April 21, 2022

Samsung Electronics Co., Ltd.
% Kyoungju Kim
Consultant
MDLab Inc.
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Magokjungang-ro, Gangseo-gu, Seoul
South Korea, 07788

Re: K213452
Trade/Device Name: GEMS-H
Regulation Number: 21 CFR 890.3480
Regulation Name: Powered lower extremity exoskeleton
Regulatory Class: Class II
Product Code: PHL
Dated: March 23, 2022
Received: March 24, 2022

Dear Kyoungju Kim:

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
Assistant Director, Acute Injury Devices Team
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213452

Device Name
GEMS-H

Indications for Use *(Describe)*

The GEMS-H is a robotic exoskeleton that fits orthotically on the wearer's waist and thighs, outside of clothing. The device is intended to help assist ambulatory function in rehabilitation institutions 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 0.4 m/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 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

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Device Information

- Trade Name: GEMS-H
- Common Name: Powered exoskeleton
- Classification Name: Powered lower extremity exoskeleton
- Product Code: PHL
- Panel: Neurology
- Regulation Number: 21 C.F.R. § 890.3480
- Device Class: Class II
- Date prepared: 04/11/2022

Predicate Device

K181294, Honda Walking Assist Device (by Honda Motor Company, Ltd.)

Device Description

The GEMS-H is a lightweight, robotic exoskeleton designed to help assist ambulatory function of stroke patients who meet the assessment criteria, in rehabilitation institutions under the supervision of a trained healthcare professional. The GEMS-H device provides assistance to the patient during hip flexion and extension.

The device is worn over clothing around the wearer's waist and thighs and fastened with Velcro straps to assists hip flexion and extension. The device weighs 4.7 lbs (2.1 kg) and has two motors that run on a single rechargeable battery. The device is equipped with joint angle and electrical current sensors to monitor hip joint angle and torque output, respectively.

The assist torque is transmitted to the wearer's thighs via thigh support frames. A trained healthcare professional, who operates the device, can change assist settings through software that runs on the tablet PC.

Indications for use

The GEMS-H is a robotic exoskeleton that fits orthotically on the wearer's waist, and thighs outside of clothing. The device is intended to help assist ambulatory function in rehabilitation institutions 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 0.4 m/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 device is not intended for sports.

Substantial Equivalence Comparison

The subject and predicate device (K181294) have the same intended use, and nearly identical indications for use, and are similar in design, technology, functions, and principle of operation.

Both devices are intended to help assist ambulatory function in individuals with stroke who have gait deficits and exhibit gait speeds of at least 0.4 m/s and are able to walk at least 10 meters with assistance from a maximum of one person. Both are worn around the wearer's waist and thighs and assist with hip joint flexion and extension. They also have two motors that run on a single pack of rechargeable batteries. They are equipped with angle and current sensors to monitor hip joint angle and torque output respectively. Both devices provide an assistive torque that is transmitted to the wearer's thighs via thigh frames. Both devices can change assist settings through software that runs on a touchscreen tablet device.

The differences in technological characteristics between the subject and predicate are as follows:

- Range of Motion: The GEMS-H has a smaller range of motion than predicate device. Since the GEMS-H's range of motion falls within the predicate's range, this difference does not raise different safety or effectiveness questions.

- Device Weight: The GEMS-H weighs less than the predicate due to its design. The difference in weight does not raise different questions of safety or effectiveness.

- Battery Specification: The GEMS-H can be operated from a minimum of 1 hour to a maximum of 2 hours, while the predicate device only allows 1 hour of continuous operation. This difference does not raise different questions of safety or effectiveness.

- Actuator specifications: The maximum torque of the GEMS-H is larger than that of the predicate. However, even though the motors of the GEMS-H are capable of producing a maximum of 12 Nm± 15%, the maximum torque will not be reached in all cases and for all patients. The trained physical therapist can monitor the torque in real time and change the setting on the tablet PC to control the generated maximum torque. In addition, any potential risk associated with the higher maximum torque is mitigated through the exclusion criteria that exclude patients with severe osteoporosis (as determined by a physician) from study participation. Likewise, the proposed labeling contains a contraindication for patients with heterotopic ossification or severe osteoporosis. As a result, this difference in maximum torque does not raise different questions of safety or effectiveness.

