June 3, 2019

ReWalk Robotics Ltd.
Ofir Koren
General Manager, VP R&D and Regulatory Affairs
3 Hetnufa St., POB Box- 161
Yokneam, 2069203 Israel

Re: K190337
Trade/Device Name: ReWalk Restore
Regulation Number: 21 CFR 890.3480
Regulation Name: Powered Lower Extremity Exoskeleton
Regulatory Class: Class II
Product Code: PHL
Dated: March 4, 2019
Received: March 5, 2019

Dear Ofir Koren:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal

statutes and regulations administered by other Federal agencies. You must comply with all the 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Vivek Pinto, PhD
Assistant Director, Acute Injury Devices Team
DHT5B: Division of Neuromodulation
and Rehabilitation Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K190337

Device Name
ReWalk Restore

Indications for Use *(Describe)*
The ReWalk ReStore is intended to be used to assist ambulatory functions in rehabilitation institutions under the supervision of a trained therapist for people with hemiplegia/hemiparesis due to stroke who can ambulate at least 1.5m (5ft) with no more than minimal to moderate levels of assistance. The trained therapist must successfully complete a training program prior to operating the device. The device is not intended for sports or stair climbing.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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ReStore™
510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR §807.92

1. **Submission Sponsor**
   ReWalk Robotics Ltd.
   3 Hatnufa St.
   Yokneam, Israel
   2069203, POB: 161
   Establishment Registration: 3007615665

2. **Submission Correspondent**

   Ofir Koren, General Manager, VP R&D and Regulatory Affairs

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3. **Date Prepared:**
   June 3, 2019

4. **Device Identification**

Name of Device:	ReWalk ReStore™
Classification Name:	Powered Exoskeleton
Regulation:	21 CFR §890.3480
Regulatory Class:	Class II
Product Classification Code:	PHL
Classification panel**:**	Neurology

5. **Legally Marketed Predicate Device**

Predicate Manufacturer:	Parker Hannifin Corporation
Predicate Trade Name:	Indego®
Predicate 510(k):	K173530

6. **Device Description**

   The ReWalk ReStore™ ("ReStore™") device is a lightweight, wearable, battery-powered soft orthotic exosuit is intended to be used to assist ambulatory functions in rehabilitation institutions under the supervision of a trained therapist for people with hemiplegia/hemiparesis due to stroke.

   The ReStore™ device is designed to provide plantarflexion (PF) and dorsiflexion (DF) assistance to the paretic ankle during walking by transferring mechanical forces from two motors mounted on a Waistpack through Bowden cables to attachment points worn on the calf and insole. Through a set of gears, the motors actuate the Bowden cables to provide plantarflexion and dorsiflexion forces. Forces are transferred through the Bowden cables by pulling an inner cable within an outer sheath. The distal end of the outer sheath is fixed at an attachment point worn on the Calf Wrap, and the distal end of the inner cable is fixed at an attachment point worn on an insole made of flexible plastic that is worn within the shoe on the paretic foot. The relative motion that occurs between these two points when the inner cable is moved results in torques being applied across the ankle joint. The

placement of the attachment points anterior and posterior to the ankle joint result in corresponding torques to provide assistance during dorsiflexion and plantarflexion, respectively. Load cells attached to the cables provide force feedback allowing control of the level of assistance provided to the patient. Sensors attached to the shoes are used to detect gait events during walking to inform timing of the assistance from the ReStore™ device. Specifically, inertial measurement units (IMUs) are attached to shoes on both legs to provide signals corresponding to events within the gait cycle, such as heel-strike or toe-off, in order to determine the appropriate timing of assistance from ReStore™.

The ReStore™ is designed to provide adjustable levels of assistance to the patient's paretic leg. It does not constrain or provide assistance to the patient's non-paretic leg. The device enables the therapist to individually modify the level of assistance provided during plantar- and dorsiflexion as appropriate for each individual patient. The timing of assistance is based on data collected from the motion sensors on both the paretic and non-paretic feet, which determines the patient's orientation within their gait cycle.

