December 12, 2025

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

Re: K250974
Trade/Device Name: Bio Arterial Deluxe (IC-BAP-DX)
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: November 12, 2025
Received: November 12, 2025

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K250974

Please provide the device trade name(s).

Bio Arterial Deluxe (IC-BAP-DX)

Please provide your Indications for Use below.

The Bio Arterial Deluxe Arterial Blood Flow Enhancement System is intended:
• For the improvement of blood circulation in the upper and lower extremities to help prevent and reduce complications of poor circulation
• For treatment of patients with intermittent claudication, rest pain, diabetic foot, ischemic neuritis, arterial ulcers, gangrene, poor runoff
• As an adjunct therapy for patients with ischemic disease of the lower extremities, due to one or more of the following causes: amputations (minor), angioplasty/stent failure, arteriopathic wounds, graft failure, intermittent claudication, ischemia, night pain, rest pain, small vessel disease, ulcers

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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Summary

Date Prepared: December 11, 2025

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	Bio Arterial Deluxe (IC-BAP-DX)
Trade/Proprietary Name	Bio Arterial Deluxe (IC-BAP-DX)
Common/Usual Name	IC-BAP-DX Bio Arterial Deluxe
Classification Name	Compressible Limb Sleeve (21 CFR 870.5800)
Product Code	JOW
Class	Class II

III. PREDICATE DEVICE

IC-BAP-DL Bio Arterial Plus Arterial Blood Flow Enhancement System (K131327).

Reference devices K024019, K072666, K131146, K210417, and K240499 are mentioned.

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IV. DEVICE DESCRIPTION

Bio Compression Systems' Bio Arterial Deluxe is a pneumatic compression device which consists of a pneumatic compression sleeve ("garment") connected to a pneumatic compression pump ("pump"). The pump cyclically inflates the garment's sections ("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 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.

The device uses the Predicate Device's garments.

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V. INDICATIONS FOR USE

	Subject Device	Predicate Device (K131327)	Comparison
Indications for Use	The Bio Arterial Deluxe Arterial Blood Flow Enhancement System is intended: • For the improvement of blood circulation in the upper and lower extremities to help prevent and reduce complications of poor circulation • For treatment of patients with intermittent claudication, rest pain, diabetic foot, ischemic neuritis, arterial ulcers, gangrene, poor runoff • As an adjunct therapy for patients with ischemic disease of the lower extremities, due to one or more of the following causes: amputations (minor), angioplasty/stent failure, arteriopathic wounds, graft failure, intermittent claudication, ischemia, night pain, rest pain, small vessel disease, ulcers	The Bio Arterial Plus Arterial Blood Flow Enhancement System is intended as an adjunct therapy for patients with ischemic disease of the lower extremities, due to one or more of the following causes: amputations (minor), angioplasty/stent failure, arteriopathic wounds, graft failure, intermittent claudication, ischemia, night pain, rest pain, small vessel disease, ulcers	Equivalent. The addition of the improvement of blood circulation in the upper and lower extremities to help prevent and reduce complications of poor circulation indication is not a new use; devices in the category with similar characteristics have been cleared for this indication (K024019). The addition of the treatment of patients with intermittent claudication, rest pain, diabetic foot, ischemic neuritis, arterial ulcers, gangrene, poor runoff indication is not a new use; devices in the category with similar characteristics have been cleared for these indications (K131146, K240499).

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	Subject Device	Predicate Device (K131327)	Comparison
Contra - indications	Use of this device is contraindicated for patients with any of the following conditions: • Open or freshly healed ulcers or other wounds or otherwise fragile skin in the arms, core or full leg region • Infections in the limb, including cellulitis, without appropriate antibiotic coverage • 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 • Undesirable venous and lymphatic return • Sepsis in the limb or limbs • Immediately following skin grafts in or around treatment sites • Pulmonary edema • Acute thrombophlebitis	Use of this device is contraindicated for patients with any of the following conditions: • Infections in the limb, including cellulitis, without appropriate antibiotic coverage • Suspicion or confirmation of the presence of Deep Vein Thrombosis (DVT) • Inflammatory phlebitis or episodes of pulmonary embolism • Congestive Heart Failure (CHF) • Undesirable venous and lymphatic return • Sepsis in the limb or limbs • Immediately following skin grafts in or around treatment sites • Pulmonary edema • Acute thrombophlebitis	Equivalent. Subject device adds open or freshly healed ulcers or other wounds or otherwise fragile skin in the core or full leg region.
Prescription/ over-the-counter use	Prescription	Prescription	Identical

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VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

	Subject Device	Predicate Device (K131327)	Comparison
Operating Principle	Same as Predicate	Same as Predicate	Identical
Power Supply Rating	120 VAC, 60 Hz	100-240V, 50/60 Hz	Equivalent
Electrical Classification	Class II	Class II	Identical
Applied Part	Type BF	Type BF	Identical
Ingress Protection	IP21	IP21	Identical
Cycle Time	20 seconds (compression 5 seconds, non-compression 15 seconds)	20 seconds (compression 5 seconds, non-compression 15 seconds)	Identical
Pressure Range	20-150 mmHg	20-150 mmHg	Identical
Pressure Accuracy	± 20%	± 20%	Identical
Software Safety Class (IEC 62304)	A	A	Identical
Weight	3.3 lbs. (1.5 kg)	7.5 lbs. (3.4 kg)	Similiar
Dimensions	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)	Similiar
Compression Sleeves (“Garments”)	Uses Predicate’s garments and adds arm garment	200 Denier Nylon Oxford, coated with 3 mil of Polyurethane	Identical or identical material covering an additional anatomic areas (arm). This is the same anatomic areas as other cleared devices in this category with similar technological characteristics and indications (K024019)
Features	• Adjustable Pressure • Compliance/Usage Meter • Pause • Timed Treatment	• Adjustable Pressure • Compliance/Usage Meter	Minor differences in features

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

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- 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 Subject Device has an additional garment model covering an additional anatomic area (arm). This is the same area as other cleared devices in this category with similar technological characteristics and the same indications (K024019).

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 and A2:2021
- ANSI/AAMI HA60601-1-11:2015-08 and A1:2021
- 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

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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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