DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 12, 2016

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

Re: K150980
Trade/Device Name: DVT-Pro
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: March 31, 2016
Received: April 5, 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 yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular 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)*
K150980

Device Name
DVT-Pro

Indications for Use *(Describe)*

DVT-Pro is a system to prevent DVT (Deep Vein Thrombosis) by improving the blood velocity of patients.
DVT-Pro is Circulation Enhancement, Deep Vein Thrombosis Prophylaxis, Edema -Acute, Edema - Chronic, Extremity Pain Incident to Trauma or Surgery, Leg Ulcers, Venous Stasis / Venous Insufficiency.

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.

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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: May 4, 2016

I. SUBMITTER

Submitter's Name : DaeSung Maref Co., Ltd.

Submitter's Telephone: 298-24, Gongdan-Ro, Gunpo-shi, Gyeonggi-Do, Republic of Korea, 435-862

Submitter's Telephone: +82-31-459-7200

Contact person: Jae-Wha Lee / President

Official Correspondent: Dave Kim (davekim@mtech-inc.net)

(U.S. Designated agent)

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Telephone: +713-467-2607

Fax: +713-583-8988

II. DEVICE

Trade/proprietary name: DVT-Pro

Common or Usual Name: The Venous Assist System

Regulation Name : Compressible Limb Sleeve

Classification: 21 CFR 870.5800 (Product Code: JOW)

Regulatory Class: II

III. PREDICATE DEVICE

1) Primary Manufacturer : DaeSung Maref Co., Ltd.
   Device : DVT-2600
   510(k) Number : K112677 (Decision Date – Jan. 13, 2012)

This predicate has not been subject to a design-related recall.
No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

DVT-Pro device is a specialized intermittent pneumatic compression (IPC) system to prevent DVT (Deep Vein Thrombosis) and PE (Pulmonary Embolism) by improving the venous blood flow in at risk patients. The basic set of The Venous Assist System(DVT-PRO) consists of the main body, which includes the air pump that generates air pressure and control panel, air hose that transfers air pressure and sleeve (cuff) for calf and foot.

- Device Identification:

(1) Adaptor Specification

① Input Voltage and Frequency: 100-240V~, 47~63Hz

② Input Current: 0.5A max. (at 90Vac input)

③ Output Voltage : 9Vdc/2A, 15W

(2) Battery Specification

① Battery Cell type and quantity : Li-ion 18650(ICR18650 B4 2600mAh), 4-cell(2s x 2p)

② Battery Voltage : 7.4V(5200mAh)

③ Safety circuit : PCM equipped (overcharge, over discharge, overcurrent prevention)

(3) Specification

① Time range : unlimited (using time can be set : ~999hour 50min, unit : 10min)

② Interval time range : 28s, 48s

③ Pressure range :
Leg : 20 ~ 65mmHg(unit 5mmHg), Foot : 120~140mmHg(unit 10mmHg),
AUX : 20~50mmHg(unit:5mmHg)

④ Mode : DVT mode

(4) Photos

1) Main Body

Front

Right

Left

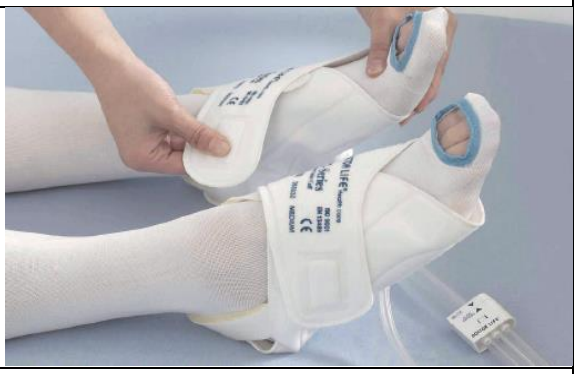
Top

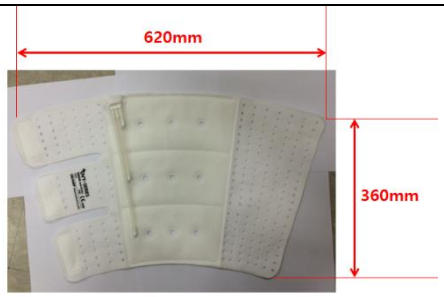
Back

2) Air Hose

3) AUX

4) Garments(cuffs)