Plantarflexion assistance occurs during the late stance and toe-off portion of the paretic leg gait cycle. This level of assistance targets a desired cable force, which can be adjusted from 0% to 25% of the patient's body weight. Dorsiflexion assistance occurs during the swing and heel-strike phase of the paretic gait cycle. This level of assistance targets a desired cable travel, which can be adjusted from 0 cm to 5 cm. Plantarflexion and dorsiflexion assistance levels are determined by the therapist based on visual evaluation of the patient's gait symmetry, the therapeutic goals of the walking session or the ability of the patient to achieve consistent ground clearance or heel-strike landing patterns with their paretic foot. The ReStore™ device includes apparel-like components, mechanical components, electrical components, cables, sensors and a handheld controller.

Table 1: (System Modes)

Mode Name	Mode Description
Assist Mode (dynamic ankle assistance)	A mode in which the cables provide assistance for ankle plantar and dorsiflexion during forward walking on level ground (treadmill or over ground). The level of assistance provided by the device can be adjusted by the therapist.
Slack Mode (no assistance)	A mode in which the cables are positioned so as to not provide any resistance to movement by the subject during his/her full range of movement.
Brace Mode (fixed ankle position)	A mode in which the cables are retracted in a configuration that restricts the ankle movement in the plantar and/or dorsiflexion directions to maintain ankle position.

During treadmill walking with ReStore™ in Slack Mode, no assistance is provided by ReStore. Patients should be evaluated for their baseline treadmill walking ability, and overhead harnessing, body weight support, or the integrated ReStore™ Support Handle should be used for safety if determined appropriate by the therapist.

7. Intended Use / Indication for Use

The ReWalk ReStore is intended to be used to assist ambulatory functions in rehabilitation institutions under the supervision of a trained therapist for people with hemiplegia/ hemiparesis due to stroke who can ambulate at least 1.5m (5ft) with no more than minimal to moderate levels of assistance. The trained therapist must successfully complete a training program prior to operating the device. The device is not intended for sports or stair climbing.

8. Substantial Equivalence Discussion

The following table compares the ReStore™ to the predicate device with respect to indications for use, principles of operation, technological characteristics, materials, and performance. The comparison of the devices in Table 2 below provides more detailed information regarding the basis for the determination of substantial equivalence. The subject device does not raise any new or different questions of safety or effectiveness based on the similarities to the predicate device.

Table 2: (Substantial Equivalence Discussion)

Characteristic	Parker Hannifin Corporation Indego®	ReWalk Robotics Ltd. ReStore™	SE Justification
510(k) number	K173530	K190337	N/A
Product Code	PHL	PHL	Same
Regulation Name	Powered Exoskeleton	Powered Exoskeleton	Same
Regulation No.	890.3480	890.3480	Same
Indication for Use	The Indego® orthotically fits to the lower limbs and trunk. The device is intended to enable individuals with spinal cord injury at levels T3 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 C7 to L5 to perform ambulatory functions in rehabilitation institutions in accordance with the user assessment and training certification program. Finally, the Indego® is also intended to enable individuals with hemiplegia (with motor function of 4/5 in least one upper extremity) due to cerebrovascular accident (CVA) to perform ambulatory functions in rehabilitation institutions in accordance with the user assessment and training certification program. The Indego is not intended for sports or stair climbing.	The ReWalk ReStore is intended to be used to assist ambulatory functions in rehabilitation institutions under the supervision of a trained therapist for people with hemiplegia/ hemiparesis due to stroke who can ambulate at least 1.5m (5ft) with no more than minimal to moderate levels of assistance. The trained therapist must successfully complete a training program prior to operating the device. The device is not intended for sports or stair climbing.	Comparable - The intended use of enabling individuals to perform ambulatory functions in rehabilitation institutions is the same. Indego® has broader indications, namely for individuals with spinal cord injury in addition to individuals with hemiplegia (with motor function of 4/5 in least one upper extremity) due to cerebrovascular accident (CVA). The ReStore™ indications are a subset of these indications (individuals with hemiplegia due to stroke). This difference does not raise any new or different questions of safety or effectiveness, as is demonstrated by clinical data.

