DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 4, 2014

Caremed Supply, Inc.
% Michael Lee
President
AcmeBiotechs Co., Ltd.
No.45, Minsheng Rd.
Danshui Town
New Taipei City, 251 TW

Re: K141064
Trade/Device Name: VESOFLOW PLUS DVT Compression Devices
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: October 20, 2014
Received: October 27, 2014

Dear Michael 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K141064

Device Name: VESOFLOW®PLUS DVT Compression Device
Model Name: IPCS/SQS

Indications for Use:

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.

Prescription Use ___X___ AND/OR Over-The-Counter Use____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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510(k) Summary

5.1 Type of Submission: Traditional

5.2 Preparation Date: 16th April 2014

5.3 Submitter:

Address:	7F., No. 2, Lane 235, Bao Chiao Rd., Xin Tien Dist., New Taipei City 23145, Taiwan
Phone:	+886-2-29179808
Fax:	+886-2-29186505
Contact:	Tsung-Hsuan Liu (oscar@caremed.com.tw)
Registration number:	8022590

5.4 Identification of the Device:

Proprietary/ Trade name:	VESOFLOW®PLUS DVT Compression Device, Model Name: IPCS/SQS
Classification Name:	Sleeve, Limb, Compressible
Device Classification:	II
Regulation Number:	870.5800
Panel:	Cardiovascular
Product Code:	JOW

5.5 Identification of the Predicate Device:

Predicate Device Name:	VESOFLOW
Manufacturer:	Caremed Supply Inc.
Regulation number:	870.5800
Product Code:	JOW
510(k) Number:	K110977

5.6 Intended Use and Indications for Use of the subject device.

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.

5.7 Device Description

VESOFLOW®PLUS that counteracts blood stasis and coagulation changes – two of the three major factors that promote deep vein thrombosis (DVT). VESOFLOW® PLUS 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.

VESOFLOW®PLUS is used to prevent pooling of blood in a limb by inflating periodically a sleeve around the limb. Therefore, VESOFLOW®PLUS is identified as a compressible limb sleeve.

5.8 Non-clinical Testing

A series of safety tests were performed to assess the safety and effectiveness of the VESOFLOW®PLUS SQS and IPCS Deep Vein Thrombosis (DVT) Compression Devices.

Testing Item	**Standard and regulations applied**
Biocompatibility	ISO 10993-1:2009/Cor. 1:2010(E) Biological evaluation of medical devices – Part 1: Evaluation and testing with a risk management process.
	ISO 10993-5:2009 (E) Biological evaluation of medical devices – Part 5: Tests for *in vitro* cytotoxicity.
	ISO 10993-10:2010(E) Biological evaluation of medical devices

	– Part 10: Tests for Tests for irritation and skin sensitization.
	ISO 10993-12 Biological Evaluation Of Medical Devices -- Part 12: Sample Preparation And Reference Materials. (Biocompatibility)
	ISO/IEC 17025:2005 General Requirements for the Competence of Testing and Calibration Laboratories.
	USP 35 Biological reactivity tests, *in vitro*
Software	IEC 62304 First Edition 2006-05, Medical Device Software - Software Life Cycle Processes. (Software/Informatics)
Electromagnetic Compatibility & Electrical Safety	EN 60601-1-2 : 2007/AC:2010 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests.
	IEC 60601-1-2 : 2007 Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests. (General I (QS/RM))
	IEC 61000-3-2 : 2005+A1:2008+A2:2009 Electromagnetic compatibility (EMC) - Part 3-2: Limits - Limits for harmonic current emissions (equipment input current ≤16 A per phase).
	IEC 61000-3-3 : 2008 Electromagnetic compatibility (EMC) - Part 3-3: Limits - Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current ≤16 A per phase and not subject to conditional connection.
	IEC 61000-4-2 : 2008 Electromagnetic compatibility (EMC) - Part 4-2: Testing and measurement techniques - Electrostatic discharge immunity test.
	IEC 61000-4-3 : 2006+A1:2007+A2:2010 Electromagnetic compatibility (EMC) - Part 4-3: Testing and measurement techniques - Radiated, radio-frequency, electromagnetic field immunity test.

