June 25, 2024

Thermabright
Liane Parker
Official Correspondent
4035 Cinwood Street NW
Massillon, Ohio 44646

Re: K232640
Trade/Device Name: Venowave VW5
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: June 3, 2024
Received: June 3, 2024

Dear Liane Parker:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Nicole M. Gillette -S

Nicole Gillette
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232640

Device Name
VENOWAVE VW5

Indications for Use *(Describe)*

The Venowave VW5 series of devices are prescriptive and induce improved vascular and lymphatic flow of the lower limbs. Venowave device are intended to treat the following:

Indications for Use:
- Management of the symptoms of post thrombolytic syndrome (PTS)
- Prevention of deep vein thrombosis (DVT)
- Prevention of primary thrombosis
- Treatment of lymphedema
- Diminishing post-operative pain and swelling
- Treatment of leg swelling due to vascular insufficiency
- Treatment of varicose veins
- Treatment of chronic venous insufficiency
- Enhancing blood circulation
- Treatment of intermittent claudication

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.

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"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."

1. 510(K) SUMMARY

I. **Submitter:** Therma Bright, Inc.
345 Danforth Ave.
Toronto, Ontario, Canada M4K 1N7

Contact: Liane Parker RN CPHM
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Massillon, Ohio 44646
Email: liane@quantifyrc.com
Phone: 740-792-1264
FAX: 740-888-0306

Date Prepared: 06/03/2024

II. **DEVICE:**

Trade Name: Venowave VW5
Common Name: Wave Generating Device
Classification Name: Sleeve, Limb
Product Code: JOW
Regulation No. 870.5800

III. **PREDICATE DEVICE:** K073028 **Trade Name:** Venowave VW5

IV. **Device Description:**

The Venowave VW5 is a series of compact, battery-operated peristaltic pumps that generate a wave-form motion, and when worn below the knee strapped firmly to the calf, result in compression of the calf and consequently, an increased upward volumetric displacement of venous and lymph fluid. Each of the models within the family (VW5-6;VW5-10; VW5-20; and VW5-30) is distinguished by the maximum number of times the wave plate cycles each minute (6, 10, 20 and 30 cycles/minute respectively). Clinical preference to choose a specific frequency of motion for each specific patient based upon that patient's clinical symptoms, severity of disease, and perceived compliance with treatment has been the motivation for creating each model within the series. Venowave is intended for use on patients who are 18 years of age or older.

V. **Intended Use:**

The Venowave VW5 series of devices are prescriptive and induce improved vascular and lymphatic flow of the lower limbs. Venowave is intended for use on patients who are 18 years of age or older. Venowave devices are intended to treat the following:

• Management of the symptoms of post thrombolytic syndrome (POTS)
• Prevention of deep vein thrombosis, (DVT)
• Prevention of primary thrombosis
• Treatment of lymphedema

• Diminishing post-operative pain and swelling
• Treatment of leg swelling due to vascular insufficiency
• Treatment of varicose veins
• Treatment of chronic venous insufficiency
• Enhancing blood circulation
• Treatment of intermittent claudication

VI. COMPARISON TO THE PREDICATE:

The purpose of this Special 510(k) is to remove the contraindication from the Indications for Use statement. Additionally, the contraindication was updated and specified to be "Venowave device should not be used to treat patients who have open or freshly healed ulcers or other wounds or otherwise fragile skin between the knee and the ankle of the leg to be treated" and the labeling was updated to reflect the new contraindication.

Update	Predicate Device	Subject Device	Conclusion
Contraindication	Venowave, due to its mechanical pressure applied on the muscle, may exacerbate healing of open wounds and hence is contra-indicated for these conditions	Venowave device should not be used to treat patients who have open or freshly healed ulcers or other wounds or otherwise fragile skin between the knee and the ankle of the leg to be treated	Specified contraindication to adequately capture the risk
Design Changes	1. No Cover 2. Two metal bars connecting the motor to the waveplate mechanism.	1. Cover added to top and sides of device 2. Replaced with 2 plastic pieces connecting the motor to the waveplate mechanism.	Same operating principles
Leg Wrap	Velcro	Neoprene leg wrap	Both materials are known to be bio compatible
Speed	Multiple speed options	Fixed to 1 speed	Both devices capable of 6 cycles per minute
Battery	Two NiMh 1.5V DC AA rechargeable batteries	One rechargeable CR-V3 battery	Performance testing demonstrates equivalence
Treatment Timing	Does not have this capability	Microprocessor based circuit which can display usage data for last patient (hrs.), total use time of the device (hrs.) and remaining useable hours	Device is functionally substantially equivalent to cleared device

VII. Summary of Testing

Performance Testing	Result
Software Verification Testing and Validation	Pass
EMC: IEC 60601-1-2: 2014 IEC 60601-1-2:2014/AMD1:2020	Pass
Electrical Safety Drop Test	Pass
Battery Testing	Pass

VIII. Conclusion

Thermabright has demonstrated that the Venowave VW5 series is substantially equivalent to the predicate device based on the fundamental technologies, principles of operation and performance being unchanged from the predicate device.