DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 1, 2016

Ekso Bionics, Inc.
Thomas Looby
President and Chief Commercial Officer
1414 Harbour Way South, Suite 1201
Richmond, CA 94804

Re: K143690
Trade/Device Name: Ekso™ (version 1.1) and Ekso GT™ (version 1.2)
Regulation Number: 21 CFR 890.3480
Regulation Name: Powered Lower Extremity Exoskeleton
Regulatory Class: Class II
Product Code: PHL
Dated: March 2, 2016
Received: March 2, 2016

Dear Mr. Looby:

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" (21CFR 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)*
K143690

Device Name
Ekso™ (version 1.1) and Ekso GT™ (version 1.2)

Indications for Use *(Describe)*
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 with upper extremity motor function of at least 4/5 in both arms:

- Individuals with hemiplegia due to stroke
- Individuals with spinal cord injuries at levels T4 to L5
- Individuals with spinal cord injuries at levels of C7 to T3 (ASIA D).

The therapist must complete a training program prior to use of the device. The devices are 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
as required by 21 CFR 807.92(c)

Device name	Ekso™
Submitters name & contact info	Ekso Bionics® Inc. 1414 Harbour Way South Suite 1201 Richmond, CA 94804 **Contact Details:** Thomas Looby CEO Tel: +1 937-838-0842 Email: tom@eksobionics.com Tel: +1 (510) 984-1761 Fax: +1 (510) 927-2647
Preparation Date	March 31, 2016
Device Name & Classification	Trade Name: Ekso™ (version 1.1) and Ekso GT™ (version 1.2) Common Name: Exoskeleton Classification Name: Powered Exoskeleton Device Classification: Class II, 21 CFR 890.3480 Product Code: PHL
Indications for Use	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 with upper extremity motor function of at least 4/5 in both arms: • Individuals with hemiplegia due to stroke • Individuals with spinal cord injuries at levels T4 to L5 • Individuals with spinal cord injuries at levels of C7 to T3 (ASIA D). The therapist must complete a training program prior to use of the device. The devices are not intended for sports or stair climbing.
Device Description	The Ekso is a powered motorized orthosis. It consists of a fitted metal brace that supports the legs, feet, and torso. It is worn via straps on the body, legs, and feet. Battery powered motors drive knee and hip joints. It has an integrated solid torso containing the computer and power supply. It has a hand-held user interface to specify settings and initiate steps. The Ekso is used with a cane, crutch, or walker.

Predicate Device	Manufacturer	510(k)	Date
	Argo Medical Technologies	K131798	6/26/2014

Table 1- Comparison of Characteristics

Manufacturer	Ekso Bionics®, Inc.	Argo Medical Technologies, Inc.	Significant Differences
Trade Name	Ekso™ (version 1.1) and Ekso GT™ (version 1.2)	ReWalk™	
510(k) Number	K143690	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 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 with upper extremity motor function of at least 4/5 in both arms:Individuals with hemiplegia due to stroke, Individuals with spinal cord injuries at levels T4 to L5, and Individuals with spinal cord injuries at levels of C7 to T3 (ASIA D). The therapist must complete a training program prior to use of the device. The devices are not intended for sports or stair climbing.	The ARGO ReWalk™ orthotically fits to the lower limbs and part of the upper body and is intended to enable individuals with spinal cord injury at levels T7 to L5 to perform ambulatory functions with supervision of a specially trained companion in accordance with the user assessment and training certification program. The device is also intended to enable individuals with spinal cord injury at levels T4 to T6 to perform ambulatory functions in rehabilitation institutions in accordance with the user assessment and training certification program. The ReWalk™ is not intended for sports or stair climbing.	Similar; the Ekso is intended for stroke and for a higher SCI injury range for ASIA D. No additional safety or efficacy concerns are presented by the additional indications.