	IEC 61000-4-4 : 2012 Electromagnetic compatibility (EMC) - Part 4-4: Testing and measurement techniques - Electrical fast transient/burst immunity test.
	IEC 61000-4-5 : 2005+corr.October:2009 Electromagnetic compatibility (EMC) - Part 4-5: Testing and measurement techniques - Surge immunity test.
	IEC 61000-4-6 : 2008 Electromagnetic compatibility (EMC) - Part 4-6: Testing and measurement techniques - Immunity to conducted disturbances, induced by radio-frequency fields.
	IEC 61000-4-8 : 2009 Electromagnetic compatibility (EMC) - Part 4-8: Testing and measurement techniques - Power frequency magnetic field immunity test.
	IEC 61000-4-11 : 2004 Electromagnetic compatibility (EMC) - Part 4-11: Testing and measurement techniques - Voltage dips, short interruptions and voltage variations immunity tests.
	CISPR 11 : 2009+A1:2010 Industrial, scientific and medical equipment - Radio-frequency disturbance characteristics - Limits and methods of measurement.
Performance	IEC 60068-2-14: 2009 Environmental testing - Part 2-14: Tests - Test N: Change of temperature.
	ISTA 2A Standard
Risk Management	ISO14971 Medical Devices - Application Of Risk Management To Medical Devices. (General I (QS/RM))
	IEC 60812 Analysis Techniques For System Reliability - Procedure For Failure Mode And Effects Analysis (Fmea). (General I (QS/RM))

All the test results demonstrate VESOFLOW®PLUS SQS and IPCS Deep Vein Thrombosis (DVT) Compression Devices meet the requirements of its pre-defined acceptance criteria and intended uses.

5.9 Clinical Testing

No clinical test data was used to support the decision of safety and effectiveness.

5.10 Substantial Equivalence Determination

The VESOFLOW®PLUS SQS and IPCS Deep Vein Thrombosis (DVT) Compression Devices have similar intended use, materials, safety and similar technological characteristics with the predicate device. Information described above can demonstrate the VESOFLOW®PLUS SQS and IPCS Deep Vein Thrombosis (DVT) Compression Devices are substantial equivalent to the predicate device.

Model Name	**VESOFLOW®PLUS SQS**	**VESOFLOW SQS**
Dimension	7.54"x 5.12"x7.95"	9.8" x 8.9" x 8.1"
Weight	2.8kg	2.5kg
Pressure Range	Calf/Thigh : 45, 40 and 30mmHg Foot: 130mmHg	Calf/Thigh : 45, 40 and 30mmHg Foot: 130mmHg
Input Rating	AC 100-240V, 50/60Hz	AC 100-240V, 50/60Hz
Fuse Rating	1A/250V	1A/250V
Operating Humidity	30-75%	30-75%
Operation Temperature	15˚C- 35˚C	15˚C- 35˚C
Applied Part	Garment and Air Hose	Garment and Air Hose
Applied Mode of Pressure	Sequential	Sequential
Number of Chambers in Garment	3	3
Inflation time per chamber	12 seconds	12 seconds
Deflation time per chamber	48 seconds	48 seconds
Pressure sequence	45, 40 and 30 mmHg	45, 40 and 30 mmHg

calf/thigh		
Pressure Range Calf/Thigh	45, 40 and 30 mmHg	45, 40 and 30 mmHg
Pressure Range Foot	130 mmHg	130 mmHg
Pre-Programmed Controls	Yes	Yes
Battery Pack	Yes	Yes

Model Name	**VESOFLOW®PLUS IPCS**	**VESOFLOW IPCS**
Dimension	7.54"x 5.12"x7.95"	9.8” x 8.9” x 8.1”
Weight	2.8kg	2.5kg
Pressure Range	40 and 130mmHg	40 and 130mmHg
Input Rating	AC 100-240V, 50/60Hz	AC 100-240V, 50/60Hz
Fuse Rating	1A/250V	1A/250V
Operating Humidity	30-75%	30-75%
Operation Temperature	15˚C - 35˚C	15˚C - 35˚C
Applied Part	Garment and Air Hose	Garment and Air Hose
Applied Mode of Pressure	Intermittent	Intermittent
Number of Chambers in Garment	No	No
Inflation time per chamber (Calf/Thigh)	12 seconds	12 seconds
Deflation time per chamber (Calf/Thigh)	48 seconds	48 seconds

Inflation time per chamber (Foot)	3 seconds	3 seconds
Deflation time per chamber (Foot)	30 seconds	30 seconds
Pressure Range Calf/Thigh	40 mmHg	40 mmHg
Pressure Range Foot	130 mmHg	130 mmHg
Pre-Programmed Controls	Yes	Yes
Battery Pack	Yes	Yes

5.11 Similarity and difference

The difference between the proposed device and the predicate device is software driven. The proposed device has tested on safety and performance tests and the results were complied with the test requests. Therefore, the difference of proposed device and predicate device did not raise any problems of safety or effectiveness. The proposed device is substantially equivalent to the predicate device in intended use, design, and performance claims.

5.12 Conclusion

After analyzing bench tests, safety testing data, it can be concluded that VESOFLOW®PLUS SQS and IPCS Deep Vein Thrombosis (DVT) Compression Devices are as safe and effective as the predicate device.