DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

February 26, 2016

Parker Hannifin Corporation
% Richard Vincins
Vice President QA/RA
Emergo Group
816 Congress Avenue, Suite 1400
Austin, Texas 78701

Re: K152416
Trade/Device Name: Indego
Regulation Number: 21 CFR 890.3480
Regulation Name: Powered Lower Extremity Exoskeleton
Regulatory Class: Class II
Product Code: PHL
Dated: January 27, 2016
Received: January 28, 2016

Dear Mr. Vincins:

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 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 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 yours,

Michael J. Hoffmann -A

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K152416

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 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.

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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510(k) Summary

Indego®

K152416

1. **Submission Sponsor**

Parker Hannifin Corporation

Human Motion and Control

1390 E. Highland Road

Macedonia

Ohio, 44056

USA

Phone number: 216.896.2044

Contact: Achilleas DOROTHEOU

Title: VPBD/Head, Human Motion and Control

2. **Submission Correspondent**

Emergo

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Austin, TX 78701

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Contact: Richard A. VINCINS, Vice President, QA/RA

Email: project.management@emergogroup.com

3. **Date Prepared**

26 February 2016

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 Device

DEN130034/K131798, ReWalk™, Argo Medical Technologies, Inc.

6. Device Description

Parker Hannifin's Indego® device is a wearable powered exoskeleton that actively assists individuals to stand and walk. Unique in design, the Indego consists of five (5) snap-together components (the lumbar/hip section, right and left upper leg sections, and right and left lower leg sections) weighing 26 pounds total. The hip component houses a rechargeable battery pack, central processor, and Bluetooth module, 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 battery technology (smaller size), motors (smaller and more powerful), and micro controllers. Visual cues from LED lights on the hip unit and vibratory feedback inform both the therapist and patient 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. 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. Through the use of a Bluetooth connection, the Indego device's mode of operation and operational parameters such as gait speed and step length/height, will be able to be changed or modified in real time. The device can be utilized in multiple indoor and outdoor locations within a rehabilitation setting 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 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.

8. Substantial Equivalence Discussion

The following table compares the Indego to the predicate device with respect to indications for use, principles of operation, technological characteristics, materials, and performance testing. The comparison of the devices 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 device.

Table 1 - Comparison of Characteristics

Manufacturer	Parker Hannifin Corporation	Argo Medical Technologies, Inc.	Significant Differences
Trade Name	Indego®	ReWalk™	
510(k) Number	K152416	DEN130034/K131798	N/A
Product Code	PHL	PHL	Same
Regulation Number	890.3480	890.3480	Same
Regulation Name	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 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	The Argo ReWalk™ orthotically fits to the lower limbs and part of the upper body and is intended to enable individuals with spinal cord injury at levels T7 to L5 to perform ambulatory functions with supervision of a specially trained companion in accordance with the user assessment and training certification program. The device is also intended to enable individuals with spinal cord injury at levels T4 to T6 to perform ambulatory	Same

Manufacturer	Parker Hannifin Corporation	Argo Medical Technologies, Inc.	Significant Differences
Trade Name	Indego®	ReWalk™	
	institutions in accordance with the user assessment and training certification program. The Indego is not intended for sports or stair climbing.	functions in rehabilitation institutions in accordance with the user assessment and training certification program. The Indego is not intended for sports or stair climbing.	
Body Coverage	Worn over legs and around hips and lower torso	Worn over legs and upper body with backpack	Similar; the components are worn around the legs and torso with the control unit of Indego integrated into the hip segment whereas the ReWalk has a separate backpack control unit. No additional safety or efficacy concern as the component configuration is similar for the legs, hip, and torso of the patient.
Size of Components	Modular Small, Medium, and Large upper leg, lower leg, and hip components; control unit integrated in hip unit	Adjustable upper leg, lower leg, and multiple size pelvic bands; with a backpack control unit	Similar; both units have an upper leg, lower leg, and hip component with ReWalk having an additional backpack unit. No additional safety or efficacy concerns as the components cover the same areas of the patient including the legs, hip, and torso.
Mobility Aid	Crutches or walkers	Crutches	Similar; both devices utilize crutches as a stability/mobility aid.

