January 31, 2018

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

Re: K173530
Trade/Device Name: Indego®
Regulation Number: 21 CFR 890.3480
Regulation Name: Powered lower extremity exoskeleton
Regulatory Class: Class II
Product Code: PHL
Dated: November 14, 2017
Received: November 15, 2017

Dear Audrey 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 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)*
K173530

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. Finally, the Indego® is also intended to enable individuals with hemiplegia (with motor function of 4/5 in at 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.

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®

K173530

1. Submission Sponsor

Parker Hannifin Corporation

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2. Submission Correspondent

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3. Date Prepared

January 8, 2018

4. Device Identification

Trade/Proprietary Name:	Indego®
Common/Usual Name:	Powered Exoskeleton
Classification Name:	Powered Exoskeleton
Regulation Number:	890.3480
Product Code:	PHL
Device Class:	Class II
Classification Panel:	Neurology

5. Legally Marketed Predicate Devices

K152416/K171334, 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.

In the original operational mode of the device, called Motion+, 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). Alternatively, the device can be placed in a second operating mode, referred to as Therapy+, in which the device responds to the motion of users who are able to initiate stepping on their own. When operating in Therapy+, the user walks normally while the system detects step initiation and assists the user. Therapy+ may be used only in a clinical setting under clinical supervision. 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 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. Tall hip wings and a tall torso pad 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 allows it to be utilized in multiple indoor and outdoor locations within a rehabilitation or personal setting.

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 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 at 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.

8. Substantial Equivalence Discussion

The following table compares the Indego to the predicate devices with respect to indications for use, principles of operation, technological characteristics, materials, and performance. The comparison of the devices in Table 5A below 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 5A – Comparison of Characteristics

Manufacturer	Parker Hannifin Corporation	Parker Hannifin Corporation	Ekso Bionics	Differences
Trade Name	Indego® Subject Device	Indego® Primary Predicate	Ekso ™ Secondary Predicate	
510(k) Number	K173530	K152416/K171334	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. Finally, the Indego® is also intended to enable individuals with hemiplegia (with motor function of 4/5 in least one upper extremity) due to	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 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	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 of the Indego in individuals with hemiplegia due to CVA are shared with the Ekso device. The expanded indications for use of the Indego are also supported by the clinical study data provided, and do not raise any new questions for safety and effectiveness.

Manufacturer	Parker Hannifin Corporation	Parker Hannifin Corporation	Ekso Bionics	Differences
Trade Name	Indego® Subject Device	Indego® Primary Predicate	Ekso ™ Secondary Predicate	
	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.		program prior to use of the device. The devices are not intended for sports or stair climbing.	
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. This does not raise any new safety or efficacy questions as the component configuration is similar.
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. This does not raise any new safety or efficacy questions as the components cover mostly the same areas of the patient.

Manufacturer	Parker Hannifin Corporation	Parker Hannifin Corporation	Ekso Bionics	Differences
Trade Name	Indego® Subject Device	Indego® Primary Predicate	Ekso ™ Secondary Predicate	
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. There are no new safety or efficacy concerns as the clinical data supports walking over a wide range of surfaces.
Control Method	Uses postural cues and user motion to trigger all transitions	Uses postural cues to trigger all transitions	Handheld interface for PT; weight shift to initiate steps	Similar to the Indego predicate and Ekso - movement is activated by user. The subject Indego is activated by either postural cues or user motion depending on the profile mode. No new safety or efficacy questions are raised.
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 - Does not raise new safety or efficacy questions as Indego's clinical data supports safe use of the device for walking and sitting/ standing transitions.

Manufacturer	Parker Hannifin Corporation	Parker Hannifin Corporation	Ekso Bionics	Differences
Trade Name	Indego® Subject Device	Indego® Primary Predicate	Ekso ™ Secondary Predicate	
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 - All have rechargeable lithium batteries, but the Ekso is a slightly different type. All provide the power necessary for use of the device.
Battery Charge Time	Maximum of 4 hours	Maximum of 4 hours	1 hour	Same as the Indego predicate; Similar to the Ekso - the charge time difference does not present any new questions of safety or efficacy.
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
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 – the Ekso is not approved for personal use.

Manufacturer	Parker Hannifin Corporation	Parker Hannifin Corporation	Ekso Bionics	Differences
Trade Name	Indego® Subject Device	Indego® Primary Predicate	Ekso ™ Secondary Predicate	
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 - the Ekso offers visual and auditory feedback while Indego provides vibratory and visual cues. This difference is supported by clinical and usability data.
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 or allow the user to attempt to recover unassisted	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	Similar to the Indego predicate; Different from the Ekso - there are no additional safety concerns as 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; the Indego passed the currently recognized electrical safety standard.
Electromagnetic Compatibility Testing	Passed IEC 60601-1-2:2014	Passed IEC 60601-1-2:2014	Passed IEC 60601-1-2:2007	Both the subject Indego and predicate Indego are compatible with the latest version of IEC 60601-1-2:2014. Data for Ekso indicates compatibility with IEC 60601-1-2:2007. No

Manufacturer	Parker Hannifin Corporation	Parker Hannifin Corporation	Ekso Bionics	Differences
Trade Name	Indego® Subject Device	Indego® Primary Predicate	Ekso ™ Secondary Predicate	
				new concerns of safety or effectiveness.

