DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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September 8, 2017

Parker Hannifin Corporation
% Audrey Swearingen
Director Regulatory Affairs
Emergo Global Consulting, LLC
2500 Bee Cave Rd, Bldg 1, Suite 300
Austin, Texas 78746

Re: K171334
Trade/Device Name: Indego®
Regulation Number: 21 CFR 890.3480
Regulation Name: Powered Lower Extremity Exoskeleton
Regulatory Class: Class II
Product Code: PHL
Dated: August 8, 2017
Received: August 11, 2017

Dear Ms. Swearingen:

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. 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); 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 Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Vivek J. Pinto -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K171334

Device Name
Indego®

Indications for Use *(Describe)*
The Indego® orthotically fits to the lower limbs and the 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. The Indego 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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Indego®

K171334

1. Submission Sponsor

Parker Hannifin Corporation

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3. Date Prepared

September 8, 2017

4. Device Identification

Trade/Proprietary Name: Indego®

Common/Usual Name: Powered Exoskeleton

Classification Name: Powered lower extremity exoskeleton

Regulation Number:	890.3480
Product Code:	PHL
Device Class:	Class II
Classification Panel:	Neurology

5. Legally Marketed Predicate Devices

Primary Predicate: K152416, Indego®, Parker Hannifin Corporation

K161443, Ekso™, Ekso Bionics

6. Device Description

Parker Hannifin's Indego® device is a wearable powered exoskeleton that actively assists individuals to stand and walk; these are patients with walking impairments resulting from lower extremity weakness or paralysis. The Indego consists of snap-together components weighing 26 pounds total. The hip component houses a rechargeable battery pack, central processor, and Bluetooth radio, while each upper leg component houses two motors as well as embedded sensors and controllers.

On-board microprocessors receive signals from integrated sensors which provide information on the user's posture and tilt. This allows the device to function in a manner similar to the Segway personal mobility device, which is controlled by the user's tilt. A user similarly controls the motions of the Indego by means of postural changes (e.g., to walk forward, the user just leans forward). The technology of the design links the low weight and low profile to advanced battery technology (smaller size), motors (smaller and more powerful), and micro controllers (state-of-the art). Visual cues from the LED lights on the hip and vibratory feedback inform both the patient and therapist or trained support person of the status and mode of operation.

The Indego controls are self-contained, with forearm crutches or a walker used solely for stability. Users can perform sit-to-stand and stand-to-sit transitions and walk along even or uneven terrain up to about five degree (5°) grades. Taller torso "wings" are provided to support users who may need additional trunk support while walking. A physical therapist can configure, operate, and monitor the device during therapy and training to make adjustments as needed. This is achieved through the support of a wireless application that will run on mobile/wifi connected smart devices such as an iPod or iPhone. The patient and physical therapist will be able to work in concert to achieve the actions of transitioning from sitting to standing, standing to walking, stop walking, and return from standing to sitting. The untethered, free roaming design of the device will allow it to be utilized in multiple indoor and outdoor locations in either a rehabilitation setting with a certified Indego Specialist or a personal setting with a trained support person.

7. Indication for Use Statement

The Indego® orthotically fits to the lower limbs and the 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 trained support person 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. The Indego is not intended for sports or stair climbing.

8. Substantial Equivalence Discussion

The Indego clinical data supporting these expanded indications for use (rehabilitation and personal) and substantial equivalence to the predicate devices comes from five sources; a 16-subject Pilot Study, a 45-subject Multi-Site Trial, postmarket clinical data (37 subjects), a 4-subject Personal Use Training Program Study and postmarket personal use data (5 subjects). A comparison of this data to that of the predicate device, which demonstrates that Indego Specialists are successfully working with patients with SCI C7 to L5 ASIA A, B, C or D, can be found in Table 5A below.