Characteristic	Parker Hannifin Corporation Indego®	ReWalk Robotics Ltd. ReStore™	SE Justification
Patient Population	Individuals with hemiplegia (with motor function of 4/5 in at least one upper extremity) due to cerebrovascular accident (CVA)	Individuals with hemiplegia / hemiparesis due to stroke	Similar – Both devices are indicated for use by individuals with hemiplegia (hemiparesis which is subset of Hemiplegia is also included in ReStore™). ReStore™ does not require use of upper extremity mobility aids. Indego® inherently requires use of mobility aides like crutches for support, and thus requires motor function of 4/5 in at least one upper extremity. This similarity does not raise any new or different questions of safety or effectiveness, as is demonstrated by clinical data.
Device construction and materials	The Indego® device is composed of rigid frame and textile strapping providing body weight support to the patient	ReStore™ device is composed of textile frame and strapping worn by patient	Different - ReStore™ provides the ankle joint with assistance without supporting the patient, while the Indego® provides assistance within a rigid body supporting frame. Both frames enable transfer of mechanical forces from motors and gears (based on data obtained from sensors) to the wearer. This similarity does not raise any new or different questions of safety or effectiveness, as is demonstrated by clinical data.
Body Coverage	Worn over legs and around hips and lower torso	Worn over legs and around lower torso	Similar – ReStore™ provides assistance to paretic ankle joint, while Indego® provides assistance to knee and hip joints, thus the difference in body coverage. This similarity does not raise any new or different questions of safety or effectiveness, as is demonstrated by clinical data.

Characteristic	Parker Hannifin Corporation Indego®	ReWalk Robotics Ltd. ReStore™	SE Justification
Size of Components	Modular small, medium and large upper leg, lower leg and hip components and control unit integrated into hip unit	Modular small, medium, large and extra-large paretic leg component, control unit (waistpack) integrated into adjustable waist belt	Similar - Both devices utilize similar component sizes. This similarity does not raise any new or different questions of safety or effectiveness, as is demonstrated by clinical data.
Mobility Aid	Walker, cane or crutches	Walker, cane, crutches, harness or overhead support	Similar – Mobility aides are required for use of Indego®. Use of mobility aides for ReStore™ is per therapist discretion. This similarity does not raise any new or different questions of safety or effectiveness, as is demonstrated by clinical data.
Ability of User Mobility	Sit, stand, walk and turn	Sit, stand, walk and turn	Same
Walking Speed	~2 km/hr.	Up to 5km/hr.	Different - Both devices utilize upper limit for walking speed. The ReStore™ maximum supported speed is higher, however the gait algorithm provides consistent force and timing profiles to support wearer's natural walking speed. This difference does not raise any new or different questions of safety or effectiveness, as is demonstrated by clinical data.
Type of Surface	Smooth, grass, cement, carpet, transitions, thresholds	In the clinical trial ReStore™ was tested under the following conditions: Treadmill: Assist Mode Level Indoor Floor: All modes (Assist, Brace, and Slack mode)	Different - ReStore™ can be used on treadmills as well. The device can be used on indoor only, on surfaces including carpeting and hard floors or even surfaces. This difference does not raise any new or different questions of safety or effectiveness, as is demonstrated by clinical data.

