December 14, 2018

Honda Motor Company, Ltd.
% Mark DiPietro
Assistant Vice President, Power Equipment Division
American Honda Motor Company, Inc.
4900 Marconi Drive
Alpharetta, Georgia 30005

Re: K181294
Trade/Device Name: Honda Walking Assist Device
Regulation Number: 21 CFR 890.3480
Regulation Name: Powered lower extremity exoskeleton
Regulatory Class: Class II
Product Code: PHL
Dated: November 16, 2018
Received: November 16, 2018

Dear Mark DiPietro:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Vivek J. Pinto -S

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181294

Device Name

Honda Walking Assist Device

Indications for Use *(Describe)*

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.

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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HONDA

510(k) Summary

Administrative Information

Device Name	Honda Walking Assist Device	
Applicant Information	Company:	Honda Motor Company, Ltd. 1-4-1, Chuo, Wako-shi Saitama, 351-0193 Japan
	Contact:	Kazushi Hamaya
	Title:	Department Manager
	Email:	Kazushi_hamaya@hm.honda.co.jp
	Phone Number:	+81 80 4900-4527
Correspondent Information	Company:	American Honda Motor Company, Inc. 4900 Marconi Drive Alpharetta, Georgia 30005 United States of America
	Contact:	Mark DiPietro
	Title:	Assistant Vice President
	Email:	Mark_DiPietro@ahm.honda.com
	Phone Number:	+1 (678) 339-2623
Preparation Date	December 11, 2018	
Device Classification	Trade Name:	Honda Walking Assist Device
	Common Name:	Exoskeleton
	Classification Name:	Powered Lower Extremity Exoskeleton
	Product Code:	PHL
	Device Class:	Class II
	Regulation:	21 CFR 890.3480

Device Description

The Honda Walking Assist Device is a lightweight, robotic exoskeleton designed to help assist ambulatory function of stoke patients who meet the user assessment criteria, in rehabilitation institutes under the supervision of a trained healthcare professional. The device is worn around the user's waist and thighs, and assists with hip joint flexion and extension. The device weighs 5.95lbs and has two motors that run on a single rechargeable battery. The device is equipped with angle and current sensors to monitor hip joint angle and torque output respectively. The assist torque is transmitted to the user's thighs via thigh frames. A trained healthcare professional, who operates the device, can change assist settings through software that runs on a mobile device.

Indications for Use

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.

Comparison of Technological Characteristics to the Predicate

Predicate Device	Manufacturer	Device Name	510(k) Number
	Ekso Bionics®, Inc.	Ekso™ (Version 1.1) & Ekso GT™ (Version 1.2)	K161443

For simplicity, we will refer to the Ekso™ (Version 1.1) and Ekso GT™ (Version 1.2) devices as "Ekso." The table below highlights comparisons between the Honda Walking Assist Device and the predicate device, Ekso. These comparisons consider device intended use, indications for use, operating procedures and technological characteristics. Although there are some key differences between Ekso and the Honda

Walking Assist Device, these differences do not raise different questions of safety or effectiveness.

CATEGORY	HONDA WALKING ASSIST DEVICE (HWA)	EKSO BIONICS®, INC. – EKSO	Substantial Equivalence Comments
510(k) Number	K181294	K161443	**N/A**
Product Code	PHL	PHL	**[SAME]**
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 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.	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.	**[SIMILAR]** • HWA may be used during stair training in rehabilitation institutes under the supervision of a therapist who is within physical reach of device users, consistent with the user assessment and training certification program. Patients who require more than minimal contact by the therapist should not use the device. HWA stair training was performed during clinical testing, during which no falls or serious adverse events were reported • HWA is not intended for individuals with spinal cord injuries • HWA users must be ambulatory • The above factors do not raise different questions of safety and effectiveness since the HWA risk profile is not substantially different.
Device Weight	5.95 lbs (2.7 kg)	50 lbs (23 kg)	**[DIFFERENT]** • HWA is lighter

CATEGORY	HONDA WALKING ASSIST DEVICE (HWA)	EKSO BIONICS®, INC. – EKSO	Substantial Equivalence Comments
			• Lighter HWA weight does not raise different questions of safety and effectiveness
Body Coverage	Worn around the waist & thighs	Worn over legs & upper body with rigid torso	**[SIMILAR]** • HWA is not worn above the waist or below the knees • HWA users can wear bracing (e.g. an Ankle-Foot Orthosis) • Reduced HWA body coverage or the use of supplementary bracing does not raise different questions of safety and effectiveness
Mobility Aid	Optional (e.g., walker, cane)	Walker, crutches, cane	**[DIFFERENT]** • HWA does not require a mobility aid • The absence of a mobility aid with HWA does not raise different questions of safety and effectiveness. The HWA is indicated for ambulatory individuals and intended to be used with a trained healthcare professional in a rehabilitation institute.
Patient 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.	• 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)	**[DIFFERENT]** • HWA users must be ambulatory • HWA is only for stroke patients • Differences were addressed in the clinical study and do not raise different questions of safety and effectiveness
Device limit on user's gait speed	None	~2 km/hr	**[DIFFERENT]** • HWA does not limit gait speed • The above factor does not raise different questions of safety and effectiveness since a trained healthcare professional screens,