Table 5A – Comparison of Clinical Data

Summary of Ekso Data (taken directly from K143690 clearance letter dated April 1, 2016)	Summary of Indego Data
Study 1: • 44 subjects total • C1-L2 • ASIA A, B, C, D • Total sessions: ~1188	Study 1: (Pilot Study) • 16 completed subjects total • C5-L1 • ASIA A, B, C • Total sessions: 80
Study 2: • 12 subjects total • C7-L1 • ASIA A, B • Total sessions: ~288	Study 2: (Multi-Site Trial) • 45 completed subjects total • T3-L3 • ASIA A, B, C • Total sessions: 1215
	Postmarket clinical data: • 37 subjects total • C2-T6 • ASIA A, B, C, D • Total sessions: 313
	Study 3: (Personal Use Training Program Study) • 4 personal user and support person teams • T8 – T10 • ASIA A and C • 40 hours of training per team
	Postmarket personal use data • 5 personal user and support person teams worldwide (none of whom participated in Study 3) • T4 – L1 • ASIA A and C • 40 hours of training per team • 1 additional user (SCI T12 A) and support person have begun the Indego Personal Use Training Program and have so far completed approximately 30 hours of training
TOTAL SCI SUBJECTS: **56** **TOTAL SESSIONS:** **1476** **SCI LEVEL:** **C1-L2** **ASIA RANGE:** **A, B, C, D**	**TOTAL SCI SUBJECTS:** **107** **TOTAL SESSIONS:** **1608** **SCI LEVEL:** **C2-L3** **ASIA RANGE:** **A, B, C, D** **Personal Use Training Hours:** **390** **Combined months of Indego Personal Use in home & community settings with trained support person:** **38**

Table 5B below compares the subject Indego to the predicate devices with respect to indications for use, principles of operation, technological characteristics, materials, and performance. The comparison of the devices found in Table 5B provides more detailed information regarding the basis for the determination of substantial equivalence. The subject device does not raise any new issues of safety or effectiveness based on the similarities to the predicate devices.

Table 5B – Comparison of Characteristics

Manufacturer	Parker Hannifin Corporation	Parker Hannifin Corporation	Ekso Bionics	Significant Differences
Trade Name	Indego®	Indego®	Ekso ™	
510(k) Number	TBD	K152416	K161443	N/A
Product Code	PHL	PHL	PHL	Same
Regulation Number	890.3480	890.3480	890.3480	Same
Regulation Name	Powered Exoskeleton	Powered Exoskeleton	Powered Exoskeleton	Same
Indications for Use	The Indego® orthotically fits to the lower limbs and the 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. The Indego is not intended for sports or stair climbing.	The Indego® orthotically fits to the lower limbs and the trunk; the device 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 Indego is not intended for sports or stair climbing.	The Ekso™ (version 1.1) and Ekso GT™ (version 1.2) are intended to perform ambulatory functions in rehabilitation institutions under the supervision of a trained physical therapist for the following population: • Individuals with hemiplegia due to stroke (upper extremity motor function of at least 4/5 in at least one arm) • Individuals with spinal cord injuries at levels T4 to L5 (upper extremity motor function of at least 4/5 in both arms) • Individuals with spinal cord injuries at levels of C7 to T3 (ASIA D with upper extremity motor function of at least 4/5 in both arms). The therapist must complete a training program prior to use of the device. The devices are not intended for sports or stair climbing.	Comparable. The intended use of enabling individuals with SCI to perform ambulatory functions under supervision are the same among the subject and predicate devices. The expanded indications of use in additional SCI levels are shared with the Ekso device. Parker Hannifin does not include the ASIA D limitation because the Indego® has been used successfully with these higher injury levels without respect to ASIA level. Parker Hannifin placed the responsibility for evaluating patients' upper extremity motor function on the prescribing physician and requires the patient to exhibit sufficient upper body strength to use forearm crutches, front wheeled walker, or platform walker stability aid. The expanded indications for use of the Indego are supported by the clinical study data provided and clinical training protocol tested and utilized, and do not raise any new questions for safety and effectiveness.