Manufacturer	Parker Hannifin Corporation	Argo Medical Technologies, Inc.	Significant Differences
Trade Name	Indego®	ReWalk™	
			No additional safety or efficacy concerns are presented by providing the added mobility aid option for the Indego patients to utilize.
Ability of User Mobility	Sit, stand, walk, and turn	Sit, stand, walk, and turn	Same
Walking Speed	~2 km/hr	~2 km/hr	Same
Grade of Inclination	5 degrees	5 degrees	Same
Type of Surface	Smooth, grass, cement, carpet, transitions, thresholds	Smooth, grass, cement, carpet	Similar; Indego provides greater ground clearance which is user-selectable. No additional safety or efficacy concerns as clinical data supports ambulation over a wide range of surfaces.
Patient population	Adults over age of 18 with Spinal Cord Injury (SCI) from T4 to L5	Adults over age of 18 with Spinal Cord Injury (SCI) from T4 to L5	Same
Height of Patient	61” to 75” (1.55 m to 1.91 m)	63” to 75” (1.60 m to 1.90 m)	Similar; the Indego can accommodate a shorter height with a difference of two inches (5 cm) and does not present any additional safety or efficacy concern.
Weight of Patient	Up to 250 lbs (113 kg)	Up to 220 lbs (100 kg)	Similar; the Indego can accommodate a

Manufacturer	Parker Hannifin Corporation	Argo Medical Technologies, Inc.	Significant Differences
Trade Name	Indego®	ReWalk™	
			heavier weight; this does not add any safety or efficacy concerns as the verification and validation testing supports the requirements.
Control Method	Uses postural cues to trigger all transitions	Remote control worn on the wrist to change modes; postural cues for stepping	Similar; the movement activation is preceded by the user setting the mode on the control units. No additional safety or efficacy concerns because the postural cues are triggers for the movement activation of the device.
Range of Motion	Hip: 110° flexion to 30° extension Knees: 110° flexion to 10° extension	Hip: 104° flexion to 34° extension Knees: 112° flexion to 2° extension	Similar; there is a larger range of motion for the Indego device to allow easier sit-to-stand transitions. No additional safety or efficacy concerns as clinical data supports the safe use of the device for ambulation and sitting/standing transitions.

Manufacturer	Parker Hannifin Corporation	Argo Medical Technologies, Inc.	Significant Differences
Trade Name	Indego®	ReWalk™	
Weight	26 lbs. (12 kg)	66 lbs. (30 kg) with 5 lbs. (2.3 kg) backpack	Different; Indego is less weight of the predicate device; the lessened weight of the device does not add any concern for safety or efficacy as can be managed by an individual.
Rechargeable Battery	Rechargeable lithium ion. 33.3V, 36A peak current, 12A continuous current. 159Wh fully charged; 1.5 hours of continuous walking per charge	Rechargeable lithium ion primary with lithium polymer secondary. 25.9V, 30A peak current, 10.4A continuous current; 2 hours of continuous walking per charge	Similar; the battery types are slightly different, but provide the necessary power for the operation of the device. No additional safety or efficacy concern as the battery power has been tested per specification.
Battery Charge Time	Maximum of 4 hours	Minimum of 4 hours	Similar; the predicate takes a minimum of 4 hours and a maximum of 7 hours to be charged. No additional safety or efficacy concern as similar charging time.
Expected Useable Life	5 years	5 years	Same
Training Program	Yes	Yes	Same
Certification Program	Yes	Yes	Same
User Feedback	Provides vibratory feedback and LED indicators on top of hip	Provides vibratory feedback from backpack and LED indicators on	Similar; both devices provide vibratory feedback and the LED

Manufacturer	Parker Hannifin Corporation	Argo Medical Technologies, Inc.	Significant Differences
Trade Name	Indego®	ReWalk™	
	unit, visible to the wearer	user's wrist controller	indicators to communicate information to the user and do not increase any safety or efficacy concerns.
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	None	Different; there are no additional safety concerns or efficacy as the fall detection methods will help reduce the risk of injury to the user.
Failsafe Feature	In event of power failure – knees become locked and hips free (similar to typical passive leg braces)	In the event of a power failure the ReWalk collapses slowly whether user is in safe condition for sitting or not	Similar; the Indego user is allowed to remain standing in the event of a malfunction. No additional safety or efficacy concerns as the failsafe features allow the user to recover during a fault with the device.
Operating Temperature	32°F to 88°F (0°C to 31°C)	-13°F to 105°F (-25°C to 40°C)	Similar; the operating temperature is similar that would be expected in a typical setting for the use of the device.
Operating Humidity	30% to 75% RH	Not available	Not applicable
Electrical Safety Testing	Passed ANSI/AAMI ES60601-1:2005/(R)2012	Passed IEC 60601-1:2005	Similar; the Indego passed the currently recognized electrical safety standard.