The following table summarizes the similarities and differences between the subject and predicate devices.

	Subject Device	Primary Predicate Device	Differences/Similarity
FDA 510(k) No.	K213452	K181294	-
Company	Samsung Electronics Co., Ltd.	Honda Motor Company	-
Trade/Device Name	GEMS-H	Honda Walking Assist Device	-
Regulation No.	21 CFR 890.3480	21 CFR 890.3480	Identical
Regulation Name	Powered exoskeleton	Powered exoskeleton	Identical
Regulatory Class	Class 2	Class 2	Identical
Product Code	PHL	PHL	Identical
Indication for use	The GEMS-H is a robotic exoskeleton that fits orthotically on the wearer's waist and thighs, outside of clothing. The device is intended to help assist ambulatory function in rehabilitation institutions 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 0.4 m/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 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 0.4 m/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.	Identical
Body coverage	Worn around the waist & thighs	Worn around the waist & thighs	Identical
Mobility aid	Optional (e.g., walker, cane, harness)	Optional (e.g., walker, cane)	Similar
Device limit on patient's gait speed	None	None	Identical
Type of Surface for training	Smooth, cement, carpet	Smooth, cement, carpet	Identical

	Subject Device	Primary Predicate Device	Differences/Similarity
Height of Patient	61 in to 75 in (1.55 m to 1.91 m)	55 in to ~79 in (1.4 m to 2.0 m)	Similar
Weight of Patient	99 lbs (45 kg) up to 220 lbs (100 kg) and BMI < 35 kg/ m^2	≤220 lbs (100 kg)	Similar
Control Method	Handheld interface to allow physical therapist to control and operate the device remotely	Handheld interface for physical therapist	Identical
Device Range of Motion	Hip: 100° flexion to 40° extension	Hips: 113° flexion to 47° extension	Different. The subject device has a smaller motion range than the predicate device. This difference does not raise different safety or effectiveness questions.
Device Weight	4.7 lbs (2.1 kg)	5.95 lbs (2.7 kg)	Similar. The GEMS-H weighs less than the predicate device; the difference in weight does not raise different questions of safety or effectiveness.
Battery specifications	• Rechargeable lithium ion. • 21.6V, 2,950 mAh, • 2 hr charge time • Minimum 2 Hr. of continuous walking* (with gain = 7, delay = 0.25 s) • Minimum 1 Hr. of continuous walking* (with gain = 8, delay = 0.25 s) * at a walking speed of about 1.9 ~ 2.5 MPH (0.8 ~ 1.1 m/s)	• Rechargeable lithium ion, • 22.2 V, 1 A-h, • 2 hr charge time • 1 hr continuous operation	Similar. The GEMS-H can be operated from a minimum of 1 hour to a maximum of 2 hours, while the predicate device only allows 1 hour of continuous operation. This difference does not raise different questions of safety or effectiveness.
Actuator Specifications	2 motors (2 at hip) 12 Nm ± 15% max torque	2 motors (2 at hip) 4 Nm max torque	Different. The maximum torque of the GEMS-H is larger than that of the predicate. However, even though the motors of the GEMS-H are capable of producing a maximum of 12 Nm± 15%, this is the maximum allowable torque and is not recommended for all patients under all training conditions. Rather, the trained physical therapist shall monitor the torque in real time and change the setting on the tablet PC to