Manufacturer	Parker Hannifin Corporation	Parker Hannifin Corporation	Ekso Bionics	Significant Differences
Trade Name	Indego®	Indego®	Ekso ™	
Body Coverage	Worn over legs and around hips and lower torso	Worn over legs and around hips and lower torso	Worn over legs and upper body with rigid torso	Same as the Indego predicate; Similar to the Ekso - the components of the Indego are worn around the legs and torso with the control unit integrated into the hip piece. Ekso has separate backpack control units.
Size of Components	Modular Small, Medium and Large upper leg, lower leg and hip components; control unit integrated in hip unit	Modular Small, Medium and Large upper leg, lower leg and hip components; control unit integrated in hip unit	Adjustable upper leg, lower leg and hip width; control unit integrated into rigid torso piece	Same as the Indego predicate; Similar to the Ekso - all three units have upper leg, lower leg and hip component. Ekso has rigid torso piece.
Mobility Aid	Walker, cane or crutches	Walker, cane or crutches	Walker, cane or crutches	Same
Ability of User Mobility	Sit, stand, walk and turn	Sit, stand, walk and turn	Sit, stand, walk and turn	Same
Walking Speed	~2 km/hr	~2 km/hr	~2 km/hr	Same
Type of Surface	Smooth, grass, cement, carpet, transitions, thresholds	Smooth, grass, cement, carpet, transitions, thresholds	Smooth, cement, carpet	Same as the Indego predicate; Similar to the Ekso - Indego provides more ground clearance than Ekso.
Control Method	Uses postural cues to trigger all transitions	Uses postural cues to trigger all transitions	Handheld interface for PT; weight shift to initiate steps	Same as the Indego predicate; Similar to the Ekso - movement is activated by user.
Range of Motion	Hip: 110° flexion to 30° extension Knees: 110° flexion to 10° extension	Hip: 110° flexion to 30° extension Knees: 110° flexion to 10° extension	Hips: 135° flexion to 20° extension Knees: 130° flexion to 0° extension Ankles: 10° flexion to 10° extension	Same as the Indego predicate; Similar to the Ekso

Manufacturer	Parker Hannifin Corporation	Parker Hannifin Corporation	Ekso Bionics	Significant Differences
Trade Name	Indego®	Indego®	Ekso ™	
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	Rechargeable lithium ion. 33.3 V, 36A peak current, 12A continuous current. 159Wh fully charged; 1.5 hours of continuous walking fully charged	Rechargeable lithium ion batteries 48.1V, 30A peak current, 1 hour of continuous usage per charge	Same as the Indego predicate; Similar to the Ekso
Battery Charge Time	Maximum of 4 hours	Maximum of 4 hours	1 hour	Same as the Indego predicate; Similar to the Ekso
Training and Certification Program (Clinical Use)	Yes; a thorough training program that provides certification is required for clinicians before using Indego with patients	Yes; a thorough training program that provides certification is required for clinicians before using Indego with patients	Yes	Same as the Indego predicate; similar to the Ekso - the subject Indego will require clinicians to pass the same strict competencies as the predicate Indego before being cleared to work with patients in the device.
Training and Certification Program (Personal Use)	Yes; a comprehensive training program requires personal users to achieve Minimal Assist or less (FIM Score of 4 or higher) for all Indego skills including donning and doffing, walking inside and outside and walking over ramps with their support persons before being cleared to use Indego in the home and community	Yes; a comprehensive training program requires personal users to achieve Minimal Assist or less (FIM Score of 4 or higher) for all Indego skills including donning and doffing, walking inside and outside and walking over ramps with their support persons before being cleared to use Indego in the home and community	No	Same as the Indego predicate; different from the Ekso – identical to the predicate Indego, the subject Indego will require that personal users in the expanded indications for use population pass the same set of strict competencies with the same assistance requirement of Minimal Assist or less (FIM score of 4 or higher) from their support persons. The Ekso is not currently approved for use outside the rehabilitation setting.
User Feedback	Provides vibratory feedback and LED indicators on top of hip unit, visible to wearer	Provides vibratory feedback and LED indicators on top of hip unit, visible to wearer	Provides visual feedback on the handheld controller and auditory feedback	Same as the Indego predicate; Similar to the Ekso

Manufacturer	Parker Hannifin Corporation	Parker Hannifin Corporation	Ekso Bionics	Significant Differences
Trade Name	Indego®	Indego®	Ekso ™	
Fall Detection and Mitigation	Detects forward, backward and sideways falling as it is happening; the device makes adjustments during the course of the fall to position the user for minimal risk of injury	Detects forward, backward and sideways falling as it is happening; the device makes adjustments during the course of the fall to position the user for minimal risk of injury	None	Same as the Indego predicate; Different to the Ekso - Indego methods help reduce risk of injury to the user.
Failsafe Feature	In the event of power failure knees become locked and hips free (similar to typical passive leg braces)	In the event of power failure knees become locked and hips free (similar to typical passive leg braces)	In the event of power failure knees become locked and hips free (similar to typical passive leg braces)	Same
Electrical Safety Testing	Passed ANSI/AAMI ES60601-1:2005/(R)2012	Passed ANSI/AAMI ES60601-1:2005/(R)2012	IEC 60601-1:2005 with US deviations	Same
Electromagnetic Compatibility Testing	Passed IEC 60601-1-2:2007	Passed IEC 60601-1-2:2007	Passed IEC 60601-1-2:2007	Same

9. Non-Clinical Performance Data

As part of demonstrating safety and effectiveness of the Indego device and in showing substantial equivalence to the predicate devices, Parker Hannifin completed a number of tests. The Indego device meets all requirements for design characteristics, non-clinical performance testing, and electrical safety/EMC testing to confirm that the output meets the design inputs and specifications for the device.

