July 2, 2021

Daesung Maref CO., LTD.
Su Hyeon So
Assistant Researcher
298-24, Gongdan-Ro
Gunpo-Si, Gyeonggido 15809
South Korea

Re: K203498
Trade/Device Name: LX9max
Regulation Number: 21 CFR 890.5650
Regulation Name: Powered Inflatable Tube Massager
Regulatory Class: Class II
Product Code: IRP
Dated: May 14, 2021
Received: May 19, 2021

Dear Su Hyeon So:

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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K203498

Device Name
LX9max

Indications for Use *(Describe)*
A device intended to temporarily relieve minor muscle aches and pains and for temporary increase 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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

**510(k) Summary**

**K203498**

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

June 30, 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 :
  Su Hyeon, So
- Telephone No. :
  82-31-459-7211
- Fax No. :
  82-31-459-7215
- Email Address :
  rndra@dsmaref.com
- Registration No. :
  3004116008

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

- Trade /Device Name :
  LX9max
- Regulation Number :
  21 CFR 890.5650
- Regulation Name :
  Massager, Powered Inflatable Tube
- Regulation Class. :
  II
- Product Code :
  IRP

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

**Predicate Device**

- 510(k) Number :
  K182668
- Applicant :
  Rapid Reboot Recovery Products, LLC
- Trade/Device Name :
  Rapid Reboot Compression Therapy System
- Regulation Number :
  21 CFR 890.5650
- Regulation Name :
  Massager, Powered Inflatable Tube
- Regulation Class :
  II
- Product Code :
  IRP

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

**Reference Device**

- 510(k) Number :
  K203552
- Applicant :
  Rapid Reboot Recovery Products, LLC
- Trade/Device Name :
  Rapid Reboot REGEN+
- Regulation Number :
  21 CFR 890.5650
- Regulation Name :
  Massager, Powered Inflatable Tube
- Regulation Class :
  II
- Product Code :
  IRP

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

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

This product is an Intermittent Pneumatic Compression system to temporarily relieve minor muscle aches and pains and for temporary increase in circulation to the treated areas in people who are in good health.

The operating principle is that the air from the device will be delivered to the sleeve with 4 air chambers and the air pressurizes sequentially the chambers from 1$^{st}$ to 4$^{th}$.

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

A device intended to temporarily relieve 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 LX9max is substantially equivalent to legally marketed predicate device (Rapid Reboot Compression Therapy System) and Reference Devices(Rapid Reboot REGEN+) with respect to indications for use and technology characteristics. The table below presents comparisons for device :

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

| | Proposed Device | Predicate Device | Reference Device |
|---|---|---|---|
| Model Name | LX9max | Rapid Reboot Compression Therapy System | Rapid Reboot REGEN+ |
| 510(k) Number | K203498 | K182668 | K203552 |
| Manufacturer | DAESUNG MAREF CO., LTD. | Rapid Reboot Recovery Products, LLC | Rapid Reboot Recovery Products, LLC |
| Product Code | IRP | IRP | IRP |
| Device Class | II | II | II |
| Regulation Number | 21 CFR 890.5650 | 21 CFR 890.5650 | 21 CFR 890.5650 |
| Regulation name | Massager, Powered Inflatable Tube | Massager, Powered Inflatable Tube | Massager, Powered Inflatable Tube |

| | Proposed Device | Predicate Device | Reference Device |
|---|---|---|---|
| Indications For Use | A device intended to temporarily relieve 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. | This device 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 | Home environments (Indoor environments) | Clinics, hospital, athlete training, and home environments. | Clinics, hospital, athlete training, and home environments. |
| OTC or Rx only | OTC | OTC | OTC |
| Accessories | Leg sleeves, Arm sleeve, Center body sleeve | Leg sleeve, Arm sleeve, Hip sleeve | Leg sleeve, Arm sleeve, Hip sleeve |
| Specifications | | | |
| Power Source | 100-127V~, 50/60Hz | 110 V, 60Hz | 110 V, 60Hz |
| Time | 5-90 min | 10,20,30 min | 1-179 minutes |
| Pressure | 10-180mmHg ± 20 mmHg | 0-200 mmHg | 0-200 mmHg |
| Number of chamber | 4 | 4 | 4 |

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

[Table 2. Little difference with Predicate / Reference Devices]

| Justification to Support Substantial Equivalence |
| --- |
| Proposed device (LX9max) and Predicate device (Rapid Reboot Compression Therapy System) can be considered to be almost equivalent except for pressure range, time range, and sleeve type.<br><br>The pressure range of the proposed device are included within pressure range of the predicate device.<br><br>About difference of time range, Since the principle of action is the same, and the pressure of the proposed device is lower than that of the predicate device, the difference in time range does not have a serious effect on safety and effectiveness. And because the operating principle is similar, even if the sleeves are different, they operate in the same way, and the pressure is also lower than that of the predicate device & Reference device.<br><br>The reference device is from the same manufacturer as the predicate device (K182668), and has been cleared by 510(k) as a substantially equivalent device.<br><br>The operating time of the reference device is 1-179 minutes, which is larger than the operating time of the proposed device. Therefore, the differences in technological characteristics do not raise different questions of safety and effectiveness. |

**Non-Clinical Test Summary**

The LX9max complies 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 LX9max complies 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 60601-1-2:2014, Medical Electrical Equipment - Part 1 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Disturbances -Requirements and Tests

- IEC 60601 60601-1-11:2015, Medical Electrical Equipment - Part 1 1-11: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Requirements for Medical Electrical Equipment and Medical Electrical Systems Used in the Home Healthcare Environment

2) Biocompatibility
- Biocompatibility of the sleeve materials has not been verified by the FDA and contact of The sleeves/accessories to direct skin may lead to skin irritation, skin sensitization and/or cytotoxicity.

**Clinical Test Summary**

Clinical Testing was not required to demonstrate the substantial equivalence of the LX9max to its predicate / reference device.

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

The LX9max has similar intended use and technical characteristics to the predicate device. Based on that information, we conclude that the differences between the proposed device and predicate device do not introduce a new intended use and do not raise new issues of safety and effectiveness. Therefore, the subject device is substantially equivalent the predicate device.