August 8, 2025

Vive Health LLC
℅ Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive, Suite 510k
Saint Paul, Minnesota 55114

Re: K250817
Trade/Device Name: Coretech Compression System (Coretech RHB3003)
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: June 13, 2025
Received: June 13, 2025

Dear Prithul Bom:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K250817

Device Name

Coretech Compression System RHB3003 (Coretech RHB3003)

Indications for Use *(Describe)*

The Coretech Compression System RHB3003 is a sequential compression device which is intended for treatment of patients with the following conditions:
- Lymphedema
- Venous stasis ulcers
- Venous insufficiency
- Peripheral edema

The device is safe for both home and hospital use.

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.

510(K) Summary K250817

Vive Health Coretech Compression System RHB3003

Prepared July 31, 2025

Submitter

Manufacturer:	Contact Person:
Vive Health LLC	Joe Fleming - President
8955 Fontana Del Sol Way	Joe.fleming@igbrands.com
Naples FL 34109	239-248-2026

Device

Device Name:	Coretech Compression System (model RHB3003)
Common / Usual Name:	Pneumatic compression device
Classification Name:	Compressible limb sleeve (21 CFR 870.5800)
Product Code	Sleeve, limb, compressible (JOW)
Device Regulatory Class:	Class 2

Predicate

Device Name:	CircuFlow 5150
Premarket Notification Number:	K123959

Reference

Device Name:	Airos 6P	Air Compression Therapy System
Premarket Notification Number:	K223195	K201982

Device Description

The Coretech Compression System RHB3003 (Coretech RHB3003) is a compression device that delivers sequential compression to the affected upper and lower extremity of patients with lymphedema, chronic edema, peripheral edema, venous insufficiency and venous stasis ulcers.

This device helps direct and move excess fluid from an impaired lymphatic region to healthy regions, where fluid can be absorbed and processed naturally by the body. The Coretech RHB3003 controller is used to inflate the connected garment chambers. The air chambers inflate and deflate repeatedly and orderly to create circular pressure on the affected limb. The air inflates from the distal end to the proximal end of the patient. This helps to promote the flow of blood and lymph and improves microcirculation. The pressure can be adjusted to avoid discomfort to the patient and deflates as one cycle.

Indications for Use

The Coretech RHB3003 is a sequential compression device which is intended for treatment of patients with the following conditions:

- Lymphedema
- Venous stasis ulcers
- Venous insufficiency
- Peripheral edema

The device is safe for both home and hospital use.

The subject and predicate devices have the same intended use and are both prescription devices.

Comparison of Technological Characteristics with the Predicate Device

The Coretech RHB3003 device and the predicate Airos 6P are the same device type and utilize the same fundamental technology, mode of action, and principles of operation. They are based on the same basic design, software, hardware, and materials, and device features are similar. They both require a power source for operation. A high-level comparison is provided below.

	Coretech RHB3003 (subject device)	**CircuFlow 5150** (predicate device)	**Airos 6P** (reference device)	**Comparison**
Product Type	Pneumatic compression device	Pneumatic compression device	Pneumatic compression device	Same
Components	Controller Garments Hoses Power adapter	Controller Garments Hoses Power adapter	Controller Garments Hoses Power adapter	Same
Mode of Action	Helps direct and move excess fluid from impaired lymphatic regions to healthy regions, where fluid can be absorbed and processed naturally by the body.	Helps direct and move excess fluid from impaired lymphatic regions to healthy regions, where fluid can be absorbed and processed naturally by the body.	Helps direct and move excess fluid from impaired lymphatic regions to healthy regions, where fluid can be absorbed and processed naturally by the body.	Same
Principles of Operation	The controller inflates the connected garment chambers in a pre-programmed sequence from distal to proximal with a pressure gradient that provides high distal pressures. The garment chambers are sequentially inflated, pressure is held, and then all chambers are deflated simultaneously.	The controller inflates the connected garment chambers in a pre-programmed sequence from distal to proximal with a pressure gradient that provides high distal pressures. The garment chambers are sequentially inflated, pressure is held, and then all chambers are deflated simultaneously.	The controller inflates the connected garment chambers in a pre-programmed sequence from distal to proximal with a pressure gradient that provides high distal pressures. The garment chambers are sequentially inflated, pressure is held, and then all chambers are deflated simultaneously.	Same
Environment of Use	Hospital, clinical, and home settings	Hospital, clinical, and home settings	Hospital, clinical, and home settings	Same
Controller Size and Weight	9" W x 4” D x 8” H 10 lb	11.0” x 6.0” x 8.0” 4 lb	10.2” W x 10.5” D x 4.3” H 6.4 lb	Similar; the subject device has a slightly smaller but heavier controller than the