Calf Cuff	Foot
	
3Chamber	1 Chamber
20-65mmHg (Unit : 5mmHg)	120-140mmHg (Unit : 10mmHg)
DVT mode	DVT mode

<table>
<tr><td>Non-woven</td><td>Non-woven</td></tr>
<tr><td> 
</td><td> 
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<tr><td>ISO10993-5 (Cytotoxicity test)
ISO 10993-10 (LLNA:BrdU-ELISA)
ISO 10993-10 (Animal Skin Irritation test)</td><td>ISO10993-5 (Cytotoxicity test)
ISO 10993-10 (LLNA:BrdU-ELISA)
ISO 10993-10 (Animal Skin Irritation test)</td></tr>
<tr><td colspan="2">RM-017, RM-053, RM-075, RM-078, RM-082, RM-083, RM-084, RM-085, RM-088, RM-101</td></tr>
<tr><td colspan="2">  </td></tr>
<tr><td colspan="2">2M</td></tr>
<tr><td colspan="2">PVC</td></tr>
</table>

- Device Characteristics (address all that apply)

(1) Components

The basic set of The Venous Assist System(DVT-PRO) consists of the main body, which includes the air pump that generates air pressure and control panel, air hose that transfers air pressure and sleeve (cuff) for calf and foot.

(2) Characteristics of the device

① Operation

The device consists of 4 parts-PCB, control panel, air pump (AC motor pump) and distributor (solenoid).

PCB consists of user input switch, LED or LCD display and button for pressure control and controls the air pump and solenoid via micro controller.

Air pump is connected to the hose and supplies air to the distributor.

Air distributor supplies the air to each air chamber in order and thus, repeats the inflation of Chamber 1 → inflation of Chamber 2 → inflation of Chamber 3 → in this order until the end of the set time.

② Electric Characteristics(Adaptor)

a. Rated Voltage: 100-240V~

b. Rated Frequency: 47~63Hz

c. Power Consumption: 0.5A max (at 90Vac Input)

③ Protection against electric shock

Class Ⅱ, Type BF

④ Software

a. File Name: DVT-PRO.c

b. Version: V1.0

c. Main features: switch, display, pump, solenoid, pressure control

V. Indications For Use:

DVT-PRO is a system to prevent DVT (Deep Vein Thrombosis) by improving the blood velocity of patients. DVT-PRO is Circulation Enhancement, Deep Vein Thrombosis Prophylaxis, Edema-Acute, Edema-Chronic, Extremity Pain Incident to Trauma or Surgery, Leg Ulcers, Venous Stasis / Venous Insufficiency.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Device Name	DVT-PRO	DVT-2600
510(k) Number	K150980	K112677
Classification	Class II Device / JOW (21 CFR 870.5800)	Class II Device / JOW (21 CFR 870.5800)
Intended Use	DVT-PRO is a system to prevent DVT (Deep Vein Thrombosis) by improving the blood velocity of patients. DVT-PRO is Circulation Enhancement, Deep Vein Thrombosis Prophylaxis Edema – Acute, Edema – Chronic, Extremity Pain Incident to Trauma or Surgery Leg Ulcers, Venous Stasis / Venous Insufficiency	DVT-2600 is a system to prevent DVT (Deep Vein Thrombosis) by improving the blood velocity of patients. DVT-2600 is Circulation Enhancement, Deep Vein Thrombosis Prophylaxis Edema – Acute, Edema – Chronic, Extremity Pain Incident to Trauma or Surgery Leg Ulcers, Venous Stasis / Venous Insufficiency
Contraindications	- Pre-existing deep vein thrombosis, phlebothrombosis or pulmonary embolism - Presumptive evidence of Congestive Heart Failure - Inflammatory Phlebitis Process - Severe arteriosclerosis or other ischemic vascular disease - Decompensated cardiac insufficiency - Carcinoma metastasis in the affected Extremity - Lymphatic return is undesirable - Severe arteriosclerosis or active infection - Acute pulmonary edema - Acute thrombophlebitis - Acute congestive cardia failure - Acute infections - Episodes of Pulmonary embolism - Wounds lesions or tumors at or in the vicinity of application	- Pre-existing deep vein thrombosis, phlebothrombosis or pulmonary embolism - Presumptive evidence of Congestive Heart Failure - Inflammatory Phlebitis Process - Severe arteriosclerosis or other ischemic vascular disease - Decompensated cardiac insufficiency - Carcinoma metastasis in the affected Extremity - Lymphatic return is undesirable - Severe arteriosclerosis or active infection