	Subject Device	Primary Predicate Device	Differences/Similarity
			control the generated maximum torque. In addition, any potential risk associated with the higher maximum torque is mitigated through the exclusion criteria that exclude patients with severe osteoporosis (as determined by a physician) from study participation. Likewise, the proposed labeling contains a contraindication for patients with heterotopic ossification or severe osteoporosis. As a result, this difference in maximum torque does not raise different questions of safety or effectiveness.
Training Program	Yes	Yes	Identical
Certification Program	Yes	Yes	Identical
Feedback	Visual & auditory feedback on both the handheld controller & device	Visual & auditory feedback on both the handheld controller & device	Identical
Fall Detection and Mitigation	None	None	Identical
Failsafe Feature	Motor torque disables; device becomes passive	Motor torque disables; device becomes passive	Identical
Operating Temperature	32°F to 86°F (0°C to 30°C)	32 °F to 86 °F (0 °C to 30 °C)	Identical
Operating	30% to 85% RH	30% to 85%	Identical
Patient population	Individuals with stroke who have gait deficits and exhibit gait speeds of at least 0.4 m/s and are able to walk at least 10 meters with assistance from a maximum of one person.	Individuals with stroke who have gait deficits and exhibit gait speeds of at least 0.4 m/s and are able to walk at least 10 meters with assistance from a maximum of one person.	Identical

Non-Clinical Testing

The subject device was tested to the following standards.

- Electrical safety testing according to ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)
- Electromagnetic compatibility (EMC) testing according to IEC 60601-1-2:2014
- Usability engineering test according to IEC 60601-1-6:2013
- Vibration testing and thermal shock testing
- Battery safety testing according to IEC 62133-2:2017 Edition 1.0
- Software Verification and validation testing according to IEC 62304:2015
- Radio frequency wireless technology according to the procedure given in FCC Rules Part 15 Subpart B and FCC Rules Part 15 Subpart C, 15.247
- ANSI IEEE C63.27-2017 American National Standard for Evaluation of Wireless Coexistence
- Particulate resistance (IP20) according to IEC 60529:2013, Edition 2.2
- Biocompatibility Testing such as In Vitro Cytotoxicity (ANSI AAMI ISO 10993-5:2009/(R)2014), Skin Sensitization (ANSI AAMI ISO 10993-10:2010/(R)2014) and Intracutaneous Reactivity (ANSI AAMI ISO 10993-10:2010/(R)2014)
- Performance testing such as cyclic loading testing vibration testing, thermal shock testing, driving part durability testing, Velcro testing and worst-case frame testing
- Other Bench testing such as Safety according to the Range of Motion, Max. angular velocity, Max. Torque Test, Static Torque Tracking Performance, Providing Assistive Torque Test at DOC Walking Mode for Walking and Stopping, Generation of assistive torque patterns according to the change in option during DOC mode test, Continuous use time and Noise.

Clinical Testing

Samsung conducted a prospective, single arm, interventional, longitudinal, open-label, single center study with the GEMS-H in stroke patients. The study enrolled 53 subjects, of whom 41 completed the entire protocol. Each subject completed 18 indoor sessions of training with the GEMS-H in the outpatient clinic with a licensed physical therapist.

A summary of the clinical trial is provided below.

Title	Safety and Effectiveness on Functional Mobility Following Samsung Gait Enhancing and Motivating System-Hip (GEMS-H) Device Training in Sub-Acute and Chronic Stroke: A Pivotal Study
Protocol Number	00210372
Methodology	Prospective, single arm, interventional, longitudinal, open-label, single center

Study Period	February 12, 2020 to July 27, 2021
Study Center(s)	Shirley Ryan AbilityLab, Northwestern University, Chicago, IL
Objectives	The objective of this study was to assess safety and effectiveness of task-specific gait training in addition to balance and function mobility training in the stroke population while using the GEMS-H (developed by Samsung Electronics Co., Ltd.) in assistance mode only.
Endpoints	**Primary endpoints** 1) Safety was evaluated in terms of adverse events (AEs). AEs were evaluated at the time of their occurrence to determine severity and whether they were device-related. 2) Effectiveness was evaluated in terms of improvement of ≥0.14 m/s in the group mean change in self-selected gait speed on the 10-meter walk test (10MWT) without the device, following 18 sessions of training using the GEMS-H device in assist mode, compared to baseline. **Exploratory endpoints (main)** 1) Effect of walking without the GEMS-H at baseline to walking with the device at mid and post-training on gait speed using the 10MWT and measurement of walking endurance using the 6MWT.
Number of Subjects	41
Diagnosis and Main Inclusion Criteria	1) ≥ 30-days post stroke 2) Male and female adults, ages 18-85 years 3) Initial gait speed of ≥ 0.4 m/s and ≤ 0.8 m/s 4) Adequate cognitive function (Mini-Mental State Examination [MMSE] score >17) 5) Ability to walk at least 10 m with maximum 1 person assist 6) Physician approval for patient participation 7) Able to safely fit into device specification and tolerate minimum assistance
Study Product(s), Dose, Route, Regimen	GEMS-H
Duration of administration	After baseline testing was completed, subjects began 18 training sessions with the GEMS-H in the outpatient clinic with a licensed physical therapist. The training sessions were customized for each individual subject. Each session included 30 minutes of gait task specific training. And an additional 15 minutes is used to focus on patient-specific goals related to functional mobility and balance. If appropriate, the 15 minutes could also be used for additional gait training. Training sessions

