March 28, 2021

Daesung Maref CO., LTD.
Su Hyeon So
Assistant Researcher
298-24, Gongdan-Ro
Gunpo-Si, Gyeonggido 15809
Korea, South

Re: K203417
Trade/Device Name: DVT-4000S
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible limb sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: February 15, 2021
Received: February 24, 2021

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,

Fernando Aguel
Assistant Director
DHT2B: Division of Circulatory Support,
Structural and Vascular Devices
OHT2: Office of Cardiovascular 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K203417

Device Name
DVT-4000S

Indications for Use *(Describe)*
A device intended to prevent Deep Vein Thrombosis/Pulmonary Embolism (DVT/PE) by increasing venous blood flow to a patient who has a risk of DVT/PE.

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

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

November 13, 2020

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	DVT-4000S
Regulation Number	21 CFR 870.5800
Classification Name	Compressible Limb Sleeve
Regulation Class	II
Product Code	JOW

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

Predicate Device

- 510(k) Number :

  K112677

- Applicant :

  DAESUNG MAREF CO.,LTD.

- Trade / Device Name :

  The Venous Assist System DVT-2600

- Regulation Number :

  21 CFR 870.5800

- Regulation Name :

  Compressible Limb Sleeve

- Regulation Class:

  II

- Product Code:

  JOW

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

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

A device intended to prevent DVT/PE by increasing venous blood flow to a patient who has a risk of DVT/PE.

Operating principal of this device is that the air output from the air motor is delivered to a sleeve composed of four air chambers are sequentially inflated from the first air chamber to the third chamber through solenoid valve.

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

A device intended to prevent Deep Vein Thrombosis/Pulmonary Embolism (DVT/PE) by increasing venous blood flow to a patient who has a risk of DVT/PE.

7. Determination of Substantial Equivalence

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

The DVT-4000S is substantially equivalent to legally marketed predicate device (DVT-2600) 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	DVT-4000S	DVT-2600
510(k) Number	K203417	K112677
Manufacturer	DAESUNG MAREF CO., LTD.	DAESUNG MAREF CO., LTD.
Product Code	JOW	JOW
Device Class	II	II
Regulation Number	21 CFR 870.5800	21 CFR 870.5800
Regulation Name	Compressible Limb Sleeve	Compressible Limb Sleeve
Indications For Use	A device intended to prevent Deep Vein Thrombosis/Pulmonary Embolism (DVT/PE) by increasing venous blood flow to a patient who has a risk of DVT/PE.	A device intended to prevent DVT/PE by increasing venous blood flow to a patient who has a risk of DVT/PE.
Intended Use environment	Professional healthcare environment	Professional healthcare environment

Accessories	Calf sleeve Thigh sleeve Foot sleeve Boots sleeve	Calf sleeve Thigh sleeve Foot sleeve Boots sleeve
Specifications		
Power Source	100-240VAC, 50/60Hz 90VA	100-240VAC, 50/60Hz 35VA
Pressure	LEG : 20-60mmHg FOOT : 120-140mmHg	LEG : 20-60mmHg FOOT : 120-140mmHg
Battery	3500mAh	-
Number of chamber	3	3

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
The DVT-4000S hardly different from the DVT-2600 except for some specification. (Power consumption, Battery) But power consumption is innherent characteristics of device. And the presence or absence of a battery does not significantly affect the purpose of use or principle of action. In addition, it was confirmed through the performance test report whether it can perform the same performance as used by connecting AC power when operating with a battery. And it was confirmed with the product performance test report that it did not affect the performan\ce when using the battery. Therefore, the differences in technological characteristics do not raise different questions of safety and effectiveness.

Non-Clinical Test Summary

The DVT-4000S 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 DVT-4000S comply 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

● ISO 10993-5:2009 Third edition 2009-12-15, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity

● ISO 10993-10 Thrid Edition 2010-08-01, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

Clinical Test Summary

Clinical testing was not required to demonstrate the substantial equivalence of the DVT-4000S to its predicate device.

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

The DVT-4000S has similar 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.