Manufacturer	Ekso Bionics®, Inc.	Argo Medical Technologies, Inc.	Significant Differences
Trade Name	Ekso™ (version 1.1) and Ekso GT™ (version 1.2)	ReWalk™	
Body Coverage	Worn over legs and upper body with rigid torso	Worn over legs and upper body with backpack	Similar; the Ekso provides a rigid back frame whereas the predicate has a separate backpack. No additional safety or efficacy concern as the component configuration is similar for the legs, hip, and torso of the patient.
Size of Components	Adjustable upper leg, lower leg, and hip width; control unit integrated into the torso	Adjustable upper leg, lower leg, and multiple size pelvic bands; with a backpack control unit	Same
Mobility Aid	Walker, Crutches, Cane	Crutches	Similar; both devices utilize crutches as a stability/mobility aid. No additional safety or efficacy concerns are presented by providing the added mobility aid options for the Ekso.
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	1.15 deg	5 deg	Similar; the Ekso is intended for flat environments whereas the predicate is intended for community ambulation. No additional safety or efficacy concerns are presented by the lower grade.

Manufacturer	Ekso Bionics®, Inc.	Argo Medical Technologies, Inc.	Significant Differences
Trade Name	Ekso™ (version 1.1) and Ekso GT™ (version 1.2)	ReWalk™	
Type of Surface	Smooth, cement, carpet	Smooth, grass, cement, carpet	Similar; the Ekso is intended for indoor environments and the predicate is intended for community ambulation. The Ekso not walking on grass presents no additional safety or efficacy concerns.
Patient Population	Adults over age of 18 with hemiplegia due to stroke, Spinal Cord Injury (SCI) from T4 to L5, and SCI from C7 to L5 ASIA D	Adults over age of 18 with Spinal Cord Injury (SCI) from T4 to L5	Different; the Ekso is intended for stroke and for a higher SCI injury range for ASIA D. Safety concern associated with higher level SCI and stroke was evaluated through clinical data and indications for use that limit use of the device to patients with adequate upper extremity motor strength in each muscle group of at least 4/5 in both arms
Height of Patient	~62” to 74” (1.58 m to 1.88 m)	63” to 75” (1.60 m to 1.90 m)	Similar; the Ekso can fit one inch shorter and one inch less height and does not present any additional safety or efficacy concern.
Weight of Patient	Up to 220 lbs (100kg)	Up to 220 lbs (100kg)	Same
Control Method	Handheld interface for PT; weight shift to initiate steps	Remote control worn on the wrist to change modes; postural cues for stepping	Similar; both devices require selection of actions by the controller. Ekso initiates each step separately based on weight shift. No additional safety or efficacy concerns are presented by the Ekso method.

Manufacturer	Ekso Bionics®, Inc.	Argo Medical Technologies, Inc.	Significant Differences
Trade Name	Ekso™ (version 1.1) and Ekso GT™ (version 1.2)	ReWalk™	
Range of Motion	Hips: 135° flexion to 20° extension Knees: 130° flexion to 0° extension Ankles: 10° flexion to 10° extension	Hips: 104° flexion to 34° extension Knees: 112° flexion to 2° extension Ankles: none	Similar; there is a larger range of motion for the Ekso to allow easier sit-to stand transitions and greater comfort during walking. No additional safety or efficacy concerns as clinical data supports the safe use of the device for ambulation and sitting/standing transitions.
Weight	50 lbs (23 kg)	66 lbs. (30 kg) with 5 lbs.(2.3 kg) backpack	Different; Ekso is less weight than the predicate device; the lessened weight of the device does not add any concern for safety or efficacy.
Rechargeable Battery	Rechargeable lithium ion batteries 48.1V, 30A peak current, 1 hour of continuous usage 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	1 hour	Minimum of 4 hours	Similar; the Ekso batteries can be recharged while another set is in use. No additional safety or efficacy concerns are presented by Ekso's shorter charge.
Expected Useable Life	4 years	5 years	Similar; the Ekso is expected to have a 4 year useable life. No additional safety or efficacy concerns are presented by Ekso's shorter life.

