DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

July 15, 2015

Bio Compression Systems, Inc.
Barbara J. Whitman
Director, Regulatory Affairs and Quality Assurance
120 W Commercial Ave
Moonachie, NJ 07074

Re: K150953
Trade/Device Name: Sequential Circulator SC-2008-OC and Sequential Circulator SC-2004-OC
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: June 23, 2015
Received: June 24, 2015

Dear Barbara Whitman:

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" (21CFR 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name
Sequential Circulator SC-2008-OC and Sequential Circulator SC-2004-OC

Indications for Use *(Describe)*

The Bio Compression Systems Sequential Circulator SC-2008-OC/Sequential Circulator SC-2004-OC with associated garments are sequential, pneumatic compression devices intended for the primary or adjunctive treatment of primary or secondary lymphedema. The devices are also intended for the additional or alternate treatment of venous insufficiency and chronic venous stasis ulcers associated with venous insufficiency, as well as, general treatment for swelling of the extremities. The devices are intended for home or 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary of Safety and Effectiveness

Contact: Barbara J. Whitman
Director, Regulatory Affairs and Quality Assurance

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Date Prepared: April 8, 2015

Device Name/Classification: Sequential Circulator SC-2008-OC and Sequential Circulator SC-2004-OC
Class II
Cardiovascular and Respiratory Devices
21 CFR Part 870.5800
JOW – Compressible Limb Sleeve

Trade Name of Proposed Device(s): SC-2004-OC Sequential Circulator
SC-2008-OC Sequential Circulator

Predicate Devices:

510(k) #	Device Name	Manufacturer
K043423	SC-3008 Sequential Circulator	Bio Compression Systems, Inc.
K142640	SC-3004-DL, SC-3008-DL Sequential Circulators Digital	Bio Compression Systems, Inc.
Preamendment	SC-2004 Sequential Circulator	Bio Compression Systems, Inc.

Manufacturer and Distributor: Bio Compression Systems, Inc.
120 W. Commercial Ave., Moonachie, NJ 07074 USA

Proposed Device Description

The Bio Compression Systems, Inc. SC-2004-OC Sequential Circulator and SC-2008-OC Sequential Circulator, are pneumatic compression devices ('pumps') with associated compressible garment sleeves. The pumps are manually adjusted by the user to produce air pressure to inflate and deflate segmented inflatable chambers of garment sleeves. The garment sleeves are externally applied over affected extremities. The pumps consist of compressors capable of producing a maximum pressure of 80 mmHg and provide graduated or gradient pressurization to the chambers of the garments. The sequential inflation is applied distally to proximally with distal chambers inflated to a greater pressure than proximal ones.

As each chamber is inflated, the pressure is held constant until all chambers are inflated, in order to prevent reverse gradient flow. Once all of the chambers are inflated, they are then simultaneously released and the cycle repeats. The user can adjust the Pressure Knob on the front of the device for desired pressure.

Associated garments are available in a variety of standard sizes. The pumps can operate unilaterally and bilaterally as needed.

Indications For Use

The Bio Compression Systems Sequential Circulator SC-2008-OC/Sequential Circulator SC-2004-OC with associated garments are sequential, pneumatic compression devices intended for the primary or adjunctive treatment of primary or secondary lymphedema. The devices are also intended for the additional or alternate treatment of venous insufficiency and chronic venous stasis ulcers associated with venous insufficiency, as well as, general treatment for swelling of the extremities. The devices are intended for home or hospital use.

Description of Device Modifications/Technological Characteristics:

The Sequential Circulators SC-2004-OC and SC-2008-OC are technologically similar to the predicate devices, SC-3008 Sequential Circulator (K043423) and SC-2004 Sequential Circulator (Preamendment Device). The modification was the removal of the pressurization display gauge from the front of the device. The Pressure Knob, used to set the desired pressurization, remains substantially equivalent to that of the predicate device. The removal of the display was ease of use for the end user. Once the desired pressure is indicated by setting the Pressure Knob, the end user does not need to read any displays, as the pressurization is consistent with the desired setting.

The modification to the subject devices has not altered the fundamental technology of the predicate devices.

Performance Data

Before being released to market, every device is tested and must meet all performance specifications. In addition to aesthetic acceptance criteria, functional testing includes electrical leakage, pressure adjustment, inflation pressure in each chamber, air pressure display accuracy, and inflation/deflation cycle times. 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:

Based upon risk management, safety & performance testing, compliance with voluntary standards, and comparison to predicate devices, the Sequential Circulators SC-2004-OC and SC-2008-OC, are substantially equivalent to the predicate devices SC-3008 Sequential Circulator and the SC-2004 Sequential Circulator. The modified devices do not introduce any new potential safety risks and are substantially equivalent to the predicate devices.