Manufacturer	Parker Hannifin Corporation	Argo Medical Technologies, Inc.	Significant Differences
Trade Name	Indego®	ReWalk™	
Electromagnetic Compatibility Testing	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 device of this 510(k) submission, Parker Hannifin completed a number of tests. The Indego device meets all requirements for design characteristics, non-clinical performance testing, EMC/EMI testing, and electrical safety testing to confirm that the output meets the design inputs and specifications for the device.

The Indego device passed all testing in accordance with internal requirements, national standards, and international standards shown below to support substantial equivalence of the subject device:

- Maximum Torque Testing: testing to 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: testing to 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: performance testing designed to verify the device meets the factor of safety designated by the ANSI/AAMI ES60601-1 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: completed 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**

The Indego passed all testing stated above as shown by the acceptable results obtained.

10. Clinical Performance Data

A clinical study was performed with the investigational product, Indego, for assessing the mobility of persons with Spinal Cord Injury (SCI) while using the device. The study was conducted to evaluate the Indego device for safety and effectiveness in allowing persons with SCI who are non-ambulatory to poorly ambulatory to stand up and walk under a variety of conditions. The study was performed in compliance with Good Clinical Practices (GCP) with subjects enrolled in an IRB approved study that were consented for participation according to the intended use of the device, defined inclusion criteria, and defined exclusion criteria; with the purpose of meeting the study objectives.

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.

The clinical study was planned for 40 (forty) subjects to be enrolled, which was met. The subjects were then required to complete a series of 27 (twenty-seven) study sessions that included introduction, evaluation, training with the device, assessment from each session, and outcome measurements. 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 total number of sessions with outcome measurements recorded midway through and at the completion of the study.

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

- The Timed Up-and-Go (TUG) Test measured the ability of the subject to perform transitional motions beyond just walking, i.e. standing up, sitting down, and turning. Of the enrolled subjects 39 (thirty nine) were able to complete with minimal contact assistance (FIM score of 4) and one (1) subject was able to complete with moderate contact assistance (FIM score of 3).
- Walking speed was captured during the study through a Ten Meter Walk Test (10MWT) on indoor surfaces resulting in speeds of 0.38 m/s ± 0.08 m/s at the completion of the study. In addition as a test of sustained walking for individuals with SCI, 38 (thirty eight) subjects were able to complete a single-session walk of 600 meters in length.

- Level of assistance was measured according to WISC-II and FIM scores during the study to provide a view of task-specific level of assistance needed while performing movements using the Indego device. The WISC-II scores for all subjects averaged mean scores of 6 ± 1.0 and 7 ± 1.6 respectively for the midpoint assessment and final assessment during the study. The FIM scores as noted previously support that all subjects were capable of managing all tested terrains and scenarios presented, which included using the device indoors and outdoors; on smooth tile, concrete, asphalt, grass and carpet; and navigating sidewalks, ramps, curb cutouts, elevators, automatic doors, and latch doors.
- Study participants were requested to complete multiple questionnaires during the study trial including a Borg Rating of Perceived Exertion to capture the effort subjects felt to achieve basic level-ground walking. The averaged results of the assessment for indoor level ground walking at the end of their sessions was 10, which corresponds to an exertion level between "very light exercise" and "light exercise".
- Adverse Events (AE) reported during the study included minor instances of bruising, redness, abrasion, and swelling. The causes attributed to these reported incidents were generally related to improper fitting or improper padding. In one case of abrasion raised by a subject was related to a padding malfunction. There were no Unanticipated Adverse Events (UAE).

The clinical study concluded that the Indego device is safe and effective for its intended use and the outcomes of the study met the stated objectives. The clinical trial supports the indication for use for enabling ambulatory function in individuals with T4 to L5 level SCI in an institutional setting and individuals with T7 to L5 SCI in a personal use setting.

