		
	Warnings		
	Maintenance		
Safe practices for ReWalk functions	Don / Doff		
	Sit		
	Stand		
	Walk		
Supervising ambulation	sidewalks		
	Dry, even surfaces		
	curb cutouts		
	Carpet		
	thresholds		
	ramps/ slopes		
Safety	Surfaces		
	Skin inspection		
	Alerts and warnings		
	ByPass mode		
	Graceful Collapse		

Table 12: Companion Skills Evaluation form

Score	Score[1]	What this means
Pass	2	The companion fully understands the function or key aspects of the skill.
Pass with difficulty	1	The companion understands the function or key aspect of the skill, but with prompting.
Fail	0	Task incomplete or unsafe.

1. Scoring to be performed using the FIM scoring Criteria.

Table 13: Companion Skills Evaluation form

POSTMARKET TESTING

A postmarket surveillance study, utilizing the statutory authority in Section 522, is being required because this device is a class II device and its failure would be reasonably likely to have serious adverse health consequences. Failure of the ReWalk™ to prevent a fall would be reasonably likely to cause user injury through fall related sequelae such as traumatic brain injury (TBI), spinal cord injury (SCI), and fractures to the user, which meets the definition of "serious adverse health consequences" per 21 C.F.R. § 822.3(j). In addition, during intervention due to a loss of balance of the patient, the device may potentially harm a 'companion'.

The postmarket clinical study will consist of a registry to collect data on adverse events related to the use of the ReWalk™ device and prospectively and systematically assess the adequacy of the training program.

LABELING

Labeling has been provided and reviewed considering the Guidance on Patient Labeling and is readable and understandable. Symbols used are verbally described in the beginning of the User Guide. In addition, labeling was checked according to IEC 60601-1:2005.

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].

Labeling includes a clinician training poster, the Basic Clinical Training Certification Course, Clinical Competency checklist, the Clinical Competency Exam, and the ReWalk™ P and ReWalk™ R user guides. The Indications for Use are located in the ReWalk™ P and ReWalk™ R user guides.

RISKS TO HEALTH

Table 14 below identifies the risks to health that may be associated with use of the Powered Exoskeleton devices and the measures necessary to mitigate these risks.

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 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

Table 2: Identified Risks to Health and Mitigation Measures

SPECIAL CONTROLS:

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].

BENEFIT/RISK DETERMINATION

The risks of the device are based on non-clinical data as well as data collected from clinical studies described above. The probable risks of falls, skin injury, bruising, and hematomas with use of the ReWalk™ device are similar to other lower extremity orthotics. Additionally, users may injure themselves or their companions due to a device malfunction during normal use or while performing higher risk activities (e.g., ambulating over uneven terrain).

The probable benefits of the ReWalk™ device are also based on non-clinical data as well as data collected from clinical studies described above. The probable benefit of the ReWalk™ is the ability to stand up and walk which is currently only available with functional electrical stimulation and body weight support treadmill walking.

The probable risks are falls, changes in blood pressure (diastolic hypertension and hypotension) and heart rate, skin abrasions, bruising, pressure sores, increased spasticity, lightheadedness, and soft tissue injury.

In conclusion, given the available information, the data support that for the use of the ReWalk™ for individuals with spinal cord injury at levels T7 to L5 and individuals with spinal cord injury at levels T4 to T6 to perform ambulatory functions in rehabilitation institutions the probable benefits outweigh the probable risks. The device provides benefits, and the risks may be mitigated by the use of general and the identified special controls, including post-market surveillance.

CONCLUSION

The *de novo* for the ReWalk™ device is granted and the device is classified under the following:

Product Code: PHL
Device Type: Powered Exoskeleton
Class: II
Regulation: 21 CFR 890.3480