	were conducted indoors only. Training sessions occurred 2–3 times a week for 6–8 weeks to complete the training protocol.
Environment of use	Outpatient clinic (Indoors) with smooth, cement, carpet surfaces, stairs, slopes less than 5 degrees, and treadmills.
Statistical methods	10MWT, 6MWT, Balance and functional mobility
Summary conclusions	**Primary endpoint** **Safety:** − Over the course of the study, 738 training sessions were completed by the 41 subjects (18 training sessions per study subject). Thirty-four AEs were reported for an overall AE rate of 4.6 %. − Six AEs were determined to be possibly device-related for a potential device-related AE rate of 0.8 %. No AEs were determined to be probably or definitely related to the device. **Effectiveness**: − The group mean change from baseline to post-training (after 18 sessions) for self-selected gait speed (10 Meter Walk Test) measured without the device was +0.12 m/s ($p<0.0001$). **Exploratory endpoints (main)** **Effectiveness:** − The group mean change from baseline measured without the device to post-training (after 18 sessions) measured with the device for assessing mobility assist (10 Meter Walk Test) was +0.16 m/s ($p<0.0001$). − The group mean change from baseline measured without the device to post-training (after 18 sessions) measured with the device for assessing mobility assist (6 Minute Walk Test) was +53.28 m ($p<0.0001$). ※ The exploratory endpoints evaluated ambulatory function in stroke patients wearing the device through assessing the group mean change in the 6MWT and the 10MWT from baseline (without the device) to post-training (with the device). The study subjects achieved a mean clinically significant improvement (MCID) in gait speed as measured by the 10MWT, and in walking endurance as measured by the 6MWT. The clinical study did not have a control arm to exclude placebo effect or to support a comparative claim relative to conventional rehabilitation treatment. Therefore, this device is not intended for functional improvement after stroke.
NCT number	NCT04285060

The results from the clinical study support the use of the GEMS-H for use in stroke patients to help assist ambulatory function in rehabilitation institutions under the supervision of a trained physical therapist. The data also address the special controls in 21 CFR § 890.3480(b)(6) by assessing the level of supervision necessary and the appropriate use environment.

Training Program

The GEMS-H should be used only by trained healthcare professionals who have successfully completed a training program provided by Samsung Electronics.

The healthcare professional will be trained on the basic features of the GEMS-H, and the training is designed to enable the user to perform the following tasks:

- Properly set up the device
- Assemble the device in all available configurations
- Identify the safe environments for the device use
- Operate the device in simulated use environments representative of indicated environments and use
- Screen, evaluate, and measure patients
- Properly fit the device to the patient
- Use the mobile application
- Understand and use the operating mode and its parameters appropriate for the patient
- Safety features during operation of the device
- Use the safety checklist
- Perform physical checks
- Understand and use all safety features of the device

Conclusion

The GEMS-H has the same intended use as the predicate, and the technological differences do not raise different questions of safety or effectiveness. The non-clinical and clinical data submitted in the 510(k) demonstrate that the GEMS-H is at least as safe and effective as the Honda Walking Assist Device. Accordingly, the GEMS-H is substantially equivalent to the predicate.