CATEGORY	HONDA WALKING ASSIST DEVICE (HWA)	EKSO BIONICS®, INC. – EKSO	Substantial Equivalence Comments
			evaluates and measures HWA users for the proper gait speed
Type of Surface for Training	Smooth, cement, carpet	Smooth, cement, carpet	**[SAME]**
Device Range of Motion (ROM)	• Hips: 113° flexion to 47° extension	• Hips: 135° flexion to 20° extension • Knees: 130° flexion to 0° extension • Ankles: 10° flexion to 10° extension	**[SIMILAR]** • HWA hip joint ROM is comparable
User Height Requirement	1.4 m to 2.0 m (~55 in to ~79 in)	1.58 m to 1.88 m (~62 in to ~74 in)	**[SIMILAR]**
User Weight Requirement	≤220 lbs (100 kg)	≤220 lbs (100 kg)	**[SAME]**
Battery Specifications	• Rechargeable Li-Ion • 22.2 V, 1 A-h • 1 hr continuous operation • 2 hr charge time	• Rechargeable Li-Ion • 48.1 V, 30 A peak current • 1 hr continuous operation • 1 hr charge time	**[SIMILAR]** • HWA outputs smaller voltage & current values • HWA requires a different charge time • Varied HWA battery specs do not raise different questions of safety and effectiveness
Actuator Specifications	• 2 motors (2 at hip) • 4 Nm max torque	• 4 motors (2 hip, 2 knee) • ~[40 to 70] Nm max torque	**[DIFFERENT]** • HWA has two motors • HWA outputs much less torque • Reduced HWA motor torque does not raise different questions of safety and effectiveness
Control Method	• Handheld interface for physical therapist	• Handheld interface for physical therapist • Weight shift to initiate steps	**[DIFFERENT]** • HWA does not detect user weight shift • HWA does not initiate steps • Different HWA control methods do not raise different questions of safety and effectiveness
Life Cycle	3 years	4 years	**[SIMILAR]** • HWA has a different usable life • Shorter HWA usable life does not raise different questions of safety and effectiveness
Training Program	Yes	Yes	**[SAME]**
Certification Program	Yes	Yes	**[SAME]**
Device Feedback to the User	Visual & auditory feedback on both the handheld controller & device	Provides visual feedback on the handheld controller & auditory feedback	**[SAME]**
Fall Detection & Mitigation	None	None	**[SAME]**

CATEGORY	HONDA WALKING ASSIST DEVICE (HWA)	EKSO BIONICS®, INC. – EKSO	Substantial Equivalence Comments
Failsafe Features	Motor torque disables; device becomes passive	In event of power failure – knees become locked and hips free (similar to typical passive leg braces)	**[SIMILAR]** • HWA does not impede joint range of motion (ROM) • Unrestricted joint ROM does not raise different questions of safety and effectiveness
Operating Temperature	32 °F to 86 °F (0 °C to 30 °C)	10 °F to 95 °F (-12 °C to 35 °C)	**[SIMILAR]** • HWA has a different range of operating temperature • Reduced HWA operating temperature does not raise different questions of safety and effectiveness
Operating Humidity	30% to 85%	Not Available	**[SIMILAR]** • HWA probably has a similar range of tolerable humidity • The above factor does not raise different questions of safety and effectiveness

Non-Clinical Performance Testing

As part of our overall R&D process, several performance tests were conducted to demonstrate device safety, effectiveness and usability. The table below gives a broad overview of our bench testing and device development criteria. Testing was conducted according to a combination of internal criteria and international technical standards. The device passed all criteria under an assumed 3-year life cycle.

CATEGORY	DESCRIPTION
Durability	• Component & bulk system worst case loading
Vibration	• Component & bulk system worst case oscillations
Thermal	• Component & bulk system temperature & humidity cycles • Component exposure to thermal shock
Impact	• Component free-fall drop testing
Particulate Resistance	• Component exposure to dust particles
Disinfection	• Bulk system exposure to medical grade cleaning substances
Quality Management	• Bulk system development per ISO 13485
Risk Management	• Bulk system development per ISO 14971
Usability	• Bulk system development per IEC 60601-1-6 & IEC 62366-1

