June 22, 2021

DaeSung Maref Co., Ltd
So Hyeon
Assistant Researcher
298-24, Gongdan-ro
Gunpo-si, 15809 Korea

Re: K203019
Trade/Device Name: LF900
Regulation Number: 21 CFR 890.5650
Regulation Name: Powered Inflatable Tube Massager
Regulatory Class: Class II
Product Code: IRP
Dated: March 8, 2021
Received: March 29, 2021

Dear So Hyeon:

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)*
K203019

Device Name
LF900

Indications for Use *(Describe)*
LF900 is intended for use by medical professionals and patients at home, who are under medical supervision, in treating many conditions, such as: Primary lymphedema, Edema following trauma and sport injuries, Postimmobilization edema, Venous insufficiencies, Lymphedema.

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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510(K) Summary

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

March 8, 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 Adress :

  rndra@dsmaref.com

- Registration No. :

  3004116008

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

	Trade / Device Name	LF900
	Regulation Number	21 CFR 890.5650
	Regulation Name	Massager, Powered Inflatable Tube
	Regulation Class	II
	Product Code	IRP

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

Predicate Device

- 510(k) Number :

  K113275

- Applicant :

  BSR KOREA Corp.(K113275)

- Trade / Device Name :

  Compressible Limb Therapy System (Power-Q1000 Premium)(K113275)

- 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.

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

This product is an Intermittent Pneumatic Compression system to improve the blood circulation of the human body.

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 1st to 4th.

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

LF900 is intended for use by medical professionals and patients at home, who are under medical supervision, in treating many conditions, such as: Primary lymphedema, Edema following trauma and sport injuries, Postimmobilization edema, Venous insufficiencies, Lymphedema.

7. Determination of Substantial Equivalence

Summary of technological characteristics of the device compared to the predicate device. [21CFR 807.92(a)(6)]

The LF900 is substantially equivalent to legally marketed predicate device (POWER-Q1000 Premium) with respect to indications for use and technology characteristics.
The table below presents comparisons for device :

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

	Proposed Device	Predicate Device
Model Name	LF900	POWER-Q1000 Premium
510(k) Number	K203019	K113275
Manufacturer	DAESUNG MAREF CO., LTD.	WONJIN MULSAN Co., Ltd.
Product Code	IRP	IRP
Device Class	II	II
Regulation Number	21 CFR 890.5650	21 CFR 890.5650
Regulation Name	Massager, Powered Inflatable Tube	Massager, Powered Inflatable Tube
Indications For Use	LF900 is intended for use by medical professionals and patients at home, who are under medical supervision, in treating many conditions, such as: Primary lymphedema, Edema following trauma and sport injuries, Postimmobilization edema, Venous insufficiencies, Lymphedema.	The device is indicated for use by medical professionals and patient at home, who are under medical supervision, in treating many conditions, such as: Primary lymphedema, edema following trauma and sport injures, Post-immobilization edema, Venous insufficiencies, Lymphedema
Intended Use environment	Professional healthcare environment & Home environment	Professional healthcare environment & Home environment
OTC or Rx only	Rx only	Rx only

	Proposed Device	Predicate Device
Accessories	Leg sleeves Extension zipper Single tubing Double tubing	Leg Cuffs Single connectinig hose Double connectinig hose Extension zipper for the leg cuffs (option)
Specifications		
Power Source	100-127V~, 50/60Hz	AC 120V, 50/60Hz
Time	5-90 min	0-99 min
Pressure	10-180mmHg ± 20 mmHg	0-240mmHg ± 20 %
Operation Mode	A,B,C,D	A,B,C,D,E
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 differnence with Predicate Device]

Justification to Support Substantial Equivalence
Proposed device (LF900) and Predicate device (POWER-Q1000 Premium) can be considered to be almost equivalent except for pressure range, time range, operation mode. The time range and pressure range of the proposed device are included within the time range and pressure range of the predicate device. The operation mode simply differs in the seqeuence of pressurization, the principle of operation and usage are the same. And the pressure is also lower than that of the predicate device & Reference device. Therefore, the differences in technological characteristics do not raise different questions of safety and effectiveness.

Non-Clinical Test Summary

The LF900 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 LF900 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 Per formance - Collateral Standard: Requirements for Medical Electrical Equipment and Medical Electrical Systems Used in the Home Healthcare Environment

2) Device Performance test

The proposed device is at a safer level in terms of pressure and time compared to equivalent devices, Safety and effectiveness were confirmed by conducting verification tests for these essential performances (pressure, time, and sleeve durability).
Therefore, it can be confirmed that the proposed device (K203019) is substantially equivalent to the equivalent device (K113275).

Clinical Test Summary

Clinical testing was not required to demonstrate the substantial equivalence of the LF900 to its predicate device.
The device should only be used over full clothing and socks (because the cuffs cover the feet), never on direct skin.
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.

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

The LF900 has same 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.