- Maximum Torque Testing: verify the maximum continuous and peak torques that are applied at the knees and hips measured in Nm against defined specifications: **PASS**
- Cleaning Chemical Compatibility Testing: verify the integrity of the structural plastics with no significant degradation over five (5) year time period through routine cleaning of the device: **PASS**
- Component Life Cycle Testing: verification that the device meets the requirements for the major mechanical subsystems to perform safely during the expected use between routine servicing in simulated normal use: **PASS**
- Durability Testing: verify the device meets the factor of safety designated by the IEC 60601-1 requirements for any mechanical hazards that require the support system maintaining structural integrity and does not decrease over simulated lifetime of use of the device: **PASS**
- Battery Life Cycle Testing: testing performed for the batteries being cycled through normal use including measuring the full charge amount, capacity of battery, and cycle life over defined periods according to the specification for the battery: **PASS**
- Storage and Transport Testing: to support that the device is protected and not damaged during normal, routine shipping according to ISTA standards for drop, compression, and vibration: **PASS**
- Software verification and validation testing per FDA Guidance and IEC 62304: conformance of software development life cycle for the Indego Software System and compliance to the requirements of the FDA guidance document for software contained in a medical device.
- Electrical safety testing per ANSI/AAMI ES60601-1: **PASS**
- Electromagnetic compatibility testing per IEC 60601-1-2: **PASS**

10. Clinical Performance Data

10.1 Rehabilitation Use Data

Clinical Indego usage data from 98 subjects in over 1,600 sessions has been gathered and analyzed. Sixty-three of these patients were SCI T6 or higher and completed 823 sessions. The remaining 35 individuals had injury levels of T7 or lower and completed 828 sessions. There are three sources for the reported clinical data; the Pilot Study, the Multi-Site Clinical Trial and postmarket clinical data.

10.1.1 Pilot Study

A 2014 pilot study involving 16 SCI subjects evaluated proficiency and ease of learning to use the

Indego in a clinical setting. The study was Investigational Review Board (IRB) approved and performed in compliance with Good Clinical Practices (GCP). Informed consent was obtained from each subject prior to participation. The injury levels of the subjects enrolled ranged from C5 to L1 with 10 subjects having T7 and lower injury level, 3 with T3-T6 SCI and 3 with T2 and higher SCI.

The primary objectives of the pilot study were to:

- Evaluate the ease of learning to use the Indego
- Measure proficiency using standard mobility outcomes including the 10 Meter Walk Test (10 MWT) and 6 Minute Walk Test (6 MWT).

All 16 subjects successfully learned to use the Indego within five 90 minute sessions. In addition to all participants managing a variety of inside and outside surfaces, most were also able to ambulate over five degree ramps. An average walking speed of 0.34 m/s was accomplished in the 10 Meter Walk Test and all subjects were able to complete the 6 Minute Walk Test. Two minor adverse events were reported; one instance of bruising that was resolved in 4 days and one case of grade 1 skin redness that cleared up in 2 days. No serious adverse events were reported.

10.1.2 Multi-Site Clinical Trial

A multi-site clinical study conducted in 2015 assessed the mobility of 45 persons with SCI ranging from levels T3 to L2 while using Indego. The study was performed in compliance with GCP, the protocol was IRB approved and subjects were consented before participating.

The study objectives were defined as the following:

- Demonstrate that the Indego device is both safe and effective for the intended use for patients with SCI who are non-ambulatory or poorly ambulatory to stand up and walk under a variety of conditions.
- Demonstrate that the average walking speed for persons with SCI using the Indego device with stability aid will be equal to or greater than 0.31 m/s for indoor surfaces.

