March 8, 2021

Wonjin Mulsan Co., Ltd
HaYong Jung
89, Geomdan-ro,
Seo-gu, Incheon, 22653
Republic of Korea

Re: K200660
Trade/Device Name: Compressible Limb and Circulation Therapy System, Model POWER RECOVERY
Regulation Number: 21 CFR 890.5650
Regulation Name: Powered Inflatable Tube Massager
Regulatory Class: Class II
Product Code: IRP
Dated: December 8, 2020
Received: December 15, 2020

Dear Ha Jung:

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
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)*

K200660

Device Name
Compressible Limb and Circulation Therapy System, Model POWER RECOVERY

Indications for Use *(Describe)*
POWER RECOVERY is intended for the temporary relief of minor muscle aches and pains, and for temporary increase in blood circulation to the treated areas in people who are in good health. POWER RECOVERY simulates kneading and stroking of tissues by using an inflatable garment (cuff).

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 807.02]

Date Prepared: Feb. 17, 2021

Submitter: Wonjin Mulsan Co., Ltd.
89, Geomdan-ro, Seo-gu, Incheon, 22653, Republic of Korea
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Establishment Registration Number: 3006797972
Contact Person: HaYong Jung
Email: wonjin@wonjininc.com

Trade Name: Compressible Limb and Circulation Therapy System
Model POWER RECOVERY

Common Name: Powered Inflatable Tube Massager

Classification Name: Massager, Powered Inflatable Tube

Regulation Number: 890.5650

Product Code: IRP

Classification: Class II

Predicate Device: Rapid Reboot Compression Therapy System which was cleared for marketing under K182668

Device Description

Compressible Limb and Circulation Therapy System Model POWER RECOVERY is a powered inflatable tube massager, and comprised of a main body, an AC-DC adapter, cuffs with hose, and a hose adapter and a main hose for connecting the device to the cuffs. The device is powered from an external IEC 60601-1 compliant power supply and can optionally be powered by an internal lithium ion battery. There are three cuffs to apply to different body areas, such as leg, arm, and hip. Leg cuff and arm cuff have 6-chambers and hip cuff has 5-chambers. The cuffs can be inflating and deflating sequentially to apply the pressure on the target body areas which are controlled by the main body. The device simulates kneading and stroking of tissues by using an inflatable garment (cuff) to temporarily relieve minor muscle aches and pains and to temporarily increase blood circulation to the tested areas in people who are in good health.

Indications for Use

POWER RECOVERY is intended for the temporary relief of minor muscle aches and pains, and for temporary increase in blood circulation to the treated areas in people who are in good health. POWER RECOVERY simulates kneading and stroking of tissues by using an inflatable garment (cuff).

Technologic Characteristics

Item	Description
Operation Mode	5 modes such as SEQUENTIAL, ADDITION and MASSAGE
Pressure Range	Level 1 (60 mmHg) to Level 10 (150 mmHg)
Operation Time	10, 20, and 30 minutes
Rest Time	Adjustable at interval of 0/5/10/30 sec at SEQUENTIAL mode Fixed at 30 sec at ADDITION and MASSAGE modes

Non-Clinical Testing
The device has been tested and met the requirements of the following standards:

IEC 60601-1:2005+A1:2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R) 2012 and A2:2010/(R)2012

IEC 60601-1-6 Edition 3.1 2013-10 Medical electrical equipment - Part 1-6: General requirements for safety and essential performance - Collateral Standard: Usability

IEC 60601-1-11 Edition 2.0 2015-01 Medical electrical equipment - Part 1-11: General requirements for safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment ANSI/AAMI HA60601-1-11:2015

IEC 60601-1-2 Edition 4.0 2014-02 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances – Requirements and tests

IEC 62366-1 Edition 1.0 2015-02 Medical device – Part 1: Application of usability engineering to medical devices

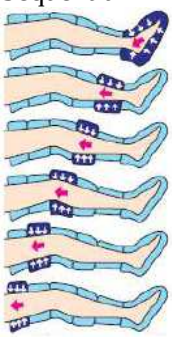
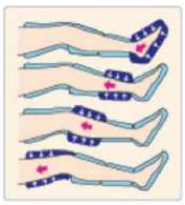
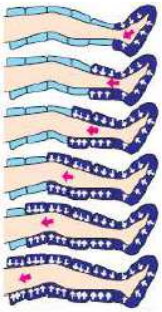
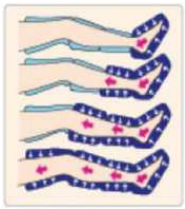
IEC 62304 Edition 1.1 2015-06 Medical device software - Software life cycle process

Clinical Testing
No clinical testing was performed.

