September 09, 2020

B-Temia Inc.
% Kristin Davenport
Of Counsel
Covington & Burling LLP
850 10th St NW
Washington, DC 20001

Re: K201539
Trade/Device Name: Keeogo Dermoskeleton System
Regulation Number: 21 CFR 890.3480
Regulation Name: Powered Lower Extremity Exoskeleton
Regulatory Class: Class II
Product Code: PHL
Dated: May 31, 2020
Received: June 9, 2020

Dear Kristin Davenport:

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)*

K201539

Device Name

Keeogo Dermoskeleton System

Indications for Use *(Describe)*

The Keeogo is robotic exoskeleton that fits orthotically on the user's waist, thigh, and shin, outside of clothing. The device is intended to help assist ambulatory function in rehabilitation settings under the supervision of a trained healthcare professional for the following population:

Individuals with stroke who have gait deficits and sufficient hip (MMT Hip ≥ 3) and knee strength (MMT Knee ≥ 2) and who are capable of standing and initiating gait movement without assistance.

The trained healthcare professional must successfully complete a training program prior to fitting and tuning the device. The device is not intended for sports.

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

General Information:	Sponsor's Name:	B-Temia, Inc.
	Address:	4780, rue St-Félix - unité 105 St-Augustin-de-Desmaures (QC) G3A 2J9 Canada
	Contact Person:	Alexandre Jokic VP Regulatory, Clinical Affairs and Quality Assurance, B-Temia Inc.
	Address:	4780, rue St-Félix - unité 105 St-Augustin-de-Desmaures (QC) G3A 2J9 Canada
	Telephone:	418-653-1010 ext. 248
	Fax Number:	418 653-0155
	Date Prepared:	May 31, 2020

Subject Device:	Trade Name:	Keeogo™ Dermoskeleton System
	Common Name:	Powered Exoskeleton
	Product Code:	PHL
	FDA Regulation:	21 CFR 890.3480 Powered lower extremity exoskeletons
	Device Classification:	Class II

Predicate Device:	Trade Name:	Honda Walking Assist Device
	Common Name:	Powered Exoskeleton
	Product Code:	PHL
	FDA Regulation:	21 CFR 890.3480 Powered lower extremity exoskeletons
	Device Classification:	Class II
	Premarket Notification:	K181294

Indications for Use:

The Keeogo™ Dermoskeleton System is robotic exoskeleton that fits orthotically on the user's waist, thigh, and shin, outside of clothing. The device is intended to help assist ambulatory function in rehabilitation settings under the supervision of a trained healthcare professional for the following population:

Individuals with stroke who have gait deficits and sufficient hip (MMT Hip ≥ 3) and knee strength (MMT Knee ≥ 2) and who are capable of standing and initiating gait movement without assistance.

The trained healthcare professional must successfully complete a training program prior to fitting and tuning the device. The device is not intended for sports.

Description of device:

Keeogo™ Dermoskeleton System is an ambulatory assistive device that is fitted to the lower body, and is powered at the knee. This computer-controlled orthosis provides complementary force to the knee joint to assist with: (1) knee flexion and extension in the swing phase of gait, and (2) eccentric knee control and extension in the weight bearing phase.

Keeogo™ Dermoskeleton System does not move through a pre-determined pattern of movement, but rather integrates seamlessly with movements initiated by the user themselves, and provides assistance based on the detected activity.

Non-Clinical Performance Data

Several performance tests were conducted with the Keeogo™ Dermoskeleton System to demonstrate safety, effectiveness, and usability: Add here

- Durability
- Vibration IEC 60601-1-11
- Electrical Safety IEC 60601-1
- Electromagnetic Compatibility (EMC) IEC 60601-1-2
- Usability IEC 62366
- Battery Safety IEC 62133:2012
- Sensor accuracy
- Biocompatibility testing in accordance with ISO 10993-1:2009, ISO 10993-5 & ISO 10993-10)

Clinical Performance

Trial Registration	URL: http://www.clinicaltrials.gov Identifier: NCT03986320		
Trial Design	Interventional, comparative, single-arm trial		
Trial Sites	• The Shirley Ryan AbilityLab (Chicago, Illinois, USA) • Human Performance and Engineering Research (HPER) (West Orange, New Jersey, USA) • James J Peters VA Medical Center - Center for the Medical Consequences of Spinal Cord Injury (Bronx, New York, USA) • Assistive Technology Clinic (ATC) (Toronto, Ontario, Canada)		
Condition	Stroke		
Test Groups	Keeogo – Intervention		
Intervention	• Week 1: 3 baseline sessions • Week 2: 3 device familiarization sessions • Week 3: 3 Keeogo testing sessions		
Total Subjects	Population	Safety Population Visit 1	Effectiveness Population
	N	55	48
	Age	58 ± 11	58 ± 11

