August 7, 2018

Bio Compression Systems, Inc.
Jonathan Ross
President
120 W Commercial Ave
Moonachie, New Jersey 07074

Re: K180248
Trade/Device Name: VascuEase IC-1200-WH
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: June 18, 2018
Received: June 25, 2018

Dear Jonathan Ross:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 -S

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180248

Device Name
VascuEase IC-1200-WH

Indications for Use *(Describe)*
VascuEase is a prescription device intended for the prophylaxis of Deep Vein Thrombosis (DVT), stimulating venous and arterial circulation, aiding in prevention of venous stasis ulcers, aiding in the healing of cutaneous ulcers, reducing acute/ chronic edema and compartmental pressures. For use in home or hospital setting.

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

APPLICANT'S INFORMATION

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DATE: August 2, 2018

DEVICE INFORMATION

DEVICE NAME:	VascuEase IC-1200-WH
Classification Panel:	Cardiological and Respiratory Devices
Classification Number:	870.5800
Product Nomenclature:	Compressible Limb Sleeve
Product Code(s):	JOW
Trade/Proprietary Name:	VascuEase IC-1200-WH
Common Name:	Pneumatic intermittent compression device

DEVICE CLASSIFICATION

Compressible Limb Sleeve Devices are classified as Class II devices, and reviewed by the Division of Cardiovascular Devices.

PREDICATE DEVICE

Vena Pro Vascular Therapy System, K133274
The secondary predicate device is the Bio Compression Systems IC-1545-DL Multi Flow, K131306

DEVICE DESCRIPTION

The VascuEase IC-1200-WH is a portable, rechargeable battery-powered, prescription device intended for home or hospital use to help prevent post-operative DVT in patients by stimulating blood flow as an aid in the prevention of DVT. The VascuEase IC-1200-WH (applicant device) provides intermittent pressure to the calf and thigh or foot through the use of inflatable garments.

There is no change in fundamental technology and no change in intended use from the predicate device, K133274.

The cycle times and pressure are preset at the factory and cannot be changed by the user. The user interface consists of an On/Off button and two-color LED indicating operational status of the unit. The device consists of a pump, inflatable garments, and interconnection tubing. The pump air compressor is capable of no more than 80 mmHg maximum pressure and has pre-set inflate/deflate cycle times. Default pressure and timing is pre-set at the factory to 50 mmHg, with a cycle of 15 seconds on and 45 seconds off, which is consistent with the majority of indications prescribed.

The garment consists of a discrete inflatable chamber, attached to the pump via interconnection tubing and Velcro. The garment is applied externally over the affected limb(s); unilateral or bilateral treatment can be applied. The garments are supplied non-sterile and are intended for single patient use.

INDICATIONS FOR USE

VascuEase is a prescription device intended for the prophylaxis of Deep Vein Thrombosis (DVT), stimulating venous and arterial circulation, aiding in prevention of venous stasis ulcers, aiding in the healing of cutaneous ulcers, reducing acute/chronic edema and compartmental pressures. For use in home or hospital setting.

TECHNOLOGICAL CHARACTERISTICS

The manufacturer believes that the technological characteristics of the VascuEase IC-1200-WH are substantially equivalent to those of the predicate devices. The user interface has been simplified and battery-powered operation provide convenience for the user.

PERFORMANCE DATA

Before being released every device is tested and must meet all performance specifications. In addition to aesthetic acceptance criteria, functional testing includes cycle timing and inflation pressure. The results demonstrate comparable inflation cycle profiles (rise times, inflation pressures, deflation times and cycle times) between the applicant and predicate devices.

STATEMENT OF SUBSTANTIAL EQUIVALENCE

Similarities

Both the applicant and the predicate devices provide continuous intermittent pneumatic pressure using inflatable garments. The applicant and predicate devices have the same indications for use, both operate within the same clinically-established parameters and both have the same performance specifications. The applicant and predicate devices use the same prescribed inflation pressures and cycle times.

Differences

The applicant and primary predicate device have no differences. Whereas the applicant and secondary predicate (K131306) are both manufactured by Bio Compression Systems, the applicant device is portable and battery-powered while the secondary predicate is mains-powered. The secondary predicate can be configured for different therapies (a higher-pressure foot version and a cryotherapy version), while the applicant device is not available in alternate configurations.

Both the predicate and the applicant devices operate within the same clinically-established parameters. The differences between the predicate and the applicant devices do not impact substantial equivalence. A table illustrating the similarities and differences is provided below.

Table of Similarities and Differences with the Predicate Device

Parameter	**VascuEase IC-1200-WH (applicant device)**	**Vena Pro Vascular Therapy System, K133274 (primary predicate)**	**IC-1545-DL, K131306 (secondary predicate)**
Intended Use	VascuEase is a prescription device intended for the prophylaxis of Deep Vein Thrombosis (DVT), stimulating venous and arterial circulation, aiding in prevention of venous stasis ulcers, aiding in the healing of cutaneous ulcers, reducing acute/chronic edema and compartmental pressures. For use in home or hospital setting.	The Vena Pro Vascular Therapy System model VP-31111 is intended to be an easy to use portable system, prescribed by a physician, to help prevent the onset of DVT in patients by stimulating blood flow in the extremities (simulating muscle contractions). This device can be used to: aid in the prevention of DVT, enhance blood circulation, diminish post-operative pain and swelling, reduce wound healing time, aid in the treatment of: stasis dermatitis, venous stasis ulcers, arterial and diabetic leg ulcers, chronic venous insufficiency and reduction of edema in the lower limbs. The unit can also be used as an aid in the prophylaxis for DVT by persons expecting to be stationary for long periods of time.	Prophylaxis of deep vein thrombosis, enhancement of venous and arterial circulation, prevention of venous stasis ulcers, assist in healing of cutaneous ulcers, reduction of acute or chronic edema, reduction of lower limb pain due to surgery or trauma, reduction of compartmental pressures
Principal of Operation	Intermittent Pneumatic Compression	Intermittent Pneumatic Compression	Intermittent Pneumatic Compression
Weight	0.7 pounds	0.7 pounds	4.25 pounds

Parameter	VascuEase IC-1200-WH (applicant device)	Vena Pro Vascular Therapy System, K133274 (primary predicate)	IC-1545-DL, K131306 (secondary predicate)
Dimensions	5.3 x 2.7 x 1.5 inches	5.3 x 2.7 x 1.5 inches	6.25 x 8 x 8.25 inches
# of Segments in garment	1	1	1
Inflation Time	15 seconds	15 seconds	15 seconds
Deflation Time	45 seconds	45 seconds	45 seconds
Inflation Pressure	50 mmHg	50 mmHg	50 mmHg
Pressure Adjustment	NA	NA	Digital, 1 mmHg increments
Pressure Display	No	No	Yes
Power Requirements	Rechargeable battery	Rechargeable battery	Electric mains
Mobility	Portable, worn	Portable, worn	Stationary, placed

CONCLUSION

Based upon safety and performance testing, compliance with voluntary standards, and comparison to the predicate devices, the manufacturer believes that the VascuEase IC-1200-WH device is substantially equivalent to the predicate devices.