August 5, 2018

Caremed Supply, Inc.
Tsung-Hsuan Liu
General Manager
7F., No. 2, Lane 235, Baoqiao Rd., Xindien Dist.
New Taipei City, 23145 Tw

Re: K181217
Trade/Device Name: VesoFlow Lite DVT Compression Device
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: April 26, 2018
Received: May 7, 2018

Dear Tsung-Hsuan Liu:

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)*

K181217

Device Name
VesoFlow Lite DVT Compression Device

Indications for Use *(Describe)*
The Caremed Supply Inc. VesoFlow Lite Deep Vein Thrombosis (DVT) Compression Device is intended to increase venous blood flow in at risk patients in order to help prevent deep vein thrombosis.

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

5.1 Type of Submission: Traditional

5.2 Date of Summary: May 3, 2018

5.3 Submitter: Caremed Supply, Inc.

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Phone: +886-2-2917-9808
Fax: +886-2-2918-6505
Contact: TSUNG-HSUAN LIU (oscar@caremed.com.tw)

5.4 Identification of the Device:

Proprietary/Trade name:	VesoFlow Lite DVT Compression Device
Classification Product Code:	JOW
Regulation Number:	870.5800
Regulation Description:	Compressible limb sleeve
Review Panel:	Cardiovascular
Device Class:	II

5.5 Identification of the Predicate Device:

Predicate Device Name:	VESOFLOW PLUS DVT Compression Devices Model Name: IPCS/SQS
Manufacturer:	Caremed Supply, Inc.
Classification Product Code:	JOW
Regulation number:	870.5800
Device Class:	II
510(k) Number:	K141064

5.6 Identification of the Reference Device:

Reference Device Name:	VesoPress DVT System, Pump Model VP500D
Applicant:	Compression Therapy Concepts, Inc.
Manufacturer:	Caremed Supply, Inc.
Classification Product Code:	JOW
Regulation number:	870.5800
Device Class:	II
510(k) Number:	K061814

5.7 Intended Use/ Indications for Use of the Device

The Caremed Supply Inc. VesoFlow Lite Deep Vein Thrombosis (DVT) Compression Device is intended to increase venous blood flow in at risk patients in order to help prevent deep vein thrombosis.

5.8 Device Description

The VesoFlow Lite DVT Compression Device is an Intermittent Pneumatic Compression System that counteracts blood stasis and coagulation changes; two of the three major factors that promote deep vein thrombosis (DVT) a potentially life threatening condition which can lead to pulmonary embolism.

The VesoFlow Lite is a non-invasive mechanical prophylactic system that massages the feet or legs in a wavelike, milking motion that promotes blood flow and deters thrombosis, helping to empty pooled or static blood from the valve cusps of the femoral vein. Fibrinolytic activity is increased, stimulating the release of a plasminogen activator. This therapy typically complements other prophylactic measures, such as antiembolic stockings and anticoagulants.

Some exciting features include:

- User friendly master control unit that is designed so that its functions are self-explanatory
- Power micro switch (ON/OFF)

- An alarm light displays a fault status with an audio alarm and LED display
- LED display that can monitor errors, sleeves statuses the device
- User friendly hanging bracket that provides easy attachment

The system consists of an air pump and single-patient-use compression sleeve – one for the foot, one for the calf and one for the thigh. The air pump and compression sleeve may be used on one lower extremity. If the air pump is used simultaneously on both lower extremities, it is important that the identical sleeve type be used on both legs (i.e. foot sleeve with foot sleeve, calf sleeve with calf sleeve, or thigh sleeve with thigh sleeve). The inflation pressure settings are pre-set by the manufacturer and cannot be changed. The compression level for the foot sleeve is 120mmHg (16kPa). The compression level for the calf and thigh sleeve is 40mmHg. The sleeve inflates and maintains compression for 12 seconds. Then, the sleeve deflates for a period of 48 seconds. As the sleeve inflates, it compresses the foot, calf or thigh which augments venous blood flow, thereby reducing stasis. This process also stimulates fibrinolysis; thus, reducing the risk of early clot formation. Regularly check the system while in use, assuring pump operation and sleeve fit.

5.9 Non-clinical Testing

A series of safety and performance tests were conducted on the subject device, VesoFlow Lite DVT Compression Device.

- Biocompatibility
- Software Validation
- Electromagnetic compatibility and electrical safety
- Reliability
- Performance
- Usability

All the test results demonstrate VesoFlow Lite DVT Compression Device meets the requirements of its pre-defined acceptance criteria and intended use, and is substantially equivalent to the predicate device.

5.10 Clinical Testing

No clinical test data was used to support the decision of substantial equivalence.

5.11 Substantial Equivalence Determination

The VesoFlow Lite DVT Compression Device submitted in this 510(k) file is substantially equivalent in intended use, design, technology/principles of operation, materials and performance to the cleared VESOFLOW PLUS DVT Compression Devices Model Name: IPCS/SQS (K141064), especially IPCS. We conducted comparative performance test with IPCS, and also compared with referenced VesoPress DVT System, Pump Model VP500D (K061814) for the specifications of Pressure, Inflation time, and Deflation time. Differences between the devices cited in this section do not raise any new issue of substantial equivalence.

