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

November 03, 2016

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

Re: K160180
Trade/Device Name: DVT-4000
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: September 28, 2016
Received: October 4, 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)*
K160180

Device Name
DVT-4000

Indications for Use *(Describe)*
DVT-4000 is a system to prevent DVT (Deep Vein Thrombosis) by improving the blood velocity of patients.
DVT-4000 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: July 18, 2016

I. SUBMITTER

Submitter's Name : DAESUNG MAREF CO.,LTD.

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Submitter's Telephone: +82-31-459-7211

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

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II. DEVICE

Trade/proprietary name: DVT-4000

Common or Usual Name: Intermittent Pneumatic Compression 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.
2) Device : DVT-2600
3) 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-4000 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 system consists of the controller, the tubing sets and Non- woven, sleeves. The system offers sequential inflation promoting venous blood movement and metabolism and then has sufficient interval time to refill with blood sufficiently after deflation. The operation of the inflation and deflation is repeated until the stop button is activated.

The device may be used with anti-coagulant materials or compression stocking to help prevent DVT and PE under a doctor's consultant.

- Device Specification:

NO	Items	Specification
1	Model	DVT-4000
2	Rating Protection Type	Class II, BF-Type Device
3	Usable Place	Indoor
4	Rated Voltage	100 - 240VAC, 50/60Hz
5	Power Consumption	60-80VA
6	Safety circuit	Protection Circuit Module(PCM) equipped

7	Setting Pressure	Leg :20~60mmHg±10mmHg Foot : 120~140mmHg±10mmHg
8	Setting Time	1min~999hours (unit:1 Min.)
9	Battery Voltage	14.4V / 2600mAh
10	Dimension	181(W) * 214(D) * 186(H)mm
11	weight	2Kg(main system only)

- Product Package

1. Controller Parts

Components		Qty.	Pictures
Main System	Main Unit	1ea	
	Power Cord	1ea	
	Extension hose	2ea	

2. Sleeve Parts & Specifications

No	Name	Image	Type	Description
1	Thigh sleeve		Non-woven sleeve	DS011 / Small size sleeve
				DS012 / Medium size sleeve
				DS013 / Large size sleeve
				DS014 / X-Large size sleeve
2	Calf sleeve		Non-woven sleeve	DS021 / Small size sleeve
				DS022 / Medium size sleeve
				DS023 / Large size sleeve
				DS024 / X-Large size sleeve
3	Foot sleeve		Non-woven sleeve	DS031 / One size sleeve

V. Indications For Use:

DVT-4000 is a system to prevent DVT (Deep Vein Thrombosis) by improving the blood velocity of patients. DVT-4000 is Circulation Enhancement, Deep Vein Thrombosis Prophylaxis, Edema-Acute, Edema-Chroni, Extremity Pain Incident to Trauma or Surgery Leg Ulcers, Venous Stasis / Venous Insufficiency.

VI. TECHNICAL COMPARISON WITH THE PREDICATE DEVICE

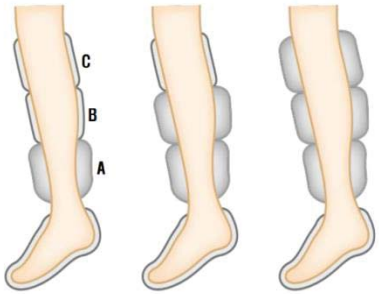
Model Name	DVT-4000	DVT-2600	Difference
510(k) Number	K160180	K112677	
Classification	Class II Device /JOW (21 CFR 870.5800)	Class II Device / JOW (21 CFR 870.5800)	Identical-
Picture			
Indications for Use	DVT-4000 is a system to prevent DVT (Deep Vein Thrombosis) by improving the blood velocity of patients. DVT-4000 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	Identical-
Standard	EN ISO 14971 EN 60601-1 EN 60601-1-2	EN ISO 14971 EN 60601-1 EN 60601-1-2	Identical-

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	- 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	Identical-
Description	DVT-4000 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 system consists of the controller, the tubing sets and garments. The system offers Sequential inflation promoting venous blood movement and metabolism and then has sufficient interval time to refill with blood sufficiently after deflation. The operation of the inflation and deflation is repeated until the stop button is activated. We recommend using the device separately or with anti-coagulant materials or compression stocking to help prevent DVT and PE under a doctor's consultant.	DVT-2600 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 system consists of the controller, the tubing sets and garments. The system offers Sequential inflation promoting venous blood movement and metabolism and then has sufficient interval time to refill with blood sufficiently after deflation. The operation of the inflation and deflation is repeated until the stop button is activated. We recommend using the device separately or with anti-coagulant materials or compression stocking to help prevent DVT and PE under a doctor's consultant.	-Identical

Mode of Compression	Sequential	Sequential	Identical-
Mode description	DVT mode 1	DVT mode 1 Lymph mode 1	DVT-4000 is designed for the DVT mode only Note 1

Power Source	Battery Specifications Battery Model/Type reference : HY- BP08 / 4ICR19 / 66-0 Battery Ratings : 14.4Vdc(2600mAh) Safety circuit : PCM equipped (overcharge, overdischarge, overcurrent prevention) Device Specification Rated voltage and Frequency: AC100~240V, 50/60Hz Rated current : 2A Power consumption : 60-80VA	①Electricity Supply: AC 100-240V~, 50/60Hz ②Power consumption: 35VA	DVT-4000 was developed with a built-in-battery adapter and replaced SMPS (power supply circuits) with an external power supply for the user convenience. The battery performance is verified in accordance with IEC62133 Note 2
Therapy Time	Continuous	Continuous	Identical-
Maximum and Minimum Pressure	20 ~ 60mmHg(Calf, Thigh, Boot), 120~140mmHg(Foot)	20 ~ 60mmHg(Calf, Thigh, Boot), 120~140mmHg(Foot)	Identical-(Note 3)
Number of Chamber	Calf, Thigh, Boots cuff : 3chamber Foot cuff : 1chamber	Calf, Thigh, Boots cuff : 3chamber Foot cuff : 1chamber	Identical-(Note 3)
Compression Interval Time	28sec, 48sec, 60sec	28sec, 48sec, 60sec	Identical-
Compression Garments Sleeve Material	Non-woven consist of Polyethylene Terephthalate ≥ 99.25% and Titanium Dioxide ≤0.35%	Non-woven consist of Polyethylene Terephthalate ≥ 99.25% and Titanium Dioxide ≤0.35%	Identical (Note 3)