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

Four Indego clinical studies have been performed in individuals with hemiplegia resulting from CVA; two 3-subject single-site pilot studies, an engineering study, and a 30-subject multisite clinical trial. The main goal of the multisite clinical trial was to show that the Indego is a safe gait training tool for individuals with hemiplegia due to CVA. The primary objective of both pilot studies was to evaluate whether the Indego could be used to improve gait parameters in subjects recovering from CVA. Additionally, an engineering study remains open to test Indego with CVA patients.

10.1 30-Subject Multisite Clinical Trial

Thirty subjects completed all six study sessions (one evaluation and five Indego training sessions) across eight clinical sites. The study was IRB approved, Good Clinical Practice (GCP) complaint and informed consent was received from all participants. Several measures were used to evaluate the quality of gait for each subject. Gait deviations, which assess a person's walking technique and the actual quality of their gait pattern, were recorded independent of the Indego in the Evaluation during Session 1 and both before and after ambulating in the Indego in Sessions 2-6. Twenty-one of 30 subjects had fewer reported gait deviations at the end of Session 6 compared to Session 1.

Data was collected from 150 Indego walking sessions, 108 of which began with unequal step length. After walking in the Indego, equal step length was reported in 26 of these 108 sessions that began with unequal step length. The average number of steps taken in the Indego increased 38% from Session 2 (the first Indego walking session) to Session 6 and the average amount of time spent walking in the Indego increased 18%. The 10MWT was used to capture walking speed independent of the Indego in Sessions 1 and 6. Twenty-three of the 30 subjects who completed the study had improved 10MWT times in Session 6.

Functional Ambulation Classification (FAC) scores measure the how independently an individual can walk. The scores range from 1, where assistance of more than 1 person is required, to 6, where the person can walk independently over level and non-level surfaces. FAC scoring criteria is shown in Table 20A below. The average FAC score across subjects was 5, corresponding to walking independently on level surfaces, and no change was observed throughout the course of the study.

There were two trial-related Adverse Events and zero trial-related Serious Adverse Events reported throughout the course of this study. The first adverse event occurred when the subject was attempting to turn in-place in the device. The subject flexed his/her knee to pivot which inadvertently triggered a stand-to-sit transition from the Indego. This caused the subject to lose his/her balance. The subject was stabilized by the physical therapists and assisted in descending to a seat. The subject was not injured. The cause of the adverse event was the unintended stand-to-sit transition. Following this event, Parker HMC developed a new sequence of events to initiate a stand-to-sit transition which includes the user or physical therapist deliberately pushing the power button to signal that they are ready to sit. This updated software was distributed to sites participating in the clinical trials beginning in May of 2017. No further events of this type were reported when using the updated software, and the issue is believed to be resolved. The second reported adverse event was a case of knee pain. The patient had a history of osteoarthritis and the physical therapist believed it was aggravated during training.

10.2 Single-Site Pilot Study 1

In the first pilot study the Vanderbilt Exoskeleton – a prototype of the Indego Exoskeleton – was used, as the Indego was not yet commercially hardened. The subjects' time since CVA ranged from 3 to 17 months, spanning the subacute and chronic stages of recovery. Each subject successfully learned to use the Indego within the first session and demonstrated improvement in gait parameters after working in the device with PT assistance. Each subject participated in three 2-hour sessions consisting of approximately 45 minutes spent walking in the Indego. Gait Speed, Asymmetry in Step Length, and Stride Length were analyzed. IRB approval was obtained for this study and informed consent was received from each subject. No adverse events were reported.

10.3 Single-Site Pilot Study 2

In the second pilot study the Indego Exoskeleton was used. The subjects' time since CVA ranged from 7 to 22 months, meaning all subjects were in the chronic phase of recovery and not expected to experience any spontaneous gait recovery. Each subject successfully learned to use the Indego within the first session and demonstrated improvement in gait parameters. Each subject participated in four 2-hour sessions consisting of 20-30 minutes walking in the exoskeleton, with time before and after the session to evaluate their gait. During these sessions, subjects used one of two different control methods for the exoskeleton, both of which proved safe and easy to use. Gait Speed and Stride Length were analyzed to determine whether the subjects were experiencing improvements in their gait parameters. Two of the three subjects experienced improvements in their gait parameters. Informed consent was obtained each subject and this study was IRB approved. There were no reported adverse events during the course of this study.

10.4 Engineering Study

Six CVA patients have completed a total of thirty sessions of experimental Indego testing at Shepherd Center (Atlanta, GA). The study is IRB approved and remains open. The purpose of the study is to trial Indego in individuals with CVA and informed consent has been obtained from each participant thus far. One adverse event, an incidence of heel discomfort, has been reported to date.

A total of 42 individuals with CVA have completed over 200 sessions in the combined four studies described above. This is summarized in Table 5B below. All four trials have demonstrated that the Indego is safe and effective when used as a gait training intervention in individuals with hemiplegia due to CVA. No additional safety concerns have been identified.

Table 5B – Summary of IRB Approved Indego CVA Clinical Trials

Trial	Number of Subjects	Number of Indego Sessions per Subject	Total Indego Sessions
30-Subject Multisite Clinical Trial	30	5	150
Single-Site Pilot Study 1	3	3	9
Single-Site Pilot Study 2	3	4	12
Engineering Study	6	Variable	30
Total	**42**	**Variable**	**201**

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; or the device has the same intended use and different technological characteristics but it can be demonstrated that the new device does not raise additional questions regarding its safety and effectiveness as compared to the predicate device(s) and that the device is substantially equivalent to the predicate device.

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