August 31, 2026

Evolym, LLC
Alex Chang
Regulatory Consultant
1209 Orange St.
Wilmington, Delaware 19801

Re: K254217
Trade/Device Name: Aerloom
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: December 24, 2025
Received: December 29, 2025

Dear Alex Chang:

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,

Meaghan Erlewein -S

For 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.	K254217

Please provide the device trade name(s).

Aerloom

Please provide your Indications for Use below.

The Aerloom system is intended for use by medical professionals and patients who are under medical supervision, for the treatment of the following conditions:

- Chronic edema
- Lymphedema
- Venous insufficiency
- Wound healing

Please select the types of uses.	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

K254217

510(k) Summary

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

I. SUBMITTER:

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Establishment Registration: 33-4391469

CONTACT: Alex Chang
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DATE PREPARED: December 23 2025

II. DEVICE:

TRADE NAME: AERLOOM

CLASSIFICATION NAME: Compressible limb sleeve

DEVICE CLASSIFICATION: CLASS II

PRODUCT CODE: JOW

III. PREDICATE DEVICE:

Manufacturer: Tactile Systems Technology Inc.

Trade Name: entré, Model PD08-U
510(k): K143185

IV. DEVICE DESCRIPTION:

The Aerloom system consists of two primary components: a controller and a multi-chambered compression garment. The system delivers sequential pneumatic compression therapy to the affected limb to support the treatment of chronic edema, lymphedema, venous insufficiency, and wound healing.

The garment is worn over lightweight clothing or a liner to avoid direct skin contact and is wrapped securely around the treatment area. It contains independently controlled air chambers that inflate and deflate in a programmed sequence, applying graduated compression in the range of 20–80 mmHg.

The controller, which houses the compression logic and pump system, is compact, portable, and powered by a rechargeable lithium-ion battery, allowing for limited mobility and untethered use during treatment. Aerloom is designed to be easy to use and suitable for use in both clinical and home settings under medical supervision.

V: INDICATIONS FOR USE:

The Aerloom system is intended for use by medical professionals and patients who are under medical supervision, for the treatment of the following conditions:

- Chronic edema
- Lymphedema
- Venous insufficiency
- Wound healing

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE:

The Aerloom device and the predicate entré device are pneumatic compression devices that use the same fundamental technology, mode of action, and operating principles.

Feature	Subject Device (Aerloom)	Predicate Device (entré)
Indications for Use	The Aerloom system is intended for use by medical professionals and patients who are under medical supervision, for the treatment of the following conditions: • Chronic edema • Lymphedema • Venous insufficiency • Wound healing	The entré System is intended for use by medical professionals and patients who are under medical supervision, for the treatment of the following conditions: • Chronic edema • Lymphedema • Venous insufficiency • Wound healing
Product Type	Pneumatic Compression Device	Pneumatic Compression Device
Components	Controller Garments Hoses Power Adaptor	Controller Garments Hoses Power adapter
Mode of Action	Helps direct and move excess fluid from impaired lymphatic regions to healthier areas, where it can be naturally absorbed and processed by the body.	Helps direct and move excess fluid from impaired lymphatic regions to healthier areas, where it can be naturally absorbed and processed by the body.
Principles of Operation	The controller inflates the connected garment chambers in a pre-programmed sequence from distal to proximal, using a pressure gradient that delivers higher pressure distally. Each chamber is inflated in sequence and held at pressure, after which all chambers are deflated simultaneously.	The controller inflates the connected garment chambers in a pre-programmed sequence from distal to proximal, using a pressure gradient that delivers higher pressure distally. Each chamber is inflated in sequence and held at pressure, after which all chambers are deflated simultaneously.
Environment of Use	Hospital, clinical, and home settings	Hospital, clinical, and home settings
Expected Service Life	5 Years	5 Years
Controller unit size and weight	5.7” x 1.5” x 1.6” 0.75 lbs	11.0” x 6.0” x 8.0” 4 lbs
Electrical Requirements	Rechargeable Li-ion Battery Pack, with max 1.00-0.60 A input from 90-264 VAC	100-240 VAC 50/60 Hz to AC Adapter with output voltage of 12.0V DC and 3.0A