Note 1. Description on Mode difference

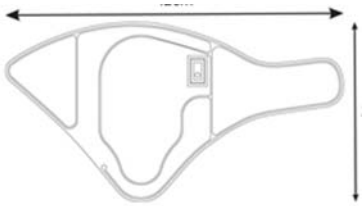
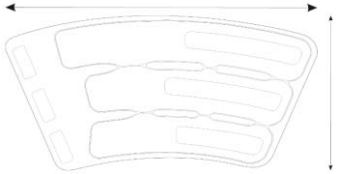
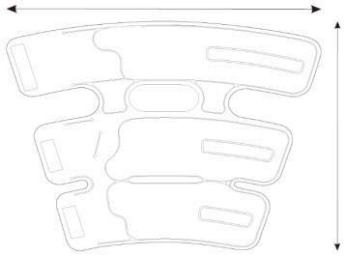
	Description	Verification Data	Performance Testing and Risk Assessment
1	DVT-4000 is designed to have one mode, the DVT mode. Some devices, including DVT-2600, the predicate device, are designed to have dual modes: DVT and Lymph mode. Through customer feedback, the DVT-4000 is designed and manufactured to function with the DVT mode exclusively instead of dual modes. Its technology, features, materials and principle of operations are identical to DVT-2600, except DVT-4000 is with a single mode only, DVT mode. .	Thigh Sleeve, Calf Sleeve, Boot Sleeve  Most frequently used DVT mode: Air pressure is applied in each chamber in sequence from the bottom to the top as shown in the Figure. A(Inflated)B(Deflated)C(Deflated) →A(Inflated)B(Inflated)C(Deflated y) →A(Inflated)B(Inflated)C(Inflated) →A(Deflated)B(Deflated)C(Deflated)	Through the performance testing, the air pressure in each chamber is properly inflated sequentially. There is no new risk associated with the DVT mode compared to the predicate device.
		Foot Sleeve A(Inflated) → A(Deflated)	

Note 2. Description on Power source difference

	Description	Verification Data	Performance Testing and Risk Assessment
1	DVT-4000 was developed with a built-in-battery adapter and replaced SMPS (power supply circuits) with an external power supply for the user convenience. The battery power is not intended to be used as the main power supply but as auxiliary power when the main power fails or when the patient is moving.	The battery performance is verified in accordance with IEC62133. .	Potential problems of having a battery were examined in the risk management report. Efficiency and risk of the battery was proved through the battery test report and the product test report conforming to the Medical Appliances Act Risk assessment and mitigating measures related to the application of a battery are described in the risk management report. .

Note 3. Description of Sleeve

Garments	Foot Sleeve	Calf Sleeve	Thigh Sleeve	Boots Sleeve
Image				
Chamber	1 chamber	3 chamber	3 chamber	3 chamber
Sleeve port	1 port (Foot sleeves use different connecting ports separately and; incompatible with other sleeve types.)	3 port	3 port	3 port
Pressure	120~140±10mmHg	20~60±10mmHg	20~60±10mmHg	20~60±10mmHg
Mode	DVT mode			

Sleeve Material	Non-woven sleeves consist of Polyethylene Terephthalate ≥99.25% and Titanium Dioxide ≤0.35%			
Size				
	420mmX230mm (One size)	500mmX310mm (Small) 620mmX360mm (Medium) 770mmX380mm (Large) 970mmX380mm(X-Large)-	600mmX545mm (Small) 750mmX640mm (Medium) 930mmX670mm (Large) 1130mmX670mm (X-Large)	635mmX710mm (One size)
Location on the body	Foot	Calf	Thigh	Both foot and calf

Biocompatibility test	ISO10993-10 : Intracutaneous Reactivity (test report no. : GB16001) ISO10993-10 : Skin sensitization (test report no. : GB16002) ISO10993-5 : Cytoxicity (test report no. : GB16050)	
Hose Image	 The sleeve is provided in a state that the hose has been connected.	
Hose Length	2 meters	
Hose Material	Polyvinyl chlorid (PVC)	

VII. PERFORMANCE DATA

The following performance testing was performed in support of the substantial equivalence determination.

Electrical safety and EMC performance testing

Electrical safety and performance testing were conducted according to standard IEC 60601-1: 2005 + CORR. 1:2006 + CORR. 2:2007 + AM1:2012 and EMC testing was conducted in accordance with standard IEC 60601-1-2:2007.

Biocompatibility testing (ISO10993-5, ISO10993-10)

Biocompatibility for the sleeve material is tested and the testing reports are available as follows:

ISO10993-10 : Intracutaneous Reactivity (test report no. : GB16001)

ISO10993-10 : Skin sensitization (test report no. : GB16002)

ISO10993-5 : Cytoxicity (test report no. : GB16050)

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 "moderate" 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. The intended use of the subject device has not changed as a result of the modifications.

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-4000 is substantially equivalent in comparison with DVT-2600, the predicate device as described herein.