	Gender	26 female, 29 male	23 female, 25 male
	Hemiparesis	25 left-side, 30 right-side	23 left-side, 25 right-side
	Stroke Legacy	70 ± 81 months	74 ± 84 months
	MMT	Hip: MMT ≥ 3+ (flexors & extensors), Knee: MMT ≥ 2 (flexors & extensors)	Hip: MMT ≥ 3+ (flexors & extensors), Knee: MMT ≥ 2 (flexors & extensors
Clinical Outcome Assessments	• Baseline (each of three baseline test visits) • Intervention (each of three device test visits) • Post (after 9 visits)		
Results	**<u>Gait Quality Assessment, Wisconsin Gait Scale</u>** **Units:** scalar **Scale Range:** [13.35, 42] = **[healthy gait, max gait disability]** **Mean (SD)** **Baseline:** 20.36 (3.22) **Gait with Device:** 17.76 (2.54) **Change from Baseline (Paired test)** **Minimum Clinically Important Difference:** 2.25 **Improvement: 2.60 (1.71)** **95% Confidence interval for Improvement:** 2.60 ± 0.55 **Significance: P-Value =** $p < 0.001$ **Safety results:** No Serious Adverse Event was reported either for the participant (primary outcome) or physical therapist / clinician (secondary outcome). **Effectiveness results:** Participant group showed a statistically significant improvement in the WGS (secondary outcome) with the use of the Keeogo™ ($p < 0.001$) All the participants showed an improvement with one effectiveness assessment (WGS, 30SCT, TST-up, TST-down, ClinRO, PRO; assessments described under secondary and tertiary outcomes). Seventy-five percent showed an improvement with more than 50% of the effectiveness assessments.		

Substantial Equivalence

CATEGORY	KEEOGO™	HONDA WALKING ASSIST DEVICE (HWA)	Substantial Equivalence Comments
510(k) Number	TBA	K181294	**N/A**
Product Code	PHL	PHL	**[SAME]**

CATEGORY	KEEOGO™	HONDA WALKING ASSIST DEVICE (HWA)	Substantial Equivalence Comments
Sub-Product Code	N/A	N/A	**[SAME]**
Regulation Name	Powered Lower Extremity Exoskeleton	Powered Lower Extremity Exoskeleton	**[SAME]**
Device Class	Class II	Class II	**[SAME]**
Regulation	21 CFR 890.3480	21 CFR 890.3480	**[SAME]**
Indications for Use	The Keeogo Dermoskeleton System is a robotic exoskeleton that fits orthotically on the user's waist, thigh, and shin, outside of clothing. The device is intended to help assist ambulatory function in rehabilitation settings under the supervision of a trained healthcare professional for the following population: Individuals with stroke who have gait deficits and sufficient hip (MMT Hip ≥ 3) and knee strength (MMT Knee ≥ 2) and who are capable of standing and initiating gait movement without assistance. The trained healthcare professional must successfully complete a training program prior to fitting and tuning the device. The device is not intended for sports	The Honda Walking Assist Device is a robotic exoskeleton that fits orthotically on the user's waist and thigh, outside of clothing. The device is intended to help assist ambulatory function in rehabilitation institutes under the supervision of a trained healthcare professional for the following population: Individuals with stroke who have gait deficits and exhibit gait speeds of at least 0.4m/s and are able to walk at least 10 meters with assistance from a maximum of one person. The trained healthcare professional must successfully complete a training program prior to use of the device. The devices are not intended for sports.	**[SIMILAR]** - The patient population is the same - The Keeogo indication defines the necessary physical characteristics of the patient population in terms of minimum hip and knee strength, while the predicate describes the patient characteristics in terms of minimum gait speed - Hip and knee strength correlate to gait speed, as supported by data reported in literature - The difference in how minimum physical characteristics are described and determined does not raise different questions of safety or effectiveness

CATEGORY	KEEOGO™	HONDA WALKING ASSIST DEVICE (HWA)	Substantial Equivalence Comments
Device Weight	15 lbs (6.8 kg)	5.95 lbs (2.7 kg)	**[SIMILAR]** - Difference in weight is due to the Keeogo's design (covers area between hip and shin) compared to the predicate that covers the area between the hip and above the knee. This difference in weight does not raise different questions of safety or effectiveness
Body Coverage and Area of Assistance	Worn around the waist & legs; assistance provided to knee joint	Worn around the waist & thighs; assistance provided at hip	**[SIMILAR]** - As described above, the Keeogo covers the area between the hip and shin and provides assistance at the knee. The Honda device covers the area between hip and above the knee and provides assistance at the hip. - The differences in body coverage and area to which assistance is applied do not raise different questions of safety or effectiveness
Mobility Aid	Optional (e.g., walker, cane)	Optional (e.g., walker, cane)	**[SAME]**
Patient Population	• Individuals with stroke who have gait deficits and sufficient hip (MMT Hip ≥ 3) and knee strength (MMT Knee ≥ 2) and who are capable of standing and initiating gait movement without assistance.	• Individuals with stroke who have gait deficits and exhibit gait speeds of at least 0.4m/s and are able to walk at least 10 meters with assistance from a maximum of one person.	**[SAME]** - The patient population is the same, *i.e.*, individuals with stroke who have gait deficits - The difference in how minimum physical user characteristics are described and measured does not raise different questions of safety or effectiveness
Device limit on user's gait speed	None	None	**[SAME]**
Type of Surface for Training	Smooth, cement, carpet	Smooth, cement, carpet	**[SAME]**