	- Bone fractures or dislocations at or in the vicinity of application	
Standard	EN ISO 14971 EN 60601-1 EN 60601-1-2	EN ISO 14971 EN 60601-1 EN 60601-1-2 EN 60601-1-4
Mode of Compression	Sequential	Sequential
No of Modes	DVT mode 1	Lymph mode 1 Foot mode 1
Therapy Time	Continuous	Continuous
Maximum and minimum pressure	20 ~ 65mmHg(Leg), 120~140mmHg(Foot) 20~50mmHg(AUX)	20 ~ 60 mmHg (Leg), 120 ~140 mmHg (Foot)
Number of chambers	Calf cuff : 3chamber Foot cuff : 1chamber	Leg sleeves / Foot cuffs
Compression cycle time	40s,60s/1cycle	12 sec 1 cycle
Compression applicator garments sleeve material	Non-woven	Nylon / Fabric
Operating Temperature	10~40 °C	-20C ~40° C
Operating Humidity	30 ~ 75%	90%
Atmospheric Pressure	700 - 1060 hPa	
Size	140 (W) x 143 (D) x 45 (H) mm	200 (W) x 170(D) x 190 (H) mm
Weight	0.8 kg	2 kg
Input Voltage	100 ~240VAC / 47 ~ 63 Hz	100 ~240VAC / 50~ 60 Hz
Input Current	0.5 A max at 90VAC Input	
Output Voltage	9Vdc / 2A, 15W	
Battery Spec	Li-ion 18650(ICR18650 B4 2600mAh), 4-cell(2s x 2p)	
Battery Voltage	7.4V (5200mAh)	

Photo		

The contraindications is revised to include additional medical conditions which predate or concurrent to the treatment of DVT-Pro. Contraindications listed here should be considered for using a pneumatic device with cuffs. There is no direct cause and effect relationship between disease associated with the contraindication and the treatment of DVT equipment.

DVT-Pro was developed as a dedicated DVT treatment device and deleted the Lymph Mode of the predicate device to reduce the size and weight of the product. DVT-Pro was developed as a portable device with a built-in battery adapter and replaced SMPS (power supply circuits) with an external power supply for the user's convenience. DVT-Pro used the critical parts with less weight than the predicate device.

Weight of the critical components

	DVT-PRO	DVT-2600(3000)
Pump	200g	285g
Solenoid Valve	140g	250g
Internal frame	0g	325g
SMPS	0g	130g
Case	175g	469
Total	515g	1459g

Weight difference of the critical components is approximately 944g (1459 - 515).

The risk management report contains the analysis of overall hazard situations generated from the parts with less weight and adapting an external power adapter during the development of a portable device. The technical report of the device validated the outcome.

VII. PERFORMANCE DATA

The following performance data was 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 his 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.

All test results were satisfactory.

VIII. 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 DVT-Pro is substantially equivalent in comparison with DVT-2600, the predicate device as described herein.