February 16, 2022

Bio Compression Systems, Inc.
Marc Somelofski
Director of RA/QA
120 West Commercial Ave
Moonachie, New Jersey 07074

Re: K213533
Trade/Device Name: Sequential Circulators SC-1004-DL, SC-1008-DL, SC-2004-DL, SC-2008-DL, SC-4004-DL, SC-4008-DL
Regulation Number: 21 CFR 890.5650
Regulation Name: Powered Inflatable Tube Massager
Regulatory Class: Class II
Product Code: IRP
Dated: January 17, 2022
Received: January 19, 2022

Dear Marc Somelofski:

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/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 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 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,

Heather Dean, PhD
Assistant Director, Acute Injury Devices Team
DHT5B: Division of Neuromodulation
and Physical Medicine Devices
OHT5: Office of Neurological
and Physical Medicine 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213533

Device Name
Sequential Circulator models SC-1004-DL, SC-1008-DL, SC-2004-DL, SC-2008-DL, SC-4004-DL, SC-4008-DL

Indications for Use *(Describe)*
Intended to temporarily relieve minor muscle aches and/or pains, and to temporarily increase circulation to the treated area in people who are in good health.

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
K213533

Date Prepared: January 24, 2022

I. SUBMITTER

Bio Compression Systems, Inc.
120 West Commercial Avenue
Moonachie, NJ 07074, USA
Phone: +1-201-939-0716

Contact Person: Marc L. Somelofski

II. DEVICE

Device Name	Sequential Circulators SC-1004-DL, SC-1008-DL, SC-2004-DL, SC-2008-DL, SC-4004-DL, SC-4008-DL
Trade/Proprietary Name	Sequential Circulators SC-1004-DL, SC-1008-DL, SC-2004-DL, SC-2008-DL, SC-4004-DL, SC-4008-DL
Common/Usual Name	Sequential Circulators SC-1004-DL, SC-1008-DL, SC-2004-DL, SC-2008-DL, SC-4004-DL, SC-4008-DL
Classification Name	Powered inflatable tube massager (21 CFR 890.5650)
Product Code	IRP
Class	Class II

III. PREDICATE DEVICE

2004-OC Massage System, 2008-OC Massage System (K122112).

Reference devices K030437, K122154, K133483, K160608, K183169, and K210967 are mentioned.

IV. DEVICE DESCRIPTION

Bio Compression Systems' Sequential Circulators are powered inflatable tube massagers which consist of a segmented pneumatic sleeve ("garment") connected to a pneumatic compression pump ("pump"). The pump cyclically inflates the garment's segments ("chambers") in sequence from the distal end toward the trunk of the body. The sequential inflation of the garment simulates kneading and stroking of tissues with the hands, increasing circulation on the limb worn.

The core components of the pump are the motor, air compressor, disc valves, and micro switch. The air compressor generates air flow into a stationary disc valve. The motor moves a rotating disc valve. The geometry of the disc valve directs air flow and cyclically triggers the micro switch.

The pump is controlled by softkeys and an LED display (models SC-1004-DL, SC-1008-DL, SC-2004-DL, SC-2008-DL) or by a touch screen LCD (models SC-4004-DL, SC-4008-DL).

The device uses the Predicate Device's garments.

V. INDICATIONS FOR USE

	Subject Device (K213533)	**Predicate Device (K122112)**	**Comparison**
Indications for Use	Intended to temporarily relieve minor muscle aches and/or pains, and to temporarily increase circulation to the treated area in people who are in good health.	The 2004-OC and 2008-OC Massage Systems are powered inflatable tube massagers intended to temporarily relieve minor muscle aches and/or pains, and to temporarily increase circulation to the treated areas. The devices are intended for home use by people who are in good health.	Subject Device indications are more concise. Other devices in the category with similar technological characteristics have been cleared for these indications (Reference Devices K160608, K210967).
Prescription/ over-the-counter use	Over-The-Counter	Over-The-Counter	Identical

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

	Subject Device (K213533)	Predicate Device (K122112)	Comparison
Operating Principle	Same as Predicate	An air compressor generates air flow in a stationery disc valve. A motor turns the top disc valve which directs air and trigger's a micro switch.	Identical
Power Supply Rating	100-240V, 50/60 Hz	120 VAC, 60 Hz	Equivalent - the Subject Device and Predicate Device both connect to mains power. This is the same as other similar cleared devices (Reference Device K160608).
Rated Input	12VDC, 3A	120 VAC, 0.5 A	Equivalent - the Subject Device has a lower input voltage. This is the same as other similar cleared devices (Reference Device K160608).
Electrical Classification	Class II	Class II	Identical
Applied Part	Type BF	Type BF	Identical
Ingress Protection	IP21	IP21	Identical
Cycle Time	• 1000 series: 60-120 seconds in 30-second increments • 2000/4000 series: 60-120 seconds in 15-second increments	• 2004-OC: 90 seconds • 2008-OC: 45 seconds	Equivalent
Treatment Time	Continuous or timed as follows: • 1000 series: 30-120 minutes adjustable in 30-minute increments • 2000/4000 series: 10-120 minutes in 5-minute increments	Continuous	Equivalent