Item	**Subject device**	**Predicate device**	**Substantial equivalence determination**
Proprietary Name	VesoFlow Lite DVT Compression Device	VESOFLOW PLUS DVT Compression Devices	
Model Name	VesoFlow Lite	IPCS	
510(k) No.	(to be assigned)	K141064	
Intended Use	The Caremed Supply Inc. VesoFlow Lite Deep Vein Thrombosis (DVT) Compression Device is intended to increase venous blood flow in at risk patients in order to help prevent deep vein thrombosis.	The Caremed Supply Inc. VESOFLOW® PLUS SQS and IPCS Deep Vein Thrombosis (DVT) Compression Devices are intended to increase venous blood flow in at risk patients in order to help prevent deep vein thrombosis.	Same
Type of use	Prescription Use	Prescription Use	Same
For Control Unit			
Size	9.83” x 4.37” x 8.28”	7.54” x 5.12” x 7.95”	Different but does not raise any new issue of substantial equivalence

Weight	2.4 Kg	2.8 Kg	Different but does not raise any new issue of substantial equivalence
Pressure (mmHg)	Calf/Thigh: 40; Foot: 120	Calf/Thigh: 40; Foot: 130	Different but Same as Reference Device K061814 (Calf/Thigh: 40; Foot: 80-120)
Input Rating	AC 100-240V, 50/60Hz	AC 100-240V, 50/60Hz	Same
Fuse Rating	T2AL 250V	1A/250V	Different but does not raise any new issue of substantial equivalence
IEC Classification	Class II, Type BF Not AP or AGP type	Class II, Type BF Not AP or AGP type	Same
Ingress of Water Protection	IP21	IP22	Different but does not raise any new issue of substantial equivalence
Operation Humidity	30% to 75%	30 - 75%	Same
Operation Temperature	15°C - 40°C	15°C - 35°C	Different but does not raise any new issue of substantial equivalence
Operation Atmospheric Pressure Range	700 hPa to 1060 hPa	700 hPa to 1060 hPa	Same
Mode of Operation	Continuous	Continuous	Same
Applied Part	Sleeve and Air Hose	Garment and Air Hose	Same
Applied Mode of Pressure	Intermittent	Intermittent	Same

Inflation time per chamber	12 seconds	12 seconds for Calf/Thigh, 3 seconds for Foot	Different but Same as Reference Device K061814 (all 12 seconds)
Deflation time per chamber	48 seconds	48 seconds for Calf/Thigh, 30 seconds for Foot	Different but Same as Reference Device K061814 (all 48 seconds)
Application	Non-invasive / external	Non-invasive / external	Same
Battery Pack	No	Yes	Different but does not raise any new issue of substantial equivalence
Software / Control panel	w/o Pressure and Timer display w/o Mute, Caution, and Battery symbols display w/o Timer Reset function w/o Alarm mute button w/o Maintenance alarm light	w/ Pressure and Timer display w/ Mute, Caution, and Battery symbols display w/ Timer Reset function w/ Alarm mute button w/ Maintenance alarm light	Different but does not raise any new issue of substantial equivalence
For Applied Part			
Calf Sleeves (by calf circumference)	Small: up to 12”	XS: up to 12”	Same
	Medium: up to 18”	M: up to 18”	
	Large: up to 24”	L: up to 24”	
	XL: up to 32”	B: up to 32”	
Thigh Sleeves (by thigh circumference)	Medium: up to 29”	M: up to 29”	Same
	Large: up to 36”	L: up to 36”	
	XL: up to 42”	B: up to 42”	
Foot Sleeves (by foot length)	Medium: 13”	U: 13”	Same
	Large: 16”	L: 16”	
Air Hose	extension of 60” (pair), standard	extension of 60” (pair), standard	Same
	extension of 118” (pair)	extension of 118” (pair)	
		extension of 177” (pair)	

5.12 Similarity and Difference

The VesoFlow Lite DVT Compression Device has been compared with "VESOFLOW PLUS DVT Compression Devices Model Name: IPCS" and referred to "VesoPress DVT System, Pump Model VP500D". The subject device has same intended use, principle of operation and similar technological characteristics as model: IPCS of the predicate device and reference device. Although there are some specifications that are different between two devices, the performance test has been completed to demonstrate that the differences between these parameters would not impact the safety and effectiveness of the subject device, and the specifications of Pressure, Inflation time, and Deflation time are the same as those of reference device. The subject device has also undergone safety and performance tests, and the results complied with the test requests. Therefore, the differences between the subject device and the predicate device do not raise any problem of substantial equivalence. The subject device is substantially equivalent to the predicate device in intended use, design, and performance claims.

5.13 Conclusion

After analyzing non-clinical laboratory studies and safety testing data, it can be concluded that the VesoFlow Lite DVT Compression Device is substantially equivalent to the predicate device.