Characteristic	Parker Hannifin Corporation Indego®	ReWalk Robotics Ltd. ReStore™	SE Justification
Control Method	Uses postural cues and user motion to trigger all transitions	Uses patient gait motion to trigger assistance	Similar - Both devices are activated by user motion. This similarity does not raise any new or different questions of safety or effectiveness, as is demonstrated by clinical data.
Patient height/weight	61" to 75" (155 to 191 cm) Up to 250 lbs. (113kg)	56" to 75.5" (142 to 192cm) Up to 264 lbs. (120kg)	Similar - Both devices support similar range of height/weight of patient. This similarity does not raise any new or different questions of safety or effectiveness, as is demonstrated by clinical data.
Range of Motion	Hip:110° flexion to 30° extension Knee: 110° flexion to 10° extension	Axial forces applied to the ankle joint corresponding to wearer's ankle joint range of motion	Similar - Both devices utilize assistance to the patient gait cycle by allowing movement within the joint's range of motion. This similarity does not raise any new or different questions of safety or effectiveness, as is demonstrated by clinical data.
Use environment	Rehabilitation institutions	Rehabilitation institutions	Same
Device weight	26 lbs. (11.6 kg)	11 lbs. (5 kg)	Different - ReStore™ weighs less than the Indego® device. The relatively low weight of the ReStore™ minimally affects the patient's balance. This difference does not raise any new or different questions of safety or effectiveness, as is demonstrated by clinical data.
Rechargeable Battery	Rechargeable lithium ion. 33.3 V, 36A peak current, 12A continuous current. 159Wh fully charged; 1.5 hours of continuous walking fully charged	Two off-the-shelf rechargeable lithium ion batteries: 15.0 VDC x 2 (total voltage = 30 VDC) 3.2 AH, 48Wh. Minimum 2 hours continuous walking fully charged	Similar - Both devices utilize the same battery technology and provide similar use duration.

Characteristic	Parker Hannifin Corporation Indego®	ReWalk Robotics Ltd. ReStore™	SE Justification
Battery Charge Time	Maximum of 4 hours	Maximum of 2 hours	Similar - Charge time difference between the devices does not raise questions of safety and effectiveness
Training and Certification Program (Clinical Use)	A thorough training program that provides certification is required for clinicians before using Indego® with patients	A thorough training program providing certification is required for clinicians before using ReStore™ with patients	Same
Expected Useable Life	5 years with proper servicing	3 years with proper servicing	Similar - Expected useable life difference between the devices does not raise questions of safety and effectiveness
User Feedback	Provides vibratory feedback and LED indicators on top of hip unit, visible to wearer	Provides audible feedback to therapist and wearer in addition to visual feedback via Handheld Device and LED indicators on Waistpack unit visible to therapist.	Similar - Both devices provide visual feedback to the therapist, audible or vibratory feedback to the wearer. This similarity does not raise any new or different questions of safety or effectiveness, as is demonstrated by usability and clinical data.
Fall Detection and Mitigation	Detects forward, backward and sideways falling as it occurs. The device makes adjustments during the course of the fall to position the user for minimal risk of injury or allow the user to attempt unassisted recovery	Therapist support handle on Waistbelt for therapist to provide support in case of patient loss of balance. In addition, non-paretic leg is unconstrained and free to move at all times to allow the user to attempt unassisted recovery.	Different - ReStore™ usage is accompanied by a therapist which when observes the patient loss of balance can support the patient using the Therapist support handle. This difference does not raise any new or different questions of safety or effectiveness, as is demonstrated by usability and clinical data.

Characteristic	Parker Hannifin Corporation Indego®	ReWalk Robotics Ltd. ReStore™	SE Justification
Failsafe Feature	In the event of power failure knees become locked and hips free (similar to typical passive leg braces)	In the event of most error statuses, ReStore™ defaults to brace mode and holds the cables with the ankle in a neutral position (similar to typical passive ankle foot orthoses). In the event of sudden, unexpected power failure, Bowden cables loosen and ankle joint can move freely	Similar -Similar to the predicate device, the ReStore™ defaults to a fixed position at the relevant joint during most error conditions. In the specific event of an unexpected power failure, this controlled cable movement is not possible, so the system instead releases the cables to allow the patient full range of motion for recovery. Minor differences between failsafe features are considered within ReWalk's risk management and mitigations have been demonstrated by usability and clinical data. The ReStore™ Waist Belt is designed with an integrated support handle, and a precaution regarding the use of overhead harnessing with patients requiring significant assistance or support from the Physical Therapist to ambulate short distances is intended to mitigate this risk and ensure safe and appropriate use of ReStore™.
Operating Temperature	32° to 104°F (0° to 40° C)	41° to 86°F (+5° to 30°C)	Similar – ReStore™ fits operating conditions expected in its use environment (indoors).
Operating Humidity	30% - 75% relative humidity	15% to 90% non-condensing	Similar – ReStore™ fits a wider range humidity conditions
Electrical Safety Testing	Passed ANSI/AAMI ES60601-1:2005/(R)2012	Passed ANSI/AAMI ES60601-1:05+A1:12:C1:09+A2:10	Same
Electromagnetic Compatibility Testing	Passed IEC 60601-1-2:2014	Passed IEC 60601-1-2:2014	Same
Handheld Device	Handheld Device is used for controlling and configuring through BT communication	Handheld Device is used for controlling and configuring through BT communication	Same
Wireless communication	Bluetooth Low Energy using 2.4 GHz industrial, scientific, and medical radio band	Bluetooth Low Energy using 2.4 GHz industrial, scientific, and medical radio band	Same