CATEGORY	KEEOGO™	HONDA WALKING ASSIST DEVICE (HWA)	Substantial Equivalence Comments
Device Range of Motion (ROM)	• Hips: 150° flexion to 40° extension • Knee: 166° flexion to 4° extension	- Hips: 113° flexion to 47° extension	**[SIMILAR]** - Keeogo hip joint ROM is comparable to predicate - Keeogo also has a knee ROM because it provides assistance at the knee - Minor differences in hip ROM, and additional knee ROM, do not raise different questions of safety or effectiveness
User Height Requirement	1.52 m to 1.88 m (~60 in to ~74 in)	1.4 m to 2.0 m (~55 in to ~79 in)	**[SIMILAR]** - This minor difference does not raise different questions of safety or effectiveness
User Weight Requirement	≤285 lbs (130 kg)	≤220 lbs (100 kg)	**[SIMILAR]** - Keeogo is designed to accommodate up to the 95th percentile of adult men - This minor difference in user weight does not raise different questions of safety or effectiveness
Battery Specifications	- Rechargeable Li-Ion - 39.6 V, 1 A-h - 1 hr continuous operation - 1 hr charge time	- Rechargeable Li-Ion - 22.2 V, 1 A-h - 1 hr continuous operation - 2 hr charge time	**[SIMILAR]** - The minor differences in battery specifications (voltage and charge time) do not raise different questions of safety or effectiveness

CATEGORY	KEEOGO™	HONDA WALKING ASSIST DEVICE (HWA)	Substantial Equivalence Comments
Actuator Specifications	- 2 motors (2 at knee) - Up to 40 Nm max torque	- 2 motors (2 at hip) - 4 Nm max torque	**[SIMILAR]** - Keeogo motors are located at the knees, whereas the predicate motors are located at the hip - Higher torque is required at the knee to support knees from collapsing - This difference does not raise different questions of safety or effectiveness
Control Method	- Handheld controller attached to device - Keeogo does not initiate steps	- Handheld interface for physical therapist - HWA does not initiate steps	**[SAME]**
Life Cycle	3 years	3 years	**[SAME]**
Training Program	Yes	Yes	**[SAME]**
Certification Program	Yes	Yes	**[SAME]**
Device Feedback to the User	Auditory feedback on the handheld controller that is attached to device. Visual feedback is provided on the battery to indicate the battery status and charge level.	Visual & auditory feedback on both the handheld controller & device.	**[SAME]**
Fall Detection & Mitigation	None	None	**[SAME]**
Failsafe Features	Motor torque disables; device becomes passive	Motor torque disables; device becomes passive	**[SAME]**
Operating Temperature	32 °F to 86 °F (0 °C to 30 °C)	32 °F to 86 °F (0 °C to 30 °C)	**[SAME]**
Operating Humidity	15% to 90%	30% to 85%	**[SIMILAR]** - Keeogo has a slightly larger humidity range, per 60601-1-11 - This does not raise different questions of safety or effectiveness

Training certification	Keeogo is an adjustable exoskeleton that allows fitting of the device to the user's body dimensions and adjustment of the software settings to meet the user's needs. A mobile application, which runs on a touchscreen tablet, allows the clinician to adjust the software settings during device installation to customize the level of assistance to the individual patient's need. To ensure safe and effective use, clinicians are required to complete a training program and obtain a certification prior to using the device with patients. The 15-18 hours training course is divided into 4 blocks, resulting in a certification test. The training activities allow clinicians to become familiar with the device and provide training on the following: • Screen and evaluate patients for use of Keeogo • Configure the device hardware and software settings use with patients • Practice training sessions with Keeogo • Demonstrate understanding of safety features, device controls, intended use, and patient training procedures • Understand Keeogo maintenance • Become familiar with resources for technical support
Statement on Substantial Equivalence:	The Keeogo System has the same intended use as the predicate Honda Walking Assist Device. The differences in technological characteristics between the Keeogo and the predicate do not raise new questions of safety or effectiveness. The data submitted in the 510(k) show that the Keeogo is at least as safe and effective as the Honda Walking Assist Device. As a result, the devices are substantially equivalent.