	Subject Device (K213533)	Predicate Device (K122112)	Comparison
Pressure Range	• 20-100 mmHg, adjustable in 5 mmHg increments • 10-120 mmHg, adjustable in 1 mmHg increments • 0-120 mmHg, adjustable in 1 mmHg increments	30-80 mmHg, adjustable in 1 mmHg increments	The Subject Device has a broader range of pressure selections. The Subject Device's ranges are similar to other cleared devices in this category with the same technological characteristics and indications (Reference Devices K160608, K183169, K210967).
Pressure Gradient (decrease/proximal chamber)	–1 mmHg (8-chamber models) or –2 mmHg (4-chamber models)	–1 mmHg	Equivalent – the Subject Device's 8-chamber models are identical, and the 4-chamber models have the same total gradient as the Predicate Device's model 2008-OC
Weight	• SC-1004-DL, SC-2004-DL: 3.3 lbs. (1.5 kg) • SC-1008-DL, SC-2008-DL: 3.65 lbs. (1.66 kg) • SC-4004-DL: 3.5 lbs. (1.59 kg) • SC-4008-DL: 3.85 lbs. (1.75 kg)	8 lbs. (3.63 kg)	Similar – The Subject Device's models are lighter
Dimensions	• 1000 series: 4.5" x 11.75" x 7.75" (114 mm x 298 mm x 197 mm) • 2000/4000 series: 4.5" x 12" x 7.34" (114 mm x 304 mm x 186 mm)	5.5" x 12" x 8" (140 mm x 305 mm x 203 mm)	Similar
Inflatable Sleeves ("Garments")	Uses Predicate's garments	200 Denier Nylon Oxford, coated with 3 mil of Polyurethane	Identical or identical material covering additional anatomic areas (shoulder, back, hand/wrist, ankle, elbow, knee). This is the same anatomic areas as other cleared devices in this category with similar technological characteristics and indications (K030437, K122154, K133483)

	Subject Device (K213533)	Predicate Device (K122112)	Comparison
Features	• Adjustable Cycle Time • Adjustable Pressure • Usage Meter • Focus Therapy Mode (2000/4000 series) • Pause • Pre-Therapy Mode (SC-4008-DL) • Timed Treatment • Individual Chamber Adjustment (4000 series)	• Adjustable Pressure	The Subject Device has additional features. These features are similar or the same as other cleared devices in this category with similar technological characteristics and indications (Reference Devices K160608, K183169, K210967).
Software Safety Class (IEC 62304)	A	N/A	The Subject Device has a printed circuit board and simple software. This is the same as other cleared devices in this category with similar technological characteristics and the same indications K160608, K183169, K210967).

The Subject Device has the same technological characteristics with respect to design, materials used, and construction.

- Subject Device and Predicate Device have the same operating principle and use the same disc valve assembly for operation
- Components used in Subject and Predicate Devices are identical, the same material, or have the same specifications
- The Predicate Device uses the Subject Device's compression garments.
- Subject Device and Predicate Device have the same or similar performance specifications

The differences between the Subject Device and Predicate Device exist in similar cleared devices and do not raise any different questions of safety and/or effectiveness.

- The difference in rated input and power supply rating is equivalent and the same as similar cleared devices (Reference Device K160608).
- The Subject Device's broader range of pressure selections is similar to other cleared devices in this category with the same technological characteristics and indications (Reference Devices K160608, K183169, K210967).
- The Subject Device's additional features are the same as other cleared devices in this category with similar technological characteristics and the same indications (Reference Devices K160608, K183169, K210967).
- The Subject Device has a printed circuit board and simple software. This is the same as other cleared devices in this category with similar technological

characteristics and the same indications K160608, K183169, K210967). Additionally, the Subject Device and Predicate device have the same operating principle.

- The Subject Device has additional garment models covering additional anatomic areas. These are the same areas as other cleared devices in this category with similar technological characteristics and the same indications (K030437, K122154, K133483).

VII. PERFORMANCE DATA

The following testing and performance data were provided in support of the substantial equivalence determination.

Electrical safety and electromagnetic compatibility (EMC)

- ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012
- ANSI/AAMI HA60601-1-11:2015-08
- IEC 60601-1:2005/AMD1:2012
- IEC 60601-1-2:2014
- IEC 60601-1-6:2010/AMD1:2013
- IEC 60601-1-11:2015

Predicate Device routine acceptance tests conducted on Subject Device

- Observation of operation
- Pressure testing
- HiPot (dielectric withstand test) testing

Functional verification and validation testing

- Cycle time verification and validation
- Treatment time verification and validation
- Pressure setting endpoint testing
- Operation to confirm all modes, settings, and mode/setting changes function as intended

Software Verification and Validation Testing

Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" and "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices". The software for this device is considered as a "minor" level of concern and there are no cybersecurity risks.

Clinical/Animal Studies

Clinical/animal studies were not submitted, referenced, or relied on in this premarket notification submission for a determination of substantial equivalence.

VIII. CONCLUSION

The data included in this submission demonstrates that the Subject Device is substantially equivalent to the legally marketed Predicate Device and performs comparably to the Predicate Device that is currently marketed for the same intended use.