	Coretech RHB3003 (subject device)	**CircuFlow 5150** (predicate device)	**Airos 6P** (reference device)	**Comparison**
				predicate.
Electrical Requirements	100-127V/220-240V, 50/60 Hz	100-240V, 47/63 Hz	100-240VAC, 50/60 Hz	Similar to predicate and reference device
Controller Enclosure Material	Plastic	Plastic	Plastic	Same
User Interface	Push buttons, LED touch control	Push button controls	Push buttons and Digital LCD screen	Similar; both devices utilize push buttons. The subject device is LED touch control while the predicate is only push-button control.
Wireless Functions	None	None	None	Same
Software / Hardware Type	Analog and digital electronics with microprocessor	Analog and digital electronics with microprocessor	Analog and digital electronics with microprocessor	Same
Software-Concern Level	Moderate level of concern	Moderate level of concern	Moderate level of concern	Same
Pressure Range	20-80 mmHg	20-80 mmHg	30-80 mmHg	Same as predicate and similar to the reference device.
Output	- Sequential gradient pressure mode - Peristaltic mode	- Sequential gradient pressure mode	- Sequential gradient pressure mode - Peristaltic mode	Same as the reference device. The predicate device only includes sequential gradient pressure while the subject and reference device include a

	Coretech RHB3003 (subject device)	**CircuFlow 5150** (predicate device)	**Airos 6P** (reference device)	**Comparison**
				peristaltic mode.
Cycle Time	82 seconds for both modes	Unknown	40-60 seconds for gradient Manufacturer identifies "none" for peristaltic	The predicate device cycle time is unknown. The subject device cycle time is slightly longer than the reference device gradient cycle mode.
Dwell Time	15 seconds for gradient mode and 15 seconds for peristaltic mode	25 seconds	12 seconds for gradient mode; 5 seconds for peristaltic mode	Different; the subject device dwell time is slightly shorter than the predicate and longer than the reference device.
Treatment Time	30, 45 or 60 minutes	1 hour maximum	15, 30, 45, or 60 minutes	Similar; the subject device, predicate and reference device have treatment durations up to 60 minutes
Garment Chamber Pressure Control	Pressure based	Pressure based	Pressure based	Same
Garment-Controller Connections	Fixed hose connection	Fixed hose connection	Fixed hose connection	Same
Garment Port	Standard port	Standard port	Standard port	Same
Garment Materials	Nylon fabric	Nylon fabric	Nylon fabric	Same

	Coretech RHB3003 (subject device)	**CircuFlow 5150** (predicate device)	**Airos 6P** (reference device)	**Comparison**
Garment Chambers	4 or 8	8	6	Different; the subject device may be used utilizing a 4 or 8 chamber garment while the predicate is an 8-chamber garment. The reference device utilizes a 6-chamber garment.
Device Cleanability	Cleanable using commonly available mild household products and disinfectants.	Cleanable using commonly available mild household products and disinfectants.	Cleanable using commonly available mild household products and disinfectants.	Same

Technological differences between the Coretech RHB3003 device and the predicate device, include:

- Smaller but heavier controller
- LED touch control user interface
- Inclusion of peristaltic mode
- Electrical requirements
- Shorter dwell time
- Treatment time
- Number of garment chambers

These differences do not raise any different questions of safety or effectiveness for the Coretech RHB3003 system compared to the predicate device.

Performance Data

Based on the differences compared to the predicate device, the following types of testing have been completed for the Coretech RHB3003 device to support the substantial equivalence determination:

- Electrical safety and electromagnetic compatibility (EMC) testing, following IEC 60601-1 Medical electrical equipment – General requirements for basic safety and essential performance, IEC 60601-1-11 - General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment and IEC 60601-1-6 General requirements for basic safety and essential performance – Collateral Standard: Usability
- Software verification and validation testing, following IEC 62304 Medical device software – Software life cycle processes
- Mechanical bench testing, including:
    - Start / stop function performance
    - Inflation and Deflation function performance
    - Cycle time accuracy and performance
    - Operating modes, pressure gradient performance
    - Pressure calibration performance and accuracy
    - Operating / treatment time / therapeutic performance
    - Pressure performance and accuracy
    - Burst pressure performance / garment Integrity / seam performance / leak test
    - Complete firmware / software Integration performance
    - Packaging validation
    - Noise performance
- Packaging Validation

The technological comparison and performance testing together demonstrate that Coretech RHB3003 has a similar safety and effectiveness profile as the predicate device.

Conclusion

The Coretech RHB3003 device is substantially equivalent to the legally marketed predicate device.