A total of 45 subjects completed all required 27 study sessions which included introduction, evaluation, training with the device, assessments and various outcome measurements. Twenty four of the 27 sessions included walking in the Indego. The statistical plan was descriptive in nature to test the hypothesis that the Indego system will consistently enable legged mobility for the intended population of non-ambulatory or poorly ambulatory patients. Interviews and assessments were conducted throughout the study and outcome measurements were recorded at the beginning, mid and end points.

The key outcomes measurements for the clinical study are summarized as follows:

- The average speed for the indoor 10 Meter Walk Test (10 MWT) at the end of the study for subjects with injury levels T3-T6 was 0.35 ± 0.10 m/s and 0.38 ± 0.08 m/s for participants T7 and lower SCI. Both the lower and higher injury level groups had an average Functional Independence Measure Gait (FIM) Score of 4 for the 10 MWT corresponding to minimal

contact assistance where the Indego Specialist would have only provided occasional balance support to the user. Subjects were also asked to attempt a 600 Meter Walk Test (600 MWT) at the end of the study. One hundred percent of the participants with injury levels T3-T6 were able to complete the test and 92% of the T7 and lower SCI group were able to do the same.

- The Timed Up and Go (TUG) test measured the ability of the subjects to stand up, walk 3 meters, turn, walk 3 meters back, turn and sit down. Both the T3-T6 and T7 and lower injury level groups were able to perform these activities with an average FIM score of 4, i.e. minimal contact from the Indego Specialist, in a comparable amount of time.
- Walking Index for Spinal Cord Injury (WISCI) Scores, which measure the amount of assistance an individual with SCI needs to ambulate, were also recorded for all subjects. At the end of the study, both the T3-T6 and T7 and lower injury level groups had an average WISCI score of 7 ± 1.1 and ± 1.8, respectively, indicating that both groups required about the same amount of assistance using the Indego. A WISCI score of 7 corresponds to walking in the Indego with a rolling walker or forearm crutches and physical assistance of 1 person.

Out of over 1,200 total study sessions completed, there were 46 trial-related Adverse Events (AE) and 0 (zero) Serious Adverse Events (SAE). Of the 46 trial-related AE's, 20 were known to be device related. These 20 included minor instances of bruising, redness, abrasion, and swelling, as well as one instance of a rolled ankle. The causes of these events were all determined to be related to improper fitting or improper padding except for one case of minor abrasion which was related to a padding malfunction.

The study concluded that the Indego device is safe and effective for its intended use and the outcomes of the trial met the stated objectives.

10.1.3 Postmarket Clinical Data

Several of Parker Hannifin's clinical partners were asked to provide Indego usage data for individuals with SCI levels T6 and above. Shepherd Center, Sheltering Arms Physical Rehabilitation Centers and Craig Hospital contributed data for a total of 37 patients in 313 Indego therapy sessions with injury levels ranging from C2 to T6. Twenty four of the 37 C2 to T6 SCI patients have AIS A or B injury.

All 37 subjects had blood pressure readings within functional limits during their sessions and no falls were reported. Of these 37 individuals, 19 were able to walk outside, and some even did so in their first Indego session. Sixteen of these 37 patients had SCI from T3-T6 and 62.5% of this injury level group walked outside. Nine of the 16 subjects with T3-T6 SCI had a reported FIM score of 4 or higher, corresponding to Minimal Assistance, for using Indego. There were two reported safety issues in the postmarket clinical data. One instance of "sit to therapist knee" was noted where a patient stopped for a rest break after walking approximately 75 feet and triggered a stand to sit transition after an accidentally leaning backwards. The patient was able to sit onto the therapist's knee and no injury occurred. Another subject experienced a lateral loss of balance. The therapist was able to help with patient catch their balance and return to a standing position. The session then resumed without incident.

The combined data from the 16-subject pilot study and the 45-subject multi-site clinical trial shows

comparable outcomes between higher and lower level of SCI groups. Neither of these studies identified any additional safety concerns for using the Indego in injury level groups above T6. The submitted postmarket clinical data also demonstrates the success that individuals with injury levels T6 and above can achieve while using Indego.

