July 19, 2023

Daesung Maref Co., Ltd
Su Hyeon So
Jr. RA Specialist
298-24, Gongdan-ro
Gunpo-Si, Gyeonggido 15809
Korea, South

Re: K231437
Trade/Device Name: LF900
Regulation Number: 21 CFR 890.5650
Regulation Name: Powered Inflatable Tube Massager
Regulatory Class: Class II
Product Code: IRP
Dated: June 2, 2023
Received: June 22, 2023

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,

Julia E. Slocomb -S 2023.07.19 07:58:39 -04'00'

for 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)*
K231437

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.

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

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# 510(k) Summary
# K231437

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

May 10, 2023

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

| | | |
|---|---|---|
| | Operation Principle | 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. |
| | Indication 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. |

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

Predicate Device

- 510(k) Number :

  K150033

- Applicant :

  DAESUNG MAREF CO., LTD.

- Trade / Device Name :

  LF400

- Regulation Number :

  21 CFR 890.5650

- Regulation Name :

  Massager, Powered Inflatable Tube

- Regulation Class:

  II

- Product Code:

  IRP

- Indication For Use

  LF-400 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.

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

Reference Device

- 510(k) Number :

  K203019

- Applicant :

  DAESUNG MAREF CO., LTD.

- Trade / Device Name :

  LF900

- Regulation Number :

  21 CFR 890.5650

- Regulation Name :

  Massager, Powered Inflatable Tube

- Regulation Class:

  II

- Product Code:

  IRP

- Indication 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.

## 6. Determination of Substantial Equivalence

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

The pressure of the previously approved LF900 (K203019) has been changed from 180mmHg to 140mmHg, and a sleeve type has been added.

Through the table 1 below, we assert that the modified LF900 (K231437) is substantially equivalent to the LF400 (K150033).

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

| | Proposed Device | Predicate Device | Reference Device |
|---|---|---|---|
| Model Name | LF900 | LF400 | LF900 |
| 510(k) Number | K231437 | K150033 | K203019 |
| Manufacturer | DAESUNG MAREF CO., LTD. | DAESUNG MAREF CO., LTD. | DAESUNG MAREF CO., LTD. |
| 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 |
| 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. | LF-400 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. | 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. |
| Intended Use environment | Professional healthcare environment<br>&<br>Home environment | Professional healthcare environment<br>&<br>Home environment | Professional healthcare environment<br>&<br>Home environment |

| | Proposed Device | Predicate Device | Reference Device |
|---|---|---|---|
| Specifications | Leg Sleeve<br>Arm Sleeve<br>Extension zipper<br>One touch Single tubing<br>One touch Double tubing | Leg Sleeve<br>Arm Sleeve<br>Extension zipper<br>One touch Single tubing<br>One touch Double tubing | Leg Sleeve<br>Extension zipper<br>One touch Single tubing<br>One touch Double tubing |
| Specifications | | | |
| Power Source | 100-127V~, 50/60Hz | 100-127V~, 50/60Hz | 100-127V~, 50/60Hz |
| Time | 5-90 min | 5~180min | 5-90 min |
| Pressure | 10-140mmHg | 20~140mmHg | 10-180mmHg |
| Number of chamber | 4 | 4 | 4 |

**[Table 2. Little difference with Predicate Device]**

| Justification to Support Substantial Equivalence |
|---|
| The pressure of the LF900 was changed to be the same as that of the LF400 to add the arm sleeves used for the LF400. LF900 and LF400 have the same principle of operation and intended use, and the pressure is the same, so it is judged that the two products are substantial equivalent. |

**Non-Clinical Test Summary**

According to the pressure change of LF900, retests and gap tests related to electrical safety and electromagnetic compatibility were performed, and the standards recognized by the FDA were complied with.

The following data were provided in support of the substantial equivalence determination :

1) Electrical Safety, Electromagnetic Compatibility and Performance

The proposed device (LF900) complied with the following standards for the electrical safety and electromagnetic compatibility requirements of the product after the changed maximum pressure and firmware was changed.

● 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

[Inhouse test] Product Performance Test report, RND-R-PRR-103-02(2022.06.13)
Product performance test according to pressure change of LF900 and compatibility test with the sleeve to be added.

**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.

## 7. Conclusion [21 CFR 807.92(b)(3)]

The LF900 have similar intended use and technical characteristics to the predicate device.
Based on that information, we conclude that the differences between the proposed device (LF900) and predicate device (LF400) do not introduce a new intended use and do not raise new issues of safety and effectiveness.