DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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July 19, 2016

Ekso Bionics, Inc.
% John J. Smith, MD, JD
Regulatory Counsel
Hogan Lovells U.S. L.L.P.
555 Thirteenth Street NW
Washington, DC 20004

Re: K161443
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: May 25, 2016
Received: May 25, 2016

Dear Dr. Smith:

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)*
K161443

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:

- 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.

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	**June 27, 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: • 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.
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 of Clearance**
	Ekso Bionics	K143690	4/1/2016

Table 1 - Comparison of Characteristics

Manufacturer **Trade Name**	**Ekso Bionics®, Inc.** **Ekso™ (version 1.1) and Ekso GT™ (version 1.2)**	**Predicate Ekso Bionics®, Inc.** **Ekso™ (version 1.1) and Ekso GT™ (version 1.2)**	**Differences**
510(k) Number	TBD	K143690	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™ is 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.	The Ekso™ is 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 Ekso 1.1 and 1.2 are not intended for sports or stair climbing.	Similar; the new indication is clarified to explicitly include individuals with hemiplegia due to stroke, who have upper extremity motor function of at least 4/5 in only one arm. Individuals with spinal cord injury still require upper extremity motor function of at least 4/5 in both arms.
Body Coverage	Worn over legs and upper body with rigid torso	Worn over legs and upper body with rigid torso	Same

Manufacturer **Trade Name**	**Ekso Bionics®, Inc.** **Ekso™ (version 1.1) and Ekso GT™ (version 1.2)**	**Predicate Ekso Bionics®, Inc.** **Ekso™ (version 1.1) and Ekso GT™ (version 1.2)**	**Differences**
Size of Components	Adjustable upper leg, lower leg, and hip width; control unit integrated into the torso	Adjustable upper leg, lower leg, and hip width; control unit integrated into the torso	Same
Mobility Aid	Walker, Crutches, Cane	Walker, Crutches, Cane	Same
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	1.15 deg	Same
Type of Surface	Smooth, cement, carpet	Smooth, cement, carpet	Same
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 hemiplegia due to stroke, Spinal Cord Injury (SCI) from T4 to L5, and SCI from C7 to L5 ASIA D	Same
Height of Patient	~62” to 74” (1.58 m to 1.88 m)	~62” to 74” (1.58 m to 1.88 m)	Same
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	Handheld interface for PT; weight shift to initiate steps	Same
Range of Motion	Hips: 135° flexion to 20° extension Knees: 130° flexion to 0° extension Ankles: 10° flexion to 10° extension	Hips: 135° flexion to 20° extension Knees: 130° flexion to 0° extension Ankles: 10° flexion to 10° extension	Same
Weight	50 lbs (23 kg)	50 lbs (23 kg)	Same
Rechargeable Battery	Rechargeable lithium ion batteries 48.1V, 30A peak current, 1 hour of continuous usage per charge	Rechargeable lithium ion batteries 48.1V, 30A peak current, 1 hour of continuous usage per charge	Same
Battery Charge Time	1 hour	1 hour	Same
Expected Useable Life	4 years	4 years	Same
Training Program	Yes	Yes	Same
Certification Program	Yes	Yes	Same

Manufacturer **Trade Name**	**Ekso Bionics®, Inc.** **Ekso™ (version 1.1) and Ekso GT™ (version 1.2)**	**Predicate Ekso Bionics®, Inc.** **Ekso™ (version 1.1) and Ekso GT™ (version 1.2)**	**Differences**
User Feedback	Provides visual feedback on the handheld controller and auditory feedback	Provides visual feedback on the handheld controller and auditory feedback	Same
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 event of power failure– knees become locked and hips free (similar to typical passive leg braces)	Same
Operating Temperature	10° to 95°F (-12° to -35° C)	10° to 95°F (-12° to -35° C)	Same
Operating Humidity	Not available	Not available	Same
Electrical Safety Testing	IEC 60601-1:2005 with US deviations	IEC 60601-1:2005 with US deviations	Same
Electromagnetic Compatibility Testing	Passed IEC 60601-1-2: 2007	Passed IEC 60601-1-2: 2007	Same

Table 2 - Clinical Information

Study	Description

Study 1	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
	• 34 had affected upper extremity (UE) motor function of less than 4/5 in one arm (95 walking sessions)
	  ○ 19 (56%) of these had UE motor function of 0 (59 walking sessions)
	  ○ 2 (6%) of these had UE motor function 0/2 (3 walking sessions)
	  ○ 2 (6%) of these had UE motor function 0/3 (5 walking sessions)
	  ○ 2 (6%) of these had UE motor function 2/2+ (4 walking sessions)
	  ○ 1 (3%) of these had UE motor function 2/3 (3 walking sessions)
	  ○ 8 (24%) of these had UE motor function 3-/3+ (21 walking

	sessions) ○ 38% (13/34) of these were female ○ 74% (25/34) of these suffered an ischemic stroke ○ 97% (33/34) of these had a severe stroke • 1 patient had affected upper extremity motor function of 4/5 (3 walking sessions) • 19 patients were not recorded in upper extremity motor function ○ 16 of these used a cane or an arm sling (62 walking sessions) ○ 19% (3/16) of these were female ○ 63% (10/16) of these suffered an ischemic stroke ○ 88% (14/16) of these had a severe stroke Results • 50 patients (93%) safely performed ambulatory functions with only one arm to maintain stability • There were no falls or other adverse events reported
Study 2	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 • 7 used a cane or an arm sling (121 walking sessions) ○ 7 used a cane (120 walking sessions) ○ 3 used an arm sling with a cane (45 walking sessions) ○ 1 used an arm sling with a walker (1 walking session) ○ 100% (7/7) of these suffered an ischemic stroke Results • 7 patients (88%) safely performed ambulatory functions with only one arm to maintain stability • There were no falls or other adverse events reported

The data summarized above includes a total of 216 walking sessions in which 57 patients with hemiplegia due to stroke performed ambulatory functions in the Ekso device using only one arm to control the assistive device. The direct evidence demonstrates that 34 patients safely performed ambulatory functions with UE motor function of at least 4/5 in only one arm. The indirect evidence documents that regardless of upper extremity motor function, 23 patients were able to safely perform ambulatory functions in the Ekso device using only one arm to control the assistive device. The ability of such patients to support themselves and recover from a stumble is equivalent to that of a patient who has upper extremity strength of at least 4/5 in only one arm.

In sum, the data submitted for this population is representative of the ability of stroke patients with upper extremity strength of at least 4/5 in only one arm to maintain stability using an assistive device. The lack of adverse events over 216 walking sessions in 57 patients demonstrates the safety and

effectiveness of the Ekso device in individuals with hemiplegia due to stroke with upper extremity motor function of at least 4/5 in at least one arm.

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 the clinical data and training described above, the Ekso has been demonstrated to be appropriate for its intended use and is considered to be substantially equivalent to the predicate device.