DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

January 11, 2017

Daesung Maref Co., Ltd
% Dave Kim
Medical Device Regulatory Affairs
Mtech Group
8310 Buffalo Speedway
Houston, Texas 77025

Re: K160178
Trade/Device Name: Lympha-Flow(LF1200)
Regulation Number: 21 CFR 890.5650
Regulation Name: Powered Inflatable Tube Massager
Regulatory Class: Class II
Product Code: IRP
Dated: December 16, 2016
Received: December 21, 2016

Dear Dave Kim:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Michael J. Hoffmann -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160178

Device Name
Lympha-Flow(LF1200)

Indications for Use *(Describe)*
Lympha-Flow(LF1200) 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.

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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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

This summary of 510(k) information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date 510k summary prepared: December 16, 2016

I. SUBMITTER

Submitter's Name :	DaeSung Maref Co., Ltd.
Submitter's Address:	298-24, Gongdan-ro, Gunpo-si, Gyeonggi-do, Republic of Korea, 15809
Submitter's Telephone:	+82-31-459-7211
Contact person:	Jae-Wha Lee / President
Official Correspondent: (U.S. Designated agent)	Dave Kim **(**davekim@mtech-inc.net**)**
Address:	8310 Buffalo Speedway, Houston, TX 77025
Telephone:	+713-467-2607
Fax:	+713-583-8988

II. DEVICE

Trade/proprietary name:	Lympha-Flow(LF1200)
Common or Usual Name:	Intermittent Pneumatic Compression system
Regulation Name :	Powered Inflatable Tube Massager
Classification:	21 CFR 890.5650 (Product Code: IRP)
Regulatory Class:	II

III. PREDICATE DEVICE

1) Primary Manufacturer : DaeSung Maref Co., Ltd.
   Device : LX7 (V7)
   510(k) Number : K102320 (Decision Date – Mar. 4, 2011)

This predicate has not been subject to a design-related recall.

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

Lympha-Flow(LF1200) is the pressurization system helping to relieve the symptom of lymphedema and prevent aggravation of symptoms by applying the air pressure to limbs.

Lympha-Flow(LF1200) comprises of 12-step sleeves and accelerates the circulation of body fluid by evenly distributing the pressure to limbs.

- Device Specification:

NO	Items	Specification
1	Model	Lympha-Flow(LF1200)
2	Rating Protection Type	Class II, BF-Type Device
3	Usable Place	Indoor
4	Rated Voltage	100 - 240VAC, 50/60Hz
5	Power Consumption	30-50VA
6	Rated Fuse	T3.15AL / 250V
7	Setting Pressure	0~230mmHg (unit:10mmHg)
8	Setting Time	5~100 Minutes (unit:5 Min.)
9	Mode	A, B, C
10	Dimension	263(W) * 274(D) * 230(H)mm
11	weight	5.2Kg(main system only)

V. Indications For Use:

Lympha-Flow(LF1200) 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, Post immobilization edema, Venous insufficiencies, Lymphedema.

VI. TECHNICAL COMPARISON WITH THE PREDICATE DEVICE

Model Name	Lympha-Flow(LF1200)	LX7(V7)	Difference
510(k) Number	K160178	K102320	
Classification	Class II Device / IRP (21 CFR 890.5650)	Class II Device / IRP (21 CFR 890.5650)	-
Picture			
Indications For Use	Lympha-Flow(LF1200) 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, Post immobilization edema, Venous insufficiencies, Lymphedema	LX7(V7) 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, Post immobilization edema, Venous insufficiencies, Lymphedema.	-
Description	Lympha-Flow(LF1200) is a pneumatic pressure treatment system that repeats expansion of sleeves to help blood circulation and prevent blood clots or clogs.	LX7(V7) is a pneumatic pressure treatment system that repeats expansion of sleeves to help blood circulation and prevent blood clots or clogs.	-
Standard	EN ISO 14971 EN 60601-1 EN 60601-1-2	EN ISO 14971 EN 60601-1 EN 60601-1-2	-