10.2 Personal Use Data

10.2.1 Personal Use Training Program Study

Four subjects with injury levels T8 A, T10 C, T10 A and T10 A and their support persons successfully completed a 2015 research study designed specifically to evaluate the adequacy and success of the Indego Personal Use Training Program. Users and their support persons completed a 40-hour Personal Use Training Program within a rehabilitation setting. Training included users and their support persons walking with Indego over both indoor surfaces and outdoor surfaces (e.g. grass, ramps, sidewalks). Users were also required to use Indego in an apartment setting to practice activities of daily living (e.g. washing dishes, cooking and folding laundry). All user and support person teams were required to pass competencies similar to those required for current Indego Personal users. At the completion of this study, subjects were asked to rate their Indego training. They responded that they felt the Personal Use Training Program was adequate and they were confident in their ability to use the Indego with their support person. Seven minor Adverse Events were reported in the course of this study including skin redness, a swollen knee, skin lesions, bruising and an involuntary bowel movement. All Adverse Events were resolved by the end of the study and no Serious Adverse Events occurred.

10.2.2 Postmarket Personal Use Data

There are currently 5 trained Indego personal users worldwide. One of these individuals is a European user with an injury level of T4 A. The other 4 are from the United States and have injury levels of T7 A, T7 C, L1 C and T10 C. All five personal users were contacted and asked to complete a questionnaire about their Indego training. All five users indicated that their training translated well to using the Indego in their homes and communities with their support persons. These teams have all reported using the Indego in their home for activities of daily living in addition to walking over various indoor and outdoor surfaces following their completed training. One instance of a fall has been noted by a personal user and support person team. It was reported that one of the user's forearm crutches slipped out of their hand and as their support person was bending down to retrieve it, the user lost their balance and fell. No injuries occurred. No other falls, Adverse Events or Serious Adverse Events have been reported.

Thoracic SCI patients with injuries ranging from T2 to T12 have sensory innervation and full muscle strength bilaterally in their upper extremities. So, the neurological level of injury for these individuals is determined only by the most caudal level of intact sensation and not by muscle preservation. The literature [1], [2] shows that patients with spinal cord injury levels ranging from T2 to T9 can achieve similar levels of function post SCI, and the clinical data provided for Indego is further support.

Because there is much variation in functionality post SCI among different injury levels, clinical presentation is important in determining if a patient is appropriate for Indego. Therefore, the current comprehensive clinical evaluation will continue to be required for all new users of the Indego.

All Indego user and support person teams must pass strict competencies to be cleared for home and community use of the device. These requirements include passage of competency skills with Minimal Assist or less, corresponding to a Functional Independence Measure (FIM) score of 4 or higher, and these specifications will not be relaxed for the inclusion of the expanded indications for use population. This will ensure that there are no additional risks and no increased burden of assistance on the trained support person for users with T3 and lower SCI. There are currently five trained and approved personal users. In a previous research study, four personal users and support persons completed the Indego Personal Use Training Program for the purpose of assessing its efficacy. In addition to all 9 of the individuals who have already successfully completed and passed the Indego Personal Use Training Program, 75 of the 98 patients in the combined Indego clinical data achieved the personal use competency requirement of a FIM score of 4 or higher. There were 39 clinical subjects with injury levels T3-T6 and of these 39, 32 required only Minimal Assist or less (FIM score of 4 or higher).

Personal users have reported using the Indego in their homes for activities of daily living as well as walking over a variety of outdoor surfaces including sidewalks, gravel, streets, grass and ramps after completing the Indego Personal Use Training Program in the clinic. Of the 98 subjects represented in the combined clinical data, 80 have walked outside in the Indego.

The Indego 522 Postmarket Surveillance Study (PS160003) which monitors the effectiveness of the rehabilitation and personal use training programs and safety of using the device in the home and clinic is in progress. Any new Indego user and support person teams who purchase a device for home use from the expanded indications for use population will be enrolled and monitored as part of this study. The first Indego 6-Month Interim Postmarket Surveillance Study report was submitted on time to the FDA and deemed adequate by the agency.

11. Statement of Substantial Equivalence

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device. Alternatively, the device may have the same intended use but different technological characteristics and it can be demonstrated that the new device is substantially equivalent and does not raise additional questions regarding its safety and effectiveness as compared to the predicate device(s).

Based on the data, the subject Indego is determined to be substantially equivalent to the previously cleared Indego and Ekso predicate devices.

12. References

[1] Lee, B.A., Leiby, B.E. and Marino, R.J. (2016) Neurological and functional recovery after thoracic spinal cord injury. The Journal of Spinal Cord Medicine.

[2] McKinely, W. (2015) Functional Outcomes per Level of Spinal Cord Injury. Medscape.