Conclusions
Wonjin Mulsan Co., Ltd. believes that all applicable items of information specified in this submission have been supplied in full. The enclosed non-clinical data demonstrate that the subject device described herein raises no new questions concerning safety or effectiveness and may therefore be properly considered by the Agency as substantially equivalent to the predicate device that has previously been legally distributed in interstate commerce in the United States.

Comparison with Predicate Devices

Item	Subject Device	Predicate Device	Differences Discussion
Model	POWER RECOVERY	Rapid Reboot Compression Therapy System	NA
Manufacturer	Wonjin Mulsan Co., Ltd.	Rapid Reboot Recovery Products, LLC	NA
Classification	Class II Device, IRP (21 CFR 890.5650)	Class II Device, IRP (21 CFR 890.5650)	NA
510(k) number	K200660	K182668	NA
Indications for use	POWER RECOVERY is intended for the temporary relief of minor muscle aches and pains, and for temporary increase in blood circulation to the treated areas in people who are in good health. POWER RECOVERY simulates kneading and stroking of tissues by using an inflatable garment (cuff).	The Rapid Reboot Compression Therapy System is indicated for the temporary relief of minor muscle aches and pains and for temporary increase in circulation to the treated areas in people who are in good health. The Rapid Reboot Compression Therapy System simulates kneading and stroking of tissues by using an inflatable garment.	Identical
Prescriptive or OTC	OTC	OTC	Identical
Environment of Use	Clinics, hospital, athlete training, and home environments	Clinics, hospital, athlete training, and home environments	Identical
Power Source(s)	15 VDC via in IEC 60601-1 compliant power supply (100-240 VAC input), Optional integrated rechargeable battery	110VAC, 60Hz	Minor difference
Weight	2 kg including battery	2.63 kg (5.8 pounds)	Minor difference
Dimensions (W x H x D)	114 x 141 x 245 mm	25.4 x 16.51 x 12.7 cm (10” x 6.5” x 5”)	Minor difference
Device pressure range	60-150 mmHg	0-200 mmHg	Pressure range of subject device is smaller than that of predicate device.
Treatment Time	User can select operation time among 10, 20, and 30 minutes.	User determines therapy time. Choose from 10, 20, or 30 minute session time, with option to add additional 10 minutes to any therapy time.	Identical
Number of inflatable appliance segments	6 or less for leg and arm cuffs 5 or less for hip cuff	4	Minor difference

Sleeve and chamber	Leg: 6-chambers Arm: 6-chambers Hip: 5-chambers	Leg: 4-chambers Arm: 4-chambers Hip: 4-chambers	Minor difference
Anatomical site	Leg (including of foot, calf, knee, upper leg) Hip (including of upper leg, glutes, hips, lower lack) Arm (including of entire arm, shoulder)	Leg (including of foot, calf, knee, upper leg) Hip (including of upper leg, glutes, hips, lower lack) Arm (including of entire arm, shoulder, upper chest and back)	Identical
Mode of compression	Sequential, Addition, and Massage	Sequential and Peristaltic	Refer to the visual description below.
Mode of compression (visual description)	Sequential 	Mode A 	Sequential mode of POWER RECOVERY is similar to Mode A of the predicate.
	Addition 	Mode B 	Addition mode of POWER RECOVERY is similar to Mode B of the predicate.
	Massage: Combination of SEQUENTIAL and Addition modes	None	Massage mode of POWER RECOVERY is a combination of SEQUENTIAL and Addition modes.

Appearance and size of Cuffs	Leg   355x97mm (14” x 38.4”)	Leg  X-Short: 14” x 41” Short: 14” x 43” Medium: 14” x 45” Long: 14” x 48” X-Long: 14” x 52”  	Minor difference
	Hip   780x775mm (30.7” x 30.5”)	Hip  Regular: 26” x 32” Large: 26” 35” 	Minor difference

	Arm   300x945mm (11.8” x 37.2”)	Arm  Regular: 18” x 38” Long: 18” x 44” 	Minor difference
Other accessories	 AC-DC Adapter   Main Hose Hose Adapter  Carrier	“Not publicly available in the official 510K Summary”	Minor difference