June 22, 2020

Dimedi Co., Ltd.
℅ Sanglok Lee
Manager
Wise Company Inc.
#303, 142, Gasan digital 1-ro
Geumcheon-gu, 08507 Kr

Re: K192337
Trade/Device Name: Zeroveno
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: May 18, 2020
Received: May 28, 2020

Dear Sanglok Lee:

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,

for 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)*
K192337

Device Name
ZEROVENO

Indications for Use *(Describe)*
The ZEROVENO device induces improved vascular and lymphatic flow of the lower limbs. The device is intended to treat the following:

- Management of the symptoms of post thrombotic syndrome (PTS)
- Prevention of deep vein thrombosis, (DVT)
- Treatment of lymphedema
- Treatment of leg swelling due to vascular insufficiency
- Treatment of varicose veins
- Treatment of chronic 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

The assigned 510(k) Number: K192337

01. Date of Submission: August 23, 2019

02. Applicant

Company name: DIMEDI Co., Ltd.
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03. Submission Correspondent

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04. Proposed Device Identification

Proprietary Name: ZEROVENO
Classification Name: Compressible limb sleeve
Device Class: Class II
Regulation Number:21 C.F.R.870.5800
Product Code: JOW

05. Indication for use

The ZEROVENO device induces improved vascular and lymphatic flow of the lower limbs. The device is intended to treat the following:
- Management of the symptoms of post thrombotic syndrome (PTS)
- Prevention of deep vein thrombosis, (DVT)
- Treatment of lymphedema
- Treatment of leg swelling due to vascular insufficiency
- Treatment of varicose veins
- Treatment of chronic venous insufficiency

06. Predicate devices

- Predicate Device
510(k) Number: K073028
Device Name: Venowave VW5-10
Manufacturer: SARINGER LIFE SCIENCE TECHNOLOGIES INC.

07. Device Description

ZEROVENO is a product designed to distribute the pressure applied to the leg by changing the position of the contact part which supports the load of the leg alternately with the pressing pressure periodically.

The swept volume or volume of blood or lymph fluid displaced upwards for each cycle is the product of the wavelength (14cm), the width of the wave sheet (8cm) and the depth of the wave (1cm) or approximately 0.1 L/cycle.

ZEROVENO has a maximum continuous operation time of 20 hours on a low-speed basis when the built-in lithium-ion battery is fully charged. Detailed specification of ZEROVENO is as below.

Product Name/Model Name	Sequential Compression Device/ ZEROVENO
Rated Voltage(Main Part)	DC 5 V, 1.0 A
Rated Voltage(Adapter)	Input: AC 100 - 240 V, 50 - 60 Hz, 0.3 A Output: DC 5 V, 2.0 A)
Inner Power(Battery)	DC 3.63 V, 3350 mAh
Power Consumption	5 VA
Dimension	Main body: 186.5mm(D)×111.9mm(W)×52.7mm(H) Band: 580mm(D)×200mm(W)×8mm(H) Charging adapter: 84mm(D)×47mm(W)×31mm(H)
Weight	Main body: 400g Dedicated Band: 70g Charging adapter: 130g
Pressing pressure	≥ 80 N, < 100N
Alternating cycle	L step : 12sec ±20% H step : 6sec ±20%
Operating environment	Temperature: 10 to 40 ℃ Humidity: 30 to 75% Atmospheric pressure: 700 to 1,060 hPa
Transportation and storage environment	Temperature: -20 to 60 ℃ Humidity: 10 to 90% Atmospheric pressure: 700 to 1,060 hPa
Life cycle	2.5 years

08. Performance Standards

No performance standards have been established for such device under Section 514 of the Federal Food, Drug, and Cosmetic Act. However, ZEROVENO voluntarily complies with the standards below.

- IEC 60601-1
- IEC 60601-1-6
- IEC 60601-1-2
- IEC 62304

09. Performance Data & Substantial Equivalence:

The following table compares the ZEROVENO to the predicate devices with respect to intended use, technological characteristics and principles of operation, etc.

Table. Comparison of Technology Characteristics

	Subject device	**Predicate device**

MANUFACTURER	DIMEDI, Korea	SARINGER LIFE SCIENCE TECHNOLOGIES INC., Canada
Property name	ZEROVENO	VW5-10
510(k) Number	Not assigned	K073028
Product Code	JOW	JOW
Picture		
Principle of operation	ZEROVENO deploys a peristaltic pumping action using a mechanical plate to compress the muscles of the calf thereby increasing upward venous and lymphatic flow.	Same
Indication for use	The ZEROVENO device induces improved vascular and lymphatic flow of the lower limbs. The device is intended to treat the following: - Management of the symptoms of post thrombotic syndrome (PTS) - Prevention of deep vein thrombosis, (DVT) - Treatment of lymphedema - Treatment of leg swelling due to vascular insufficiency - Treatment of varicose veins - Treatment of chronic venous insufficiency	Same
Patient population	1) Age: all ages except infant, Children, pregnant woman 2) Gender: Male and Female	Same
Patient contact	Main body does not contact the patient but its dedicated bend does contact intact skin of patient's calf	Same
Size (main body)	186.5mm(D)×111.9mm(W)×52.7mm(H)	190mm(D)×100mm(W)×48mm(H)

Weight (main body)	400 g (include battery)	270g (without battery)
Pressing pressure	80 N ~ 100N	50 N ~ 100N
Power(Battery)	DC 3.63V, 3350 mA	1.5V AA×2 (2000 mAh or higher).
Speed	Operating at two speeds	Same
Maximum number of times the wave plate cycles each minute	ZEROVENO: maximum 10 cycles/minute The device capable of operating at two speeds. (H step : 10 cycles/minute, L step : 5 cycles/minute)	VW5-10: maximum 10 cycles/minute The device capable of operating at two speeds.
Material of Compression Applicator (Dedicated band)	Rubber, Velcro	Rubber, Velcro

Software verification and validation testing

Software verification and validation testing were conducted and documentation was provided 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 failures or latent design flaws are unlikely to cause any injury to the patient or operator.

Mechanical testing

- Pressing pressure
- Maximum pressing height
- Pressing cycle duration
- Pressing range

10. CONCLUSIONS

The non-clinical data support the safety of the device and the hardware and software verification and validation demonstrate the ZEROVENO should perform as intended in the specified use conditions. Therefore, the ZEROVENO is substantially equivalent to the predicate device.