Manufacturer	Ekso Bionics®, Inc.	Argo Medical Technologies, Inc.	Significant Differences
Trade Name	Ekso™ (version 1.1) and Ekso GT™ (version 1.2)	ReWalk™	
Training Program	Yes	Yes	Same
Certification Program	Yes	Yes	Same
User Feedback	Provides visual feedback on the handheld controller and auditory feedback	Provides vibratory feedback from backpack and LED indicators on user's wrist controller	Similar; both devices use visual and other feedback. No additional safety or efficacy concerns from the auditory feedback on the Ekso.
Fall Detection and Mitigation	None	None	Same
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 Ekso 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 Ekso.
Operating Temperature	10° to 95°F (-12° to -35° 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	Not available	Not available	Same
Electrical Safety Testing	IEC 60601-1:2005 with US deviations	IEC 60601-1:2005	Same
Electromagnetic Compatibility Testing	Passed IEC 60601-1-2: 2007	Passed IEC 60601-1-2: 2007	Same

Table 2 - Performance Testing

Technical Area	Tests Completed
Electrical Safety and Electromagnetic Compatibility	IEC 60601-1:2005, IEC 60601-1-2:2007, low battery testing, IEC 62133, IEC 61960 parts 7.4 and 7.5, UN 38.3, UN Manual (ST/SG/AC. 10/11/Rev.5/Amend.1), battery life cycle testing
Durability	Worst case loading of knee and hip joints beyond service life, worst case loading of structure beyond service life, ankle spring

	durability, component strength testing
Thermal	IEC 60601-1:2005 (ISO 7176 not required; batteries on the Ekso are mounted to the aluminum Torso frame, enclosed in an aluminum case, and not near any flammable material. The testing conducted per IEC 60601 -1 in terms of flame retardant evaluations is sufficient to support the device functionality in terms of flame retardant materials.)
Software	Verification, Validation, and hazard analysis
Bench Testing	IEC 60601-1:2005 sec. 15.3 (IP22 not required)

Table 3 - Clinical Information

Study	Description
Study 1 - SCI	Multi-center, prospective, open-label, non-comparative, non-randomized, prospective study of patients with spinal cord injury, at 6 sites from 5 countries Duration of Intervention • 27 visits over 12-13 weeks. 44 subjects total • 35 ASIA A-B with injury levels from C7 to L2 • 21 ASIA C-D with injury levels from C1 to L2 • 32% female • mean age of 39.9 years (range 19 to 65) • mean time since injury 1146 days (range of 71 to 6790) Results • Mean 10MWT pre and post-training were 66 (N=18) and 40 (N=7) seconds, respectively. • Mean heart rates increased slightly from the pre-training measure to the mid-training measure while mean blood pressures remained stable. • One (1) subject experienced a blister on the left shoulder under the backpack strap. Five (5) patients reported pain in the hands, lower back, or ribs. No falls were reported. All issues were self-limiting and resolved without medical attention.
Study 2 - SCI	Single center, open-label, non-comparative, non-randomized, prospective study of patients with spinal cord injury. Duration of Intervention: • 24 sessions over 12 weeks.

	12 subjects total • 9 ASIA A with injury levels C7 to L1 • 3 ASIA B with injury levels T3 to T9 • 42% female • mean age of 35 (range 19 to 56) • mean time sine injury 7.6 years (range 1 to 24) Results • Mean 10MWT pre and post-training were 160 (N=12) and 78 (N=17) seconds, respectively • Mean 6MWT pre and post-training were 82 and 152 meters, respectively • One (1) subject had 2 falls without injury. No injuries were reported
Study 3 - Stroke	Single center, exploratory retrospective analysis of patients with hemiplegia due to stroke Duration of Intervention • Mean of 10 sessions (range 2 to 27) 54 subjects total used the Ekso GT • Mean time since injury 12.2 days (range of 0 to 107 days) • 36 ischemic, 18 hemorrhagic • 7 moderate, 47 severe Results • Mean 10MWT pre and post-training were 150 and 79 seconds, respectively • Mean 6MWT pre and post-training were 40 and 88 meters, respectively • Mean FIM scores pre and post-training were 24 and 49, respectively • There were no falls or other adverse events reported
Study 4 - Stroke	Single center, open-label, non-comparative, non-randomized, prospective study of patients with hemiplegia due to stroke Duration of Intervention • Mean of 3 sessions (range 1 to 9) 54 subjects total • Mean time since injury 25.1 days (range of 5 to 146 days) • 41 ischemic, 13 hemorrhagic • 4 moderate, 50 severe Results • Mean FIM scores pre and post-training were 25 and 51, respectively. • Mean blood pressure before and after session 1 was 131/80 and 128/81, respectively. • Mean heart rate before and after session 1 was 79 and 85, respectively. • There were no falls or other adverse events reported.