CATEGORY	DESCRIPTION
Biocompatibility	• Component testing for *In Vitro* Cytotoxicity (ISO 10993-5), Skin Sensitization (ISO 10993-10), Intracutaneous Reactivity (ISO 10993-10) & Acute Systemic Toxicity (ISO 10993-11)
Battery Life Cycle	• Battery certification testing per IEC 62133 & IEC 60601-1-2
Electromagnetic Compatibility (EMC)	• EMC certification testing per IEC 60601-1-2
Electrical Safety	• Electrical safety testing per ANSI/AAMI IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012 & IEC 60950-1
Software & Cybersecurity	• Software verification, validation & hazard analysis per IEC 62304 & FDA guidelines (MAJOR Level of Concern)
Radio Frequency Wireless Technology	• Bluetooth module certification testing per EN 300 328 & EN 301 489-1/-17 (FCC compliant module)

Clinical Testing - Study #1

The table below summarizes a study of the Honda Walking Assist Device for stroke patients. The objectives were to compare the safety and effectiveness of the Honda Walking Assist Device compared to task-specific gait training.

Fifty participants with chronic stroke and moderate gait impairments were randomized to receive functional, task-specific gait training (FTST) or over-ground gait training with the Honda Walking Assist Device (HWA), delivered in 18 sessions over 6-8 weeks. Training sessions were comprised of gait training and stair training, all performed and assessed within a rehabilitation institute under clinical supervision. The primary endpoint was the change in 10 Meter Walk Test (MWT) Self-selected Velocity (SSV) from baseline in gait speed. Adverse events were monitored/assessed, before and after every data collection session, through study completion. Both groups exhibited improvements in clinical outcomes after training and at a 3-month follow up. There were no significant adverse events during the study.

The results from the HWA group were reviewed to support the use of the device for assisting ambulation function and stair training in rehabilitation institutes. The data demonstrates the HWA device helps assist the ambulatory function of stroke patients who exhibit sufficient ambulatory function to operate the device safely and effectively under the supervision of a healthcare professional in a rehabilitation institute. The data also addresses special controls 21 CFR 890.3480(b)(6) by assessing the level of supervision needed and appropriate environment for use.

TRIAL REGISTRATION		URL: http://www.clinicaltrials.gov Identifier: NCT01994395	
TRIAL DESIGN		Randomized Controlled Trial	
TRIAL SITE		The Shirley Ryan AbilityLab (Chicago, Illinois, USA)	
CONDITION		Stroke	
TEST GROUPS		Functional Task Specific Training (FTST) – Control	Honda Walking Assist (HWA) – Intervention
INTERVENTION		18 total training sessions without HWA device • 45min training sessions • 3 sessions/week • 6-8 weeks duration	18 total training sessions with HWA device • 45min training sessions • 3 sessions/week • 6-8 weeks duration
TOTAL SUBJECTS (n=50)	Groups	FTST (n=25)	HWA (n=25)
	Age	62 ± 3 years	60 ± 2 years
	Gender	9 female, 16 male	8 female, 17 male
	Hemiparesis	12 right-side, 13 left-side	13 right-side, 12 left-side
	Stroke Latency	5.4 ± 0.8 years	7.1 ± 1.5 years
	Initial Gait Speed	0.65 ± 0.02 m/s	0.7 ± 0.03 m/s
CLINICAL OUTCOME ASSESSMENTS		• Pre (before study) • Mid (after 9 sessions) • Post (after 18 sessions) • Follow-Up (3 months after study)	
HWA RESULTS (n = 25)		**10 Meter Walking Test, Self-selected Velocity** Units: cm/s Mean (SD) **Baseline:** 69.91 (3.03) **Change from Baseline** **Mid:** +8.87 (2.59) **Post:** +17.41 (2.23) **3 Month Follow Up:** +19.16 (4.37)	
		No falls or significant adverse events were reported	

Training Certification

The Honda Walking Assist Device (HWA) is an adjustable exoskeleton that allows fitting of the main waist frame and thigh frames to the user's dimensions. A mobile app, which runs on a touchscreen tablet, is provided with the device and is used by the

physical therapist to select the user settings and dynamically adjust the amount of assistance provided by the device during set up.

To ensure appropriate utilization, therapists are required to complete a certification training prior to using the device with their patients. This 8-hour training course is divided into two 4-hour sessions. The HWA training activities will allow therapists to:

- Screen, evaluate and measure patients for HWA use
- Configure the HWA device and tablet accessory for patients
- Fit the exoskeleton to patients for proper donning and doffing
- Safely guard and cue patients while using the HWA
- Complete 2-3 practice training sessions with the exoskeleton
- Demonstrate competence during emergency situations
- Become familiar with available resources for technical support

Statement of Substantial Equivalence

Based on comparisons of technological characteristics, intended use, indications for use, bench testing and clinical evidence, we conclude that the Honda Walking Assist Device is appropriate for its intended use and is considered substantially equivalent to the identified predicate device. We believe that any differences in comparisons do not raise different questions of safety and effectiveness.