September 14, 2021

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

Re: K211283
Trade/Device Name: Compressible Limb and Circulation Therapy System, Model POWER-Q2300
Regulation Number: 21 CFR 890.5650
Regulation Name: Powered Inflatable Tube Massager
Regulatory Class: Class II
Product Code: IRP
Dated: August 24, 2021
Received: August 31, 2021

Dear HaYong 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,

Vivek Pinto, PhD
Director
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)*
K211283

Device Name
Compressible Limb and Circulation Therapy System, Model POWER-Q2300

Indications for Use *(Describe)*
POWER-Q2300 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-Q2300 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: Sep. 8, 2021

Submitter: Wonjin Mulsan Co., Ltd.
89, Geomdan-ro, Seo-gu, Incheon, 22653, Republic of Korea
Tel: 82-32-816-0552, Fax: 82-32-816-0557
Establishment Registration Number: 3006797972
Contact Person: HaYong Jung
Email: wonjin@wonjininc.com

Trade Name: Compressible Limb and Circulation Therapy System
Model POWER-Q2300

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

POWER-Q2300 is comprised of a main body, a power cord, cuffs, and hoses for connecting the device to the cuffs. The device is AC-powered. There are four cuffs to apply to different body areas, such as leg, arm, hip, and half-leg. The cuffs have 4-chambers. The cuff inflates and deflates sequentially to apply the pressure on the target body areas which are controlled by the main body.
Double hose is to connect main body and leg cuff. Single hose is to connect main body and arm cuff (or hip cuff or half-leg cuff). Extension zipper is for bigger leg. Blocked jack is to block an air outlet that will not be used. The colors of the cuffs and extension zipper are available in pink or gray.

Indications for Use

POWER-Q2300 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-Q2300 simulates kneading and stroking of tissues by using an inflatable garment (cuff).

Technologic Characteristics

Item	Description
Operation Mode	4 modes such as Mode A, Mode B, Mode C, and Mode D
Pressure Range	20 mmHg to 200 mmHg
Operation Time	15 and 30 minutes
Rest Time	Adjustable at interval of 0/5/10/30 sec at modes A and B Fixed at 30 sec at modes C and D

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

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

Performance testing for pressure accuracy, seam strength, and fail mode testing has been performed.

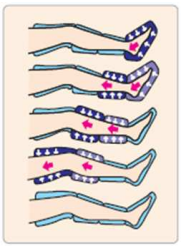
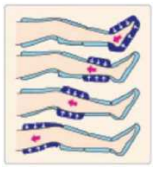
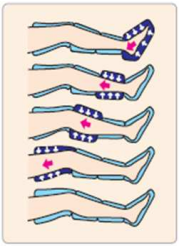
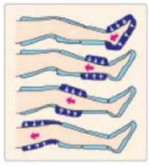
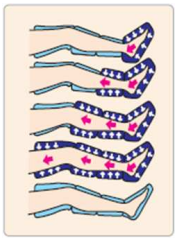
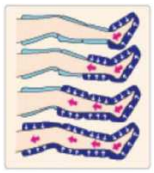
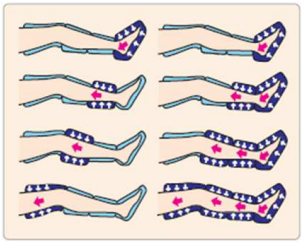
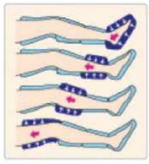
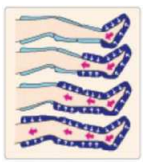
The biocompatibility of the materials has not been verified by the FDA and contact of the cuffs/ accessories to direct skin may lead to skin irritation, skin sensitization and/or cytotoxicity. The device is intended to be used only over clothing.

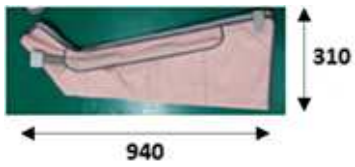
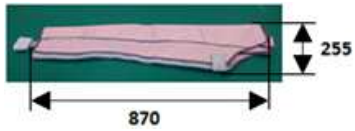
Clinical Testing
No clinical testing was performed.

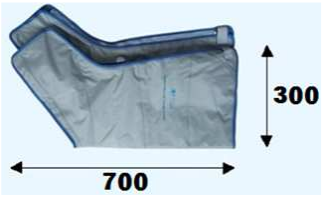
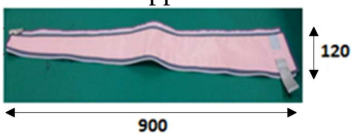
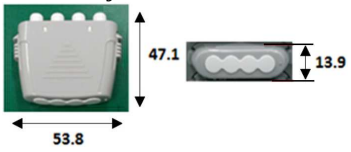
Conclusions
Wonjin Mulsan Co., Ltd. believes that all applicable items of information specified in this submission have been supplied in full. The enclosed non-clinical data demonstrate that the subject device described herein raises no new questions concerning safety or effectiveness and may therefore 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-Q2300	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		K182668	NA
Indications for use	POWER-Q2300 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-Q2300 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)	110-120VAC, 50/60Hz	110VAC, 60Hz	Minor difference
Weight	3.1 kg	2.63 kg (5.8 pounds)	Minor difference
Dimensions (W x H x D)	290 x 260 x 172 mm	25.4 x 16.51 x 12.7 cm (10” x 6.5” x 5”)	Minor difference
Device pressure range	20-200 mmHg	0-200 mmHg	Pressure range of subject device is smaller than that of predicate device.
Treatment Time	User can select operation time from 15 and 30 minutes.	User determines therapy time. Choose from 10, 20, or 30 minute session time, with option	Minor difference

		to add additional 10 minutes to any therapy time.	
Number of inflatable appliance segments	4	4	Identical
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) Half-Leg (including of foot, calf, knee)	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 except half-leg
Mode of compression	4 modes (Mode A, Mode B, Mode C and Mode D)	2 modes (Sequential and Peristaltic)	Refer to the visual description below.
Mode of compression (visual description)	Mode A 	Mode A 	Mode A of POWER-Q2300 is similar to Mode A of the predicate.
	Mode B 	Mode A 	Mode B of POWER-Q2300 is identical to Mode A of the predicate.
	Mode C 	Mode B 	Mode C of POWER-Q2300 is identical to Mode B of the predicate.
	Mode D 	Mode A  Mode B 	Mode D of POWER-Q2300 is a combination of Mode B and Mode C, and is identical to a combination of Mode A and Mode B of the predicate.

Appearance and size of Cuffs	Leg   Medium: 310x940mm Large: 390x990	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   530x720mm	Hip  Regular: 26" x 32" Large: 26" 35" 	Minor difference
	Arm   Medium: 255x870mm Large: 330x895mm	Arm  Regular: 18" x 38" Long: 18" x 44" 	Minor difference

	Half-Leg   300x700mm	None	Minor difference
Other accessories	Extension zipper  Medium: 120x900mm Large: 150x950mm	“Not publicly available in the official 510K Summary”	Minor difference
	Double hose  Length: 1,430mm		
	Single hose  Length: 1,320mm		
	Blocked jack  53.8x47.1x13.9mm		