Characteristic	Parker Hannifin Corporation Indego®	ReWalk Robotics Ltd. ReStore™	SE Justification
Drive mechanisms	Batteries, motors, gears, frame and strapping	Batteries, motors, gears, strapping and Bowden cables	Similar - Operating principle is performed by cables or structure applying appropriate force to achieve joint rotation. This similarity does not raise any new or different questions of safety or effectiveness, as is demonstrated by usability and clinical data.
Alignment (between user and device)	Alignment of hip, knee and ankle joints with strap mechanism attached to device frame	Alignment of user to device with soft shell calf strap and attachment points within the shoe	Similar - Alignment between user and device achieved by straps preventing sliding or misalignment of wearer and maintaining tightness. ReStore™ straps are attached to a soft structure and Indego® straps to a rigid structure. This similarity does not raise any new or different questions of safety or effectiveness, as is demonstrated by usability and clinical data.
Mechanical user interface	Device attached to user with strapping mechanism	Device attached to user with strapping mechanism	Same
Assistance method	Motors/gears moving rigid frame to rotates/moves hip and knee joints	Motors/gears pulling Bowden cables to rotate/move paretic ankle joint	Similar - Both devices use mechanical assistance to facilitate joint rotation. ReStore™ delivers assistance to the ankle joint while the Indego® delivers assistance to the knee and hip joints (ankle is supported by AFO). This similarity does not raise any new or different questions of safety or effectiveness, as is demonstrated by usability and clinical data.

Characteristic	Parker Hannifin Corporation Indego®	ReWalk Robotics Ltd. ReStore™	SE Justification
Biocompatibility	None	Calf Wrap Liner: Surface device - contact with intact skin (calf) for limited time duration ≤ 24 hours).In compliance with ISO 10993-1, 5 and 10	Different - ReStore™ device utilizes Calf Wrap liner applied directly on skin of wearer's paretic leg calf. This difference does not raise any new or different questions of safety and effectiveness, as demonstrated by a 3rd party Biocompatibility testing & risk assessment."
System modes	Sit, Stand and Walk	Assist, Slack and Brace	Different- Differences reflect that Restore™ is intended for a subset of the Indego® population, i.e., stroke patients only.

Characteristic	Parker Hannifin Corporation Indego®	ReWalk Robotics Ltd. ReStore™	SE Justification
Clinical study general information	30 subjects Multisite (7) clinical trial Duration: approx. 2 weeks Number of visits: 5 Primary endpoint: Assess the safety of the device during gait rehabilitation activities in post-stroke individuals undergoing physical therapy. Secondary endpoints: 1. Functional ambulation category; 2. Gait Speed, as measured via 10 meter walk test 3. Spasticity of bilateral upper and lower extremities as measured with Modified Ashworth Scale (MAS) 4. Pain measured with Face, Legs, Activity, Cry, Consolability Scale (FLACC)	44 subjects Multisite (5) clinical trial Duration: approx. 4 weeks. Number of visits:7 Primary endpoint: Assess device safety during gait rehabilitation activities in post-stroke individuals undergoing physical therapy. Secondary endpoints: 1. Device reliability 2. Device safety for Physical Therapist. Exploratory endpoints 1. 10m walk assessments. 2. Temporal/spatial measures of gait 3. 2 minute walk tests in 3 modes. 4. Subject satisfaction 5. Physical Therapist satisfaction	Similar - Both studies apply to acute, sub-acute and chronic as well as mild, moderate and severe stroke populations. Both studies have same primary outcome - safety measure, and similar secondary/ exploratory outcome measures concerning how well each device supports ambulatory functions.

