September 11, 2026

Bio Compression Systems, Inc.
Marc Somelofski
Vice President of RA/QA
120 W. Commercial Ave.
Moonachie, New Jersey 07074

Re: K261807
Trade/Device Name: Sequential Circulator (SC-4104-DL, SC-4108-DL)
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: August 7, 2026
Received: August 7, 2026

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 M. GILLETTE -S

Nicole Gillette
Assistant Director
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K261807

Device Name
Sequential Circulators (SC-4104-DL, SC-4108-DL)

Indications for Use *(Describe)*
Sequential Circulators are sequential pneumatic compression devices intended for either primary or adjunctive treatment of lymphedema, phlebolymphedema, post-mastectomy edema, 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.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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120 West Commercial Avenue, Moonachie, New Jersey 07074

Summary

Date Prepared: August 8, 2026

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-4104-DL, SC-4108-DL)
Trade/Proprietary Name	Sequential Circulators (SC-4104-DL, SC-4108-DL)
Common/Usual Name	Sequential Circulators (SC-4104-DL, SC-4108-DL)
Classification Name	Compressible Limb Sleeve (21 CFR 870.5800)
Product Code	JOW
Class	Class II

III. PREDICATE DEVICE

Sequential Circulator models SC-1004-DL, SC-1008-DL, SC-2004-DL, SC-2008-DL, SC-4004-DL, SC-4008-DL (K210417).

Reference device K203178 is mentioned.

IV. DEVICE DESCRIPTION

201-939-0716 ■ 800-888-0908 ■ Fax: 201-939-4503
E-Mail BioSystems@biocompression.com ■ www.biocompression.com

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 area of the body 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 device uses the Predicate Device's garments.

V. INDICATIONS FOR USE

	Subject Device	Predicate Device (K210417)	Comparison
Indications for Use	Sequential Circulators are sequential pneumatic compression devices intended for either primary or adjunctive treatment of lymphedema, phlebolymphedema, post-mastectomy edema, 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' 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.	Equivalent. The addition of the phlebolymphedema and post-mastectomy edema indications are not a new use. Devices in the category with similar characteristics have been cleared for this indication (K203178).

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	Subject Device	Predicate Device (K210417)	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) unless controlled by medication • Other indications as identified by the treating physician	Identical
Prescription/ over-the-counter use	Prescription	Prescription	Identical

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

	Subject Device	Predicate Device (K210417)	Comparison
Operating Principle	See Device Description	See Device Description	Identical
Power Supply Rating	100-240V, 50/60 Hz	100-240V, 50/60 Hz	Identical
Rated Input	12VDC, 3A	12VDC, 3A	Identical
Electrical Classification	Class II	Class II	Identical
Applied Part	Type BF	Type BF	Identical
Ingress Protection	IP21	IP21	Identical

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	Subject Device	Predicate Device (K210417)	Comparison
Cycle Time	60-120 seconds in 15-second increments	• 1000 series: 60-120 seconds in 30-second increments • 2000/4000 series: 60-120 seconds in 15-second increments	Identical
Treatment Time	Continuous or adjustable from 10-120 minutes in 5-minute increments	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	Identical
Pressure Range	20-120 mmHg, adjustable in 1 mmHg increments	• 1000 series: 20-100 mmHg, adjustable in 5 mmHg increments • 2000/4000 series: 10-120 mmHg, adjustable in 1 mmHg increments	Identical
Pressure Accuracy	± 20%	± 20%	Identical
Pressure Gradient (decrease/proximal chamber)	–1 mmHg (SC-4108-DL) or –2 mmHg (SC-4104-DL)	–1 mmHg (8-chamber models) or –2 mmHg (4-chamber models)	Identical
Software Safety Class (IEC 62304)	A	A	Identical
Weight	• SC-4104-DL: 3.5 lbs. (1.59 kg) • SC-4108-DL: 3.85 lbs. (1.75 kg)	• 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)	Identical
Dimensions	4.5” x 12” x 7.34” (114 mm x 304 mm x 186 mm)	• 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)	Identical
Compression Sleeves (“Garments”)	Uses Predicate’s garments	200 Denier Nylon Oxford, coated with 3 mil of Polyurethane	Identical

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	Subject Device	Predicate Device (K210417)	Comparison
User Interface	Soft key buttons	• 2000 series: soft key buttons • 4000 series: touch screen	Identical
Features	• Adjustable Cycle Time • Adjustable Pressure • Compliance/Usage Meter • Focus Therapy Mode • Pause • Pre-Therapy Mode (SC-4108-DL) • Timed Treatment • Individual Chamber Adjustment	• 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)	Identical

The Subject Device is based upon the Predicate Device and identical 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 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 addition of the phlebolymphedema and post-mastectomy edema indications are not a new use. Devices in the category with similar characteristics have been cleared for this indication (K203178)
- The Subject Device introduces modifications to the user interface, using soft keys over the previous version's touch screen

VII. PERFORMANCE DATA

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

Electrical safety and electromagnetic compatibility (EMC)

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- ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012 and A2:2021
- IEC 60601-1:2005/AMD1:2012 and A2:2020
- IEC 60601-1-2:2014 and A1:2020
- IEC 60601-1-6:2010/AMD1:2013 and A2:2020
- IEC 60601-1-11:2015 and A1:2020

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

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, "Content of Premarket Submissions for Device Software Functions". The software documentation level for this device is basic 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.

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