Contraindications	Acute pulmonary edema Acute thrombophlebitis Acute congestive cardiac failure Acute infections Deep Vein Thrombosis (DVT) Episodes of Pulmonary embolism Wounds lesions or tumors at or in the vicinity of application Where increased venous and lymphatic return is undesirable Bone fractures or dislocations at or in the vicinity of application	Acute pulmonary edema Acute thrombophlebitis Acute congestive cardiac failure Acute infections Deep vein thrombosis (DVT) Episodes of pulmonary embolism Wounds, lesions, or tumors at or in the vicinity of application Where increased venous and lymphatic return is undesirable Bone fractures or dislocation at or in the vicinity of application.	-
Mode of Compression	Sequential	Sequential	-
Mode description	3 modes	3 modes	-
Compression Applicator Garments Sleeve Material	Nylon(oxford)	Nylon(oxford)	-
Power Source	Electricity Supply:AC100-240V, 50/60Hz Electricity consumption:30-50VA	Electricity Supply: 230 V~,50/60 Hz Electricity consumption: 50 VA	Note 1
Pressure range	0~230mmHg (Air pump pressure range) 60~120mmHg (Recommended operating pressure range) (unit of pressure increment : 10mmHg)	0~230mmHg (Air pump pressure range) 60~120mmHg (Recommended operating pressure range) (unit of pressure increment : 20mmHg)	Note 2
Operating Time	5~100 minutes	10, 20, 30minutes	Note 3
Number of Chamber	12 chambers	4 to 8 chambers	Note 4

Note 1 AC100-240V, 50/60Hz : Design was changed to fit to the voltage used in USA.

The performance is verified in accordance with IEC60601-1. The Gap analysis between IEC 60601-1 3rd Ed and ANSI/AAMI 60601-1 3rd Edition is provided separately. The subject device is not affected by the technical variations between IEC 60601-1 and ANSI/AAMI 60601-1 standards in terms of basis safety and essential performance of a medical electrical device.

Note2: The pressure limit for LF1200 is identical to the range for LX7, between 0~230mmHg. The manufacturer recommended pressure range is the same as well, between 60~120mmHg (see page 13 of LX7 Manual). For the user convenience, the pressure setting increment has changed from 20mmmHg to 10mmHg. There is no additional risk due to the change of the unit of pressure setting increments.

Note3: The operating time for Lympha-Flow (LF1200) is determined and prescribed by a physician. A time setting for LX7, the predicate device, is limited to either 10 min., 20 min., or 30 min before resetting. . To improve the user convenience, a single operating time for Lympha-Flow (LF1200), the subject device, has been extended to 5~100 minutes with increments of 5 minutes before resetting. Just as LX7, the predicate device, the operating time of Lympha-Flow (LF1200) can be reset for additional treatment time as required by a physician's treatment plan.

Note 4: The sleeves for LF1200 have been redesigned and there are 12 (air) pressure cells in an arm sleeve, leg sleeve and full boy (pants) for Lympha-Flow (LF1200). The design change of the sleeve is to incorporate the customer requirements by increasing the number of chambers to make the air pressure gradient becomes much more segmented and continuous from one chamber to another. A smaller chamber size means that the pressure point of each chamber is more focused to a treatment area. The gap between each chamber becomes smaller and more efficient in terms of overall coverage area for LF1200 compared to LX7 for the same sleeve size. The material, sizes and operating principle remain the same for both the subject and predicate device including the recommended pressure range. The full body (pants) sleeve size is same as the LYMPHA Pant sleeve by Mego Afek (K100677). No new risk is introduced by the introduction of 12 pressure cells for each sleeve type

VI. PERFORMANCE DATA

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

Biocompatibility testing (ISO10993-5, ISO10993-10)

Electrical safety and performance testing were conducted according to standard IEC 60601-1: 2005 + CORR.1(2006) + CORR(2007) and EMC testing were conducted in accordance with standard IEC 60601-1-2:2007.

Software Verification and Validation Testing

Software verification and validation testing were conducted and documented as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "minor" level of concern, since a failure or latent flaw in the software would not directly result in serious injury or death to the patient or operator.

Animal Study

The animal study is not conducted.

Overall Performance Conclusions

All test results were satisfactory.

VII. CONCLUSIONS

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification DaeSung Maref Co., Ltd. concludes that Lympha-Flow(LF1200) Intermittent Pneumatic Compression system is substantially equivalent in comparison with LX7(V7), the predicate device as described herein.