	50/60 Hz to AC Adapter, with output voltage of 5.0V DC and 5.0A	
Controller Enclosure Material	Plastic	Plastic
User Interface	Pushbuttons and a mobile application interface for use on a mobile device.	Pushbuttons
Wireless Functions	Bluetooth Low Energy (BLE)	None
Software / Hardware	Analog and digital electronic with microprocessor	Analog and digital electronic with microprocessor
Software Concern Level	Basic Documentation Level	Moderate Level of Concern
Device Total Pressure Range	20-80 mmHg	20-80 mmHg
Output	Sequential calibrated gradient Pressure	Sequential calibrated gradient Pressure
Treatment Time	1 hour maximum	1 hour maximum
Garment-Controller Connection	Hose attached to garments	Hose attached to garments
Garment Port	Plastic push to connect	Plastic push to connect
Garment Material	Nylon and polyester fabric Polyurethane coated polyester and nylon fabric	Nylon and polyester fabric Polyurethane coated polyester and nylon fabric
Garment Chambers	7	8
Device Cleanability	Can be cleaned using commonly available mild household cleaners and disinfectants.	Can be cleaned using commonly available mild household cleaners and disinfectants.

Technological differences from the predicate device, include:

- Bluetooth connectivity for optional use with a mobile application.
- An internal battery to support portability.
- A smaller controller to support portability.

These differences do not raise new questions of safety or effectiveness for the Aerloom system compared to the predicate device.

VII. PERFORMANCE DATA:

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

Biocompatibility Testing
The Aerloom device can be supplied with either upper or lower garments that are applied over the provided circular-knit liners. These liners are biocompatible and have been tested in accordance with ISO 10993-1, ISO 10993-5, and ISO 10993-10. All patient-contacting materials are compliant with applicable biocompatibility safety standards.

Sterilization & Shelf-life Testing
The subject device is non-sterile, and components are unlikely to deteriorate with age.

Electrical Safety and Electromagnetic Compatibility (EMC)
The subject device was evaluated based on the following applicable performance and safety standards: o ANSI/AAMI ES 60601-1:2005/(R) 2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) [Including Amendment 2 (2021)], IEC 60601-1-11:2015, EN 60601-1-2:2015/A1:2021, BS EN 60601-1-2:2015+A1:2021, and IEC 60601-1-2:2014/AMD1:2020. Results demonstrated that the subject device was compliant to all applicable performance and safety standards.

Software Verification and Validation Testing
The subject device includes embedded firmware in the controller which has the ability to connect with custom software installed on a mobile device. The system software exhibits a moderate level of concern and because there is no risk of death or serious injury, this corresponds to the Basic recommended documentation level.

Software lifecycle planning and documentation as well verification and validation testing were performed in accordance with IEC 62304:2015 and as recommended by the following FDA Guidance documents for Industry and FDA Staff:

- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices
- Guidance for Industry, FDA Reviewers and Compliance on Off-The-Shelf Software Use in Medical Devices
- Guidance for Industry and Food and Drug Administration Staff Content of Premarket Submissions for Management of Cybersecurity in Medical Devices
- Guidance for Industry, FDA Reviewers and Compliance on Postmarket Management of Cybersecurity in Medical Devices

Mechanical Testing

The subject device was evaluated based on the following benchtop performance tests.

Performance Study	Overview	Status
Packaging Transportation Simulation	ASTM D4169-23e1	Completed / Pass
Pressure Verification Testing	Pressure capable of delivering 20-80 mmHg compression pressures.	Completed / Pass

Animal Study
Animal performance testing was not required to demonstrate safety and effectiveness of the Aerloom system.

Clinical Study
Clinical testing was not required to demonstrate the safety and effectiveness of the Aerloom system.

VIII. CONCLUSION:
The data included in this submission demonstrates that the Aerloom system is substantially equivalent to the primary predicate device, entré (K143185).