Study 5 - Stroke	Single center, prospective, two-arm study of patients with hemiplegia due to stroke Duration of Intervention • 6 subjects had between 25 and 27 sessions (Arm 1) • 2 subjects had 18 sessions (Arm 2) 8 subjects total • Mean time since injury 601 days (range of 333 to 1550 days) • 7 ischemic, 1 hemorrhagic • All limited household ambulators at recruitment Results • Mean 10MWT pre and post-training were 76 and 37 seconds, respectively • Mean 6MWT pre and post-training were 48 and 83 meters, respectively • Mean blood pressure before and after session 10 was 126/77 and 130/70, respectively • Mean Heart rate before and after session 10 was 73 and 78, respectively • There were no falls or other adverse events reported.

Training

The Ekso provides various dynamic programming options that enable the physical therapist to customize sessions for patients based on a wide array of clinical presentations. To ensure safe operation, certification training is required before a therapist may use the Ekso.

To optimize the integration of the technology, certification training takes place in two phases. The training program is offered for up to 4 therapists from each facility with each Ekso purchased.

Phase 1 – Initial Training Week

The first phase is a full week of training for each therapist on the basic feature set of the Ekso. During training a therapist will become competent to:

- Screen, evaluate, and measure Patients
- Setup the Ekso
- Fit the Ekso to the Patient
- Use the Safety Checklist
- Select and use the operating mode appropriate for the patient
- Safely guard and cue patient during operation of the Ekso
- Use the LCD Controller
- Perform after secession physical checks

When a therapist is determined to be at Level 1 by the Ekso Bionics Clinical Training Team, it means the therapist has demonstrated the competence to safely operate the Ekso when working with another therapist at Level 1 (or higher).

At Level 1, a therapist does not direct any other staff or team member to aid in operation of the Ekso. Two therapists are required to do the following.

- screening appropriate patients for using the Ekso
- administering a walking session
- selecting appropriate programming
- managing emergency situations.

It is important for therapists at Level 1 to continue using the Ekso after the initial training week to build their skills and be prepared for the second phase of training. It is recommended that they achieve the following prior to beginning phase 2.

- Perform 3-5 new patient evaluations and screenings for use of the Ekso
- Adjust the Ekso hardware and software for 15 to 20 Ekso walking sessions
- Manage 15 to 20 walking sessions in the Ekso with both new and recurring patients,
- Don and Doff the Ekso for 10 to 15 patient sessions
- Manage Ekso safety features (requires a variable number of sessions)

Phase 2 – Advanced Features

The Ekso Bionics Training Team returns to complete the second phase of training after a period of continued use of the Ekso by therapists at Level 1. Phase two training lasts 2-3 days and incorporates the remaining features of Ekso, and expands the possibilities for clinical use.

To progress from Level 1 to Level 2, a therapist must demonstrate the following mastery safely and independently.

- evaluating and screening appropriate persons for use of the Ekso
- directing all aspects of Ekso operation to support personnel
- device operation and selection of appropriate programming for an Ekso walking session
- managing emergency situations

At Level 2, a therapist independently operates the Ekso with support personnel of his or her choice, and is fully responsible for directing and running all aspects of the Ekso walking session. Level 2 Ekso therapists are also able to delegate appropriate (high level) patients to support personnel that they supervise and train on proper Ekso operation/spotting.

Statement of Substantial Equivalence

Based on safety and performance testing, technological characteristics, and clinical data, the Ekso has been demonstrated to be appropriate for its intended use and is considered to be substantially equivalent to the predicate device.