11. Training

Training is a critical and required component of appropriate utilization and progression to higher degrees of proficiency for Indego usage. Patients and their caregivers must undergo training developed by the manufacturer to learn and demonstrate proper use of the Indego device. The sponsor has proposed the following training program, which is a tier-based system (Table 2), with the following skills identified for basic (home/limited community) and advanced (community) skills for both the User and Support Person (Tables 3, 4, 5). Prior to moving to another level of proficiency, the Indego User needs to demonstrate sufficient proficiency utilizing a scoring metric as summarized in Table 6 and Table 7. It should be noted that the Indego device is currently indicated for usage only with supervisions of a specially trained companion in accordance with the user assessment and training certification program.

Table 2 – Indego Competency Levels

Indego Competency Levels				
	Rehabilitation Use	**Personal Use**		
		Level 1 (Home/Limited Community)	Must pass all Level 1 skills prior to advancing to Level 2	Level 2 (Community)
Location	Institution (inside and outside, level and un-level surfaces)	Home (inside and outside, level and un-level surfaces) Activities of daily living Limited community ambulation		Community Ambulation
Supervision	Indego specialist	Support Person		Support Person
User training	Learn basic or advanced skills	Learn Basic and Limited community skills		Focus on obtaining longer walking distances and faster gait speeds
Support person training	N/A	Learn basic and limited community skills		Learn community skills
Prerequisites	Meets all inclusion criteria SCI T4 and below	User meets all inclusion criteria SCI T7 and below Indego user and support person pass all Level 1 skills on competency checklist		Indego user and Support Person pass all Level 2 skills on competency checklist

Table 3 – Level 1 User and Support Person: Home/Limited Community Skills Report Card Score Sheet

Skill	Score	Pass or Fail
General knowledge of the device		
Putting on/taking off the device		
Assessing skin, pressure and appropriate fit		
Safe operation of the device (basic skills)		
Walking Level Inside		
Walking-Stop-Walking		
Turning Left/Right/180		
Walking Level Outside*		
Wall Rest in Standing		
Use of hand held controller		
Safety during unique situations		
Emergency Sit Procedure		
Proper care and storage of the device		
Verbalized understanding of approved skills		

*Skills that are suggested, but not mandatory to take device home at Level 1

Table 4 – Level 2 User: Community Skills Report Card Score Sheet

Skill	Score	Device Used (RW or FC)	Pass or Fail
Indoor ramps			
Outdoor ramps			
Manual Doors			
Automatic Doors			
Irregular outdoor surfaces (ie grass, cracked pavement, sidewalks, stony path)			
Activities of Daily Living (ADL's) (Household, Kitchen, etc)			
Verbalize understanding of approved skills			

Table 5: Level 2 Support Person: Community Skills Report Card Score Sheet

Skill	Score	Device Used (RW or FC)	Pass or Fail
Elevators			
Curb cut out			
Walking Speed of 0.4 m/s or greater during 10MWT			
*Car transfers			
Walks 600 m distance			
*Cross 2 way street			
Verbalized understanding of approved skills			

*Skills that are suggested, but not mandatory to take device home at Level 2

Table 6 – Scoring Key for Behavior Skills for Level 1 and Level 2

Score	Description of Score Assignment
1	Pass User and Support Person Safely Perform Skill
0	Fail User and Support Person Did NOT Safely Perform Skill
NS	No Score User and Support Person Did NOT perform the skill at all

Table 7: FIM Scoring Criteria – for Indego device

FIM Scoring Criteria:	
No Helper Required	
Score	**Description**
7	Complete Independence
6	Modified Independence (patient requires use of a device, but no physical assistance)
Helper (Modified Dependence)	
Score	**Description**
5	Supervision or Setup
4	Minimal Contact Assistance (patient can perform 75% or more of task)
3	Moderate Assistance (patient can perform 50% to 74% of task)
Helper (Complete Dependence)	
Score	**Description**
2	Maximal Assistance (patient can perform 25% to 49% of tasks)
1	Total assistance (patient can perform less than 25% of the task or requires more than one person to assist)
0	Activity does not occur

12. 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 that can be demonstrated that the device is substantially equivalent to the predicate device, and that the new device does not raise additional questions regarding its safety and effectiveness as compared to the predicate device(s).

The Indego, as designed and manufactured, meets the Special Controls specified in 21 CFR 890.3480, and is determined to be substantially equivalent to the referenced predicate device.