9. Non-Clinical Performance data

Comprehensive bench testing has been performed on the ReStore™ device to confirm that it meets design inputs and specifications for the device, to demonstrate substantial equivalence to the predicate device and to demonstrate safety and effectiveness. These tests include nonIclinical performance testing, EMC/EMI testing, biocompatibility testing and electrical safety testing.

The test results show that the ReStore™ device meets all design requirements and is in compliance to all applicable standards and regulations including special controls in 21CFR890.3480.

These tests include the following:

Table 3: (Non-clinical Performance Data)

Test	Test description	Result
Mechanical performance	Evaluate mechanical components ability to withstand applied loads (static and cyclic) throughout device lifecycle while ensuring system accuracy and precision performance is maintained during operation and post-fatigue	PASS
Mechanical analysis	Evaluate adequate safety margin between clinically expected loads and failure loads on system load-bearing components throughout device lifecycle	PASS
Battery performance and safety testing	Evaluate battery performance and safety under maximum load conditions, charging time and high current safety disconnection	PASS
Apparel performance	Evaluate apparel component ability to withstand applied loads static and cyclic (Durability) and cleanability throughout device lifecycle	PASS
Motion performance simulation and testing	Motion performance simulation and testing to evaluate frequency response motion latency and accuracy of the device.	PASS
Weight distribution and center of mass analysis	Evaluate Center of Mass of the Restore™ waist pack and related implications on the Restore™ patient	PASS
Wireless performance and coexistence using FDA guidance AAMI TIR 69	Evaluate wireless technology, service quality, security, and electromagnetic compatibility (EMC)	PASS
Environmental using ASTM D4169 ASTM D4332	Environmental testing conformance to standards, accompanied by certificate	PASS
Usability using FDA guidance and IEC 62366-1	Demonstrate that when used after training by intended users in the appropriate use environment, the device can be used safely and effectively without producing failure pattern that could result in negative	PASS

Test	Test description	Result
	clinical impact, injury to patients and users or device damage	
Software verification and validation using FDA Guidances IEC 62304 and AAMI TIR 57	The device meets design and cybersecurity requirements	PASS
Electrical safety using ANSI AAMI ES 60601-1	Conformance to electrical safety standards, accompanied by certificate	PASS
Electromagnetic compatibility using IEC 60601-1-2	Conformance to electromagnetic compatibility standards, accompanied by certificate	PASS
Biocompatibility using FDA guidance, ISO 10993-1/5 and 10	GLP, Conformance to biocompatibility standards	PASS

10. Clinical Performance Data

Three IRB-Approved protocols have been conducted in individuals with hemiplegia / hemiparesis resulting from Stroke. These studies consist of one 44 subject multi-site clinical trial and two engineering studies. The primary endpoint for the multi-site clinical trial was to demonstrate the safety of the ReStore™ device when used during gait training activities for individuals with hemiparesis / hemiplegia resulting from Stroke under the supervision of a trained therapist in rehabilitation institutions. Additionally, two engineering studies are ongoing at the Wyss Institute at Harvard University to develop and evaluate exosuit designs. The ReStore™ clinical validation testing was also conducted under the second engineering protocol.

10.1 44- Subject Multisite Clinical Trial

44 subjects were enrolled in a multi-site clinical trial conducted across 5 study sites. Participation consisted of 7 study visits with the ReStore™ device. All 44 subjects completed at least one study visit with the ReStore™ device, and 36 subjects completed all 7 study visits. This study was IRB-approved and conducted in accordance with principles of Good Clinical Practice (GCP). The primary endpoint for this study was to demonstrate the safety of the ReStore™ device when used during activities of gait training in rehabilitation institutions, as well as exploratory endpoints to demonstrate substantial equivalence with respect to efficacy when compared to the predicate device.

