May 14, 2021

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

Re: K210417
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 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: April 13, 2021
Received: April 15, 2021

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,

Nicole Gillette
Assistant Director (Acting)
DHT2B: Division of Circulatory Support,
Structural and Vascular Devices
OHT2: Office of Cardiovascular 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K210417

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)*
The Bio Compression Systems' Sequential Circulators are sequential, pneumatic compression devices intended for either primary or adjunctive treatment of lymphedema, peripheral edema, lipedema, venous insufficiency, and venous stasis ulcers. Sequential Circulators are also intended for the prophylaxis of deep vein thrombosis (DVT). Intended for use in a home or healthcare 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.

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120 West Commercial Avenue, Moonachie, New Jersey 07074

Section 5: Summary

Date Prepared: April 13, 2021

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	Compressible Limb Sleeve (21 CFR 870.5800)
Product Code	JOW
Class	Class II

III. PREDICATE DEVICE

Sequential Circulator models SC-3004-DL and SC-3008-DL (K142640).

Reference devices K043423, K122112, K131306, K150953, K171793, K182003, and K203178 are mentioned.

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IV. DEVICE DESCRIPTION

Bio Compression Systems' Sequential Circulators are sequential pneumatic compression device which consists of a segmented pneumatic compression 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 inflation of the garment compresses the limb on which it is worn, stimulating the movement of interstitial fluid and blood flow.

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 (K210417)	Predicate Device (K142640)	Comparison
Indications for Use	The Bio Compression Systems' Sequential Circulators are sequential, pneumatic compression devices intended for either primary or adjunctive treatment of lymphedema, peripheral edema, lipedema, venous insufficiency, and venous stasis ulcers. Sequential Circulators are also intended for the prophylaxis of deep vein thrombosis (DVT). Intended for use in a home or healthcare setting.	The Bio Compression Systems' SC-3008-DL, SC-3004-DL, SC-3004DC-DL, and SC-2008-DL are sequential, pneumatic compression devices intended for either primary or adjunctive treatment of primary or secondary lymphedema. The devices are also intended for 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 both home and hospital use.	The addition of the lipedema and deep vein thrombosis prophylaxis indications is not a new use; devices in the category with similar characteristics and indications have been cleared for these indications (Reference Devices K131306, K182003, K203178).

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	Subject Device (K210417)	Predicate Device (K142640)	Comparison
Contra - indications	Compression IS NOT recommended in the following conditions: • Infections in the limb, including cellulitis, without appropriate antibiotic coverage • The presence of lymphangiosarcoma • Suspicion or confirmation of the presence of Deep Vein Thrombosis (DVT) • Inflammatory phlebitis or episodes of pulmonary embolism • Congestive Heart Failure (CHF) unless controlled by medication • Other indications as identified by the treating physician	Compression IS NOT recommended in the following conditions: • Infections in the limb, including cellulitis, without appropriate antibiotic coverage • The presence of lymphangiosarcoma • Suspicion or confirmation of the presence of Deep Vein Thrombosis (DVT) • Inflammatory phlebitis or episodes of pulmonary embolism • Congestive Heart Failure (CHF) • Active cancer except for palliative care • Other indications as identified by the treating physician	The cancer contraindication and clarifies the CHF contraindication. Removal of the cancer contraindication does not suggest a new use. Devices in the category with similar characteristics and indications have been cleared without this contra-indication (Reference Devices K182003, K203178).
Prescription/ over-the-counter use	Prescription	Prescription	Identical

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

	Subject Device (K210417)	Predicate Device (K142640)	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	120-240V, 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 K203178).

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	Subject Device (K210417)	Predicate Device (K142640)	Comparison
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 K203178).
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	60 seconds	Similar - other devices in this category with the same operating principle have cycle times longer than 60 seconds, including Bio Compression Systems' SC-2004-OC (Reference Device K150953), which has a 90 second cycle time
Treatment Time	Continuous or adjustable as follows: • 1000 series: 30-120 minutes adjustable in 30-minute increments • 2000/4000 series: 10-120 minutes in 5-minute increments	Continuous or 60 minutes	Equivalent
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	0-120 mmHg, adjustable in 1 mmHg increments	Equivalent - Endpoint pressure values are not frequently used
Pressure Accuracy	± 20%	± 20%	Identical
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 land the 4-chamber models have the same total gradient as the Predicate Device's model SC-3008-DL

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	Subject Device (K210417)	Predicate Device (K142640)	Comparison
Software Safety Class (IEC 62304)	A	A	Identical
Weight (4-chamber model)	• 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)	• SC-3004-DL: 5.65 lbs. (2.56 kg) • SC-3008-DL: 5.9 lbs. (2.68 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)	4.5" x 11.75" x 7.75" (114 mm x 298 mm x 197 mm)	Similar
Compression Sleeves ("Garments")	Uses Predicate's garments	200 Denier Nylon Oxford, coated with 3 mil of Polyurethane	Identical
Features	• Adjustable Cycle Time • Adjustable Pressure • Compliance/Usage Meter • Focus Therapy Mode (2000/4000 series) • Pause • Pre-Therapy Mode (SC-4008-DL) • Timed Treatment • Individual Chamber Adjustment (4000 series)	• Adjustable Pressure • Compliance/ • Usage Meter • Pre-Therapy Mode • (SC-3008-DL) • Timed Treatment • Individual Chamber Adjustment	Minor differences in features. Subject Device: • has Adjustable Cycle Time – the range of which is comparable to the Predicate Device (60 seconds) and similar cleared devices (Reference Device K150953, 90 seconds). • has a Focus Therapy mode (2000/4000 series) which doubles inflation time on a group of garment chambers for the first 10 minutes – this is similar to the Predicate Device's Pre-Therapy mode which inflates the most distal group of garment chambers for the first 10 minutes • can pause treatment and treatment time – this is the same as other similar

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	Subject Device (K210417)	Predicate Device (K142640)	Comparison
			cleared devices (Reference Device K203178). • 1000 and 2000 series lack Individual Chamber Adjustment feature – this is the same as other similar cleared devices (Reference Device K150953).

The Subject Device is based upon the Predicate Device and 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 Adjustable Cycle Time range is similar to cycle times for cleared devices with the same Predicate as the Subject Device (Reference Device K150953)
- The lack of Individual Chamber Adjustment in 1000 and 2000 series is identical as cleared devices with the same Predicate as the Subject Device (Reference Device K150953)
- The differences in rated input and power supply rating are equivalent, and the Pause feature is the same as similar cleared devices Reference Device (Reference Device K203178).

VII. PERFORMANCE DATA

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

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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 continuous and timed 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

Comparative pressure testing of Subject and Predicate Device Individual Chamber Adjustment

- The standard gradient setting
- Typical upper extremity settings
- Typical fibrotic leg setting

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.

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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.

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