September 1, 2021

DaeSung Maref Co., Ltd
% Do Gyun Lim
Senior Consultant
Global Medical Standard Consulting Co., Ltd.
34, Sangamsan-ro, Mapo-gu
Seoul, 03909
Korea, South

Re: K202395
Trade/Device Name: Sp-1000, Sp-2000
Regulation Number: 21 CFR 890.5650
Regulation Name: Powered inflatable tube massager
Regulatory Class: Class II
Product Code: IRP
Dated: September 9, 2020
Received: September 10, 2020

Dear Do Gyun Lim:

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,

For Amber Ballard
Assistant 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)*
K202395

Device Name
SP-1000, SP-2000

Indications for Use *(Describe)*
SP-1000/2000 is indicated for the temporary relief of minor muscle aches and pains and for temporaryincrease in circulation to the treated areas in people who are in good health.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K202395 510(K) Summary

1. Data Prepared [21 CFR 807.92(a)(a)]

May 08, 2021

2. Submitter's Information [21 CFR 807.92(a)(1)]

- Name of Manufacturer :

  DAESUNG MAREF CO., LTD.

- Address :

  298-24, Gongdan-ro Gunpo-si, Gyeonggido Republic of Korea

- Contact Name :

  Hyoung Ju, Cho

- Telephone No. :

  82-31-459-7211

- Fax No. :

  82-31-459-7215

- Email Adress :

  rndra@dsmaref.com

- Registration No. :

  3004116008

3. Trade Name, Regulation Name, Classification [21 CFR 807.92(a)(2)]

Trade / Device Name	SP-1000, SP-2000
Common Name	Powered Inflatable Tube Massager
Regulation Number	21 CFR 890.5650
Regulation Name	Powered Inflatable Tube Massager
Regulation Class	II
Product Code	IRP

4. Identification of Predicate Device(s) [21 CFR 807.92(a)(3)]

Predicate Device

- 510(k) Number :

  K182668

- Applicant :

  Rapid Reboot Recovery Product, LLC

- Trade / Device Name :

  Rapid Reboot Compression Therapy System

- Regulation Number :

  21 CFR 890.5650

- Regulation Name :

  Powered Inflatable Tube Massager

- Regulation Class:

  II

- Product Code:

  IRP

Predicate device has not been subject to a design-related recall.

5. Description of the Device [21 CFR 807.92(a)(4)]

Operating principal of this device is that the air output from the air motor is delivered to a sleeve composed of four air chambers which are sequentially inflated from the first air chamber to the fourth chamber.
SP-1000 can adjust the pressure values of all chambers at once. The SP-2000 can adjust the pressure value for each channel. This device is composed of a power supply, a pump, a control unit, and a wearable unit. The power applied from the power supply is applied to the pump. And user can adjust the time through time control knob, during which time power is supplied to the air pump. When the set time is over, the pump will stop working. Air pump creates air pressure and transmits it to the Synchro motor. The air delivered to the synchro motor distributes the air to each channel of the sleeve. And there is a pressure control valve between the sleeve and the synchro motor, the user can adjust the pressure of each sleeve through the pressure control knob. The sleeve prevents blood from accumulating by repeatedly applying inflation/deflation to the wearing area. According to the type of the sleeve, it can apply to the leg, lower body, and arm.

6. Indications For Use [21 CFR 807(a)(5)]

SP-1000/2000 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.

7. Determination of Substantial Equivalence

Summary of technological characteristics of the device compared to the predicate device. [21CFR 807.92(a)(6)]
The SP-1000/2000 is substantially equivalent to legally marketed predicate device (Rapid Reboot Compression Therapy System) with respect to indications for use and technology characteristics.
The table below presents comparisons for devices:

[Table 1. Comparison of Proposed Device to Predicate Devices]

	Proposed Device	Predicate Device
Model Name	SP-1000 / SP-2000	Rapid Reboot Compression Therapy System
510(k) Number	K202395	K182668
Manufacturer	DAESUNG MAREF CO., LTD.	Raid Reboot Recovery Product, LLC
Product Code	IRP	IRP
Device Class	II	II
Regulation Number	21 CFR 890.5650	21 CFR 890.5650
Regulation Name	Powered Inflatable Tube Massager	Powered Inflatable Tube Massager
Indications For Use	SP-1000/2000 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 is intended for the temporary relief of minor muscle aches and pains and for the 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.
Intended Use environment	Professional healthcare environment & Home environment	Clinics, hospital, athlete training, and home environments
Type of Use	OTC	OTC
Accessories	Leg sleeves Arm sleeve Center body sleeve	Leg attachment Arm attachment Hip attachment
Specifications		
Power Source	100-127V~, 50/60Hz 200-240V~, 50/60Hz	100V, 60 Hz
Time	0-30 min	0-30 min
Pressure	0-200mmHg ± 15% mmHg	0-200mmHg
Number of chamber	4	4

The table also provides rationale for a little difference in support of substantial equivalence to the Predicate devices.

[Table 2. Little difference with Predicate Device]

Justification to Support Substantial Equivalence
There are no significant differences between SP-1000 / SP-2000 and the predicate devices that would adversely affect its use. The subject device declares the safety and effectiveness of the device through tests for appropriate standards and the accessories, though named differently, are used on the same anatomical locations as the predicate device. Therefore, It is substantially equivalent to predicates in indications for use and technology characteristics.

Non-Clinical Test Summary

The SP-1000 / SP-2000 comply with voluntary standards for electrical safety, electromagnetic compatibility, use in the home healthcare environment and usability.
The following data were provided in support of the substantial equivalence determination :

1) Electrical Safety, Electromagnetic Compatibility and Performance

The SP-1000 / SP-2000 comply with the electrical safety and electromagnetic compatibility requirements established by the standards.

- IEC 60601 : 2005/A1:2012, Medical Electrical Equipment:Part 1: General Requirements for Basic Safety and Essential Performance
- IEC 60601-1-2:2014, Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements and Tests
- IEC 60601-1-11:2015, Medical Electrical Equipment - Part 1-11: General Requirements for Basic Safety and Essential Per formance - Collateral Standard: Requirements for Medical Electrical Equipment and Medical Electrical Systems Used in the Home Healthcare Environment

K202395 510(K) Summary

Clinical Test Summary

Clinical testing was not required to demonstrate the substantial equivalence of the SP-1000 / SP-2000 to its predicate device

8. Conclusion [21 CFR 807.92(b)(3)]

The SP-1000 / SP-2000 have similar intended use and technical characteristics to the predicate devices.
Based on that information, we conclude that the differences between the proposed device and predicate devices do not introduce a new intended use and do not raise new issues of safety and effectiveness. Therefore, the subject device is substantially equivalent to the predicate device.