Safety was evaluated on the basis of frequency and severity of device-related adverse events, including serious adverse events and falls. There were zero device-related serious adverse events and zero device-related falls in this study. During the initial phase of the study, adverse events were reported in 13.5% of study visits. The majority of these adverse events were minor in severity and did not require intervention or follow up. The cause was determined to be related to improper donning and fitting techniques and a mandatory re-training was conducted for all study sites. Following the retraining, just one (1) device-related adverse event was reported in the remaining 75 study visits, reducing the frequency to 1.3% of study visits.

Several measures were used to evaluate subjects' walking in the study. Walking speed was measured using 10m walk tests at comfortable and maximal walking speeds, and assessments were performed during walking with and without the ReStore™ device. Additionally, subjects' 2-minute walk distances were measured in all three operational modes of the ReStore™ device: Slack (no assistance), Brace (fixed ankle position), and Assist (dynamic ankle assistance).

All subjects were able to complete some or all of the walking assessments in the ReStore™ device on their first study visit. The average duration of walking in Assist mode during gait training visits increased by 12.4% between Visit 2 (the first gait training visit) and Visit 6 (the last gait training visit).
Of the 36 subjects who completed all 7 study visits, the majority of subjects increased walking speed from Visit 1 to Visit 7. During walking with the ReStore™ device, 31 subjects (86.1%) increased comfortable walking speed and 29 subjects (80.6%) increased maximal walking speed. During walking assessments independent of the ReStore™ device, 23 subjects (63.9%) increased comfortable walking speed and 28 subjects (77.7%) increased maximal walking speed. Average walking distance during the 2-minute walk test increased by 47.9 ft. during walking with assistance from the ReStore™ device (Assist mode) compared to walking without assistance from the ReStore™ device (slack mode).

10.2 Engineering studies

Two ongoing protocols are being conducted at the Wyss Institute for Biologically Inspired Engineering at Harvard University (Cambridge, MA). These studies involve the development and testing of the ReStore™ device and other similar prototypes. Both studies are IRB approved and are being conducted according to principles of Good Clinical Practice (GCP). 35 unique participants have been enrolled in these two studies (10 participants are enrolled in both studies), and a total of 472 study visits have been conducted since the first study began enrolling in 2014. Device-related adverse events have been reported with low frequency and low severity. There are zero device-related serious adverse events and zero device-related falls reported in either study.

10.3 Clinical Validation Study

Nine (9) participants were enrolled in a ReStore™ validation substudy conducted under the Engineering Protocols above. The purpose of this study was to validate the ReStore™ design as well as to assess the safety and the use of the ReStore™ device during common activities of Physical Therapy. One device-related adverse event was encountered in this substudy which was resolved on its own without intervention or complications. There were zero device-related serious adverse events and zero device related falls reported in this substudy.

10.4 Summary of Clinical Performance Data

A total of 79 individuals with hemiparesis / hemiplegia resulting from stroke have completed a combined 740 study visits with the ReStore™ device or a similar prototype. All three studies have demonstrated that the ReStore™ is safe and well tolerated by individuals post-stroke and is appropriate for use during ambulatory functions in rehabilitation settings under the supervision of a trained therapist for people with hemiplegia/hemiparesis due to stroke.

Table 4: Summary of IRB-Approved ReStore™ Studies

Trial	Number of Subjects	Number of Sessions per Subject	Total Sessions
44-Subject Multisite Clinical Trial	44	7	268
Clinical Validation Study[1]	9	1	9
Engineering Studies (1 & 2)	35	Variable	472
Total	**79**	**Variable**	**740**

[1] Clinical Validation Testing was conducted as a subset of Engineering Study 2 (Wyss Study IRB16-1845) so totals from this study do not contribute to overall totals.

11. Statement of Substantial Equivalence

The ReStore™ and the predicate legally marketed device (Indego®) have the same intended use and similar indications for use (a subset of the predicate indications). In addition, both devices have similar technological characteristics. Finally, clinical and non-clinical performance data are similar as well.

The differences in the above mentioned characteristics do not raise any new or different questions of safety or effectiveness, thus the ReStore™ is substantially equivalent to its predicate device.