June 15, 2020

Ekso Bionics, Inc.
Jack Peurach
CEO
1414 Harbour Way South, Suite 1201
Richmond, CA 94804

Re: K200574
Trade/Device Name: EksoNR™
Regulation Number: 21 CFR 890.3480
Regulation Name: Powered Lower Extremity Exoskeleton
Regulatory Class: Class II
Product Code: PHL
Dated: February 27, 2020
Received: March 5, 2020

Dear Mr. Peurach:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Heather Dean, PhD
Acting Assistant Director, Acute Injury Devices
DHT5B: Division of Neuromodulation
and Physical Medicine Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
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)*

K200574

Device Name

EksoNR™

Indications for Use *(Describe)*

The EksoNR™ is intended to perform ambulatory functions in rehabilitation institutions under the supervision of a trained physical therapist for the following populations:

- Individuals with acquired brain injury, including traumatic brain injury and 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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 <u>Contact Details:</u> Jack Peurach CEO Tel: +1 510-260-7610 Email: jack@eksobionics.com Ekso Bionics Tel: +1 (510) 984-1761 Ekso Bionics Fax: +1 (510) 927-2647
Preparation Date	February 27, 2020
Device Name & Classification	Trade Name: EksoNR™ Common Name: Exoskeleton Classification Name: Powered Exoskeleton Device Classification: Class II, 21 CFR 890.3480 Product Code: PHL
Legally Marketed Predicate Device	K161443, Ekso, Ekso Bionics, Inc.
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.
Indication for Use Statement	The EksoNR™ is intended to perform ambulatory functions in rehabilitation institutions under the supervision of a trained physical therapist for the following populations: • Individuals with acquired brain injury, including traumatic brain injury and 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.

Substantial Equivalence Discussion	This device and the previously cleared (predicate) device (K161443) are essentially the same products. Differences in Indications for Use The purpose of this 510(k) is to update the indications for use relative to the predicate device. The indications for use are identical to that of the predicate device, other than the following (changed wording is **bolded**): • Individuals with **hemiplegia due to stroke** (upper extremity motor function of at least 4/5 in at least one arm) has been updated to: • Individuals with an **acquired brain injury, including traumatic brain injury and stroke** (upper extremity motor function of at least 4/5 in at least one arm) The change noted above expands the existing stroke indication to the broader acquired brain injury (ABI) population. The intended use of the device is unchanged. For the purposes of this intended use (ambulatory rehabilitation), ABI patients present similarly, are screened for device safety requirements including sufficient cognitive ability to follow instructions and safely use the device, and are treated in the same way as stroke patients (a subset of ABI). As such, gait ambulation effectiveness of the device is no different when used on the general ABI population. When used as instructed, the device is as safe to use with the general ABI population as the already cleared stroke population.

Technical Characteristics

The device is essentially unchanged from the current (predicate) device. All changes since the previous submission fall below the threshold requiring a 510(k) per the FDA's October 25, 2017, "*Guidance for Industry and FDA Staff: Deciding When to Submit a 510(k) for a Change to an Existing Device*". Even though there is no change, for completeness, the technical characteristics of the device are compared with the current device below.

Comparison of Technical Characteristics

		Current Device	
Manufacturer	**Ekso Bionics®, Inc.**	**Ekso Bionics®, Inc.**	
Trade Name	**EksoNR™**	**Ekso GT® and EksoNR™**	**Differences**
510(k) Number		K161443	N/A
Product Code	PHL	PHL	Same
Regulation Number	890.3480	890.3480	Same
Regulation Name	Powered Exoskeleton	Powered Exoskeleton	Same
Body Coverage	Worn over legs and upper body with rigid torso	Worn over legs and upper body with rigid torso	Same
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

Comparison of Technical Characteristics

		Current Device	
Manufacturer	Ekso Bionics®, Inc.	Ekso Bionics®, Inc.	
Trade Name	EksoNR™	Ekso GT® and EksoNR™	Differences
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
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
Device 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
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: 2014	Passed IEC 60601-1-2: 2007	Same, newer version

Non-clinical Performance Summary

Technical Area	Tests Completed
Electrical Safety and Electromagnetic Compatibility	IEC 60601-1:2005, IEC 60601-1-2:2014, 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)

Clinical Performance Summary

The current device utilized 5 different studies to demonstrate safety and efficacy of the current indications for use (K161443). This submission builds from those 5 studies with 2 additional clinical studies (summarized below) focusing on the specific populations added by the expanded indication for use in this submission. These studies demonstrate the device effectively enables gait ambulation and there were no reported adverse events indicating the device is safe to use with this expanded population.

Study	Description
Kessler ABI	Single center, open-label, non-comparative, non-randomized, prospective study of patients with acquired brain injury (only non-stroke patients included in this submission). Duration of Intervention • Ambulation during a mean of 5.8 sessions (range 1 to 20) 24 subjects total used the Ekso • Mean time since injury 92.2 days (range of 10 to 835 days) • 6 closed TBI • 1 TBI unspecified • 3 non-TBI anoxic • 2 non-TBI neoplasm NOS • 2 non-TBI malignant neoplasm • 3 non-TBI benign neoplasm of meninges • 1 non-TBI non traumatic hemorrhage Results • Mean Motor FIM scores pre and post-training were 20.4 and 54.2, respectively • Mean Cognitive FIM scores pre and post-training were 12.2 and 23.0, respectively • There were no falls or other adverse events reported

Kessler TBI	Single center, open-label, non-comparative, non-randomized, prospective study of patients with traumatic brain injury. Duration of Intervention • Ambulation during a mean of 4.9 sessions (range 2 to 5) 25 subjects total used the Ekso • Mean time since injury 3540 days (range of 603 to 21360 days) • All were unspecified TBI Results • Mean 10MWT pre and post-training were 17 and 18 seconds, respectively • Mean 2MWT pre and post-training were 126 and 128 meters, respectively • Mean TUG scores pre and post-training were 19.3 and 21.7, respectively • There were no falls or other adverse events reported

Substantial Equivalence Conclusion

This device is substantially equivalent to the current device. Both devices have the same technical characteristics and the same intended uses, to facilitate gait ambulation. The supporting clinical data demonstrating the use of the product with patients with Acquired Brain Injury (ABI), including both Traumatic Brain Injury (TBI) and non-Traumatic Brain Injury (non-TBI), show that the device effectively facilitates gait ambulation in the expanded patient population. The clinical data reported no adverse events demonstrating the device is safe on this patient population when used in accordance with existing labeling.