August 18, 2025

BioTAB, LLC
% Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive, Suite 510k
Saint Paul, Minnesota 55114

Re: K251086
Trade/Device Name: PnueAira (PNCU-01)
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible limb sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: July 8, 2025
Received: July 8, 2025

Dear Prithul Bom:

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K251086

Device Name
PnueAira (PNCU-01)

Indications for Use *(Describe)*
The PnueAira device and garments for legs and core are intended for use by medical professionals and patients who are under medical supervision to increase lymphatic flow in the treatment of many conditions such as:

- Lymphedema
- Primary lymphedema
- Post mastectomy edema
- Edema following trauma and sports issues
- Post immobilization edema
- Venous insufficiency
- Reducing wound healing time
- Treatment and assistance in healing stasis dermatitis, venous stasis ulcers, arterial ulcers, and diabetic leg ulcers
- Lipedema

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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PnueAira 510(k) Summary
K251086

510(k) SUMMARY

DATE PREPARED
August 11, 2025

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DEVICE INFORMATION
Proprietary Name/Trade Name: PnueAira (PNCU-01)
Common Name: Compressible Limb Sleeve
Regulation Number: 21 CFR 870.5800
Class: II
Product Code: JOW
Premarket Review: Office of Cardiovascular Devices (OHT2), Division of Circulatory Support, Structural and Vascular Devices (DHT2B)
Review Panel: Cardiovascular

PREDICATE DEVICE IDENTIFICATION
The PnueAira device is substantially equivalent to the following predicates:

510(k) Number	***Predicate Device Name / Manufacturer***	***Primary Predicate***	***Reference Device***
K223195	AIROS 6P Sequential Compression Device, Airos Medical, Inc.	X	
K182003	Lympha Press Optimal Plus, Mego Afek AC Ltd.		X

DEVICE DESCRIPTION

The PnueAira (PNCU-01) is a pneumatic compression device that uses air to systematically compress a patient's limbs affected by lymphedema and/or similar conditions. The control unit is placed on a table near the user and plugged into a power outlet. The patient wears the desired garment (i.e., core or full leg) and attaches it to the control unit via the connectors located on the garment. The patient uses the control unit to select the appropriate prescribed treatment profile, as shown on the device display, to begin their therapy profile. The device supports Peristaltic (i.e., a chamber is inflated and deflated before moving to the next chamber in a particular sequence) and Non-Peristaltic, sometimes known as sequential (i.e., all chambers are inflated in order, then all chambers are deflated simultaneously) compression modes.

The PnueAira device is designed for at-home treatment of lower extremity lymphedema. It assists in reducing lymphedema-related swelling by directing excess fluid from an impaired lymphatic area to healthier parts of the body.

The PnueAira system consists of the following components:

- Control unit
- Power Adapter
- Garments - Core and Full-leg
- Y-Connector Accessory.

INDICATIONS FOR USE

The PnueAira device and garments for legs and core are intended for use by medical professionals and patients who are under medical supervision to increase lymphatic flow in the treatment of many conditions such as:

- Lymphedema
- Primary lymphedema
- Post mastectomy edema
- Edema following trauma and sports issues
- Post immobilization edema
- Venous insufficiency
- Reducing wound healing time
- Treatment and assistance in healing stasis dermatitis, venous stasis ulcers, arterial ulcers, and diabetic leg ulcers
- Lipedema.

CONTRAINDICATIONS

The device should not be used if you have one or more of the following conditions:

- Heart failure (acute pulmonary edema, decompensated acute heart failure)
- Acute venous disease
- Acute thrombophlebitis
- Deep venous thrombosis

- Pulmonary embolism
- Severe peripheral artery disease (critical limb ischemia, including ischemic rest pain, arterial wounds, or gangrene)
- Active skin or limb infection/inflammatory disease (acute cellulitis, other uncontrolled skin, or untreated inflammatory skin disease)
- Any circumstance where increased lymphatic or venous return is undesirable. The PnueAira trunk accessory should not be used during pregnancy.
- The biocompatibility of PnueAira garments has only been evaluated for contact with intact skin and should not be used with an open wound. Wounds should be appropriately covered with an FDA-cleared dressing before the garment is applied for wound healing therapy in order to avoid any garment contact with the wound.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

BioTAB, LLC believes that the PnueAira device is substantially equivalent to the predicate devices (K223195 and K182003) based on the information summarized here:

The PnueAira device has the same intended use as the predicate devices cleared in K223195 and K182003, i.e., a device intended for use by medical professionals and patients who are under medical supervision to increase lymphatic flow in the treatment of conditions such as Lymphedema, Post-immobilization edema, Venous insufficiency, etc. This information is summarized in the following table. When comparing the PnueAira device to the predicate device (K223195), they have the same technological characteristics. The two devices include a controller (with firmware) and garments to provide therapy for specific body parts. Both use an electronic controller with firmware to systematically control the pressure chambers within the garments used by the patient for therapy delivery. The materials utilized for the electronic controller and the garments are similar. The devices are used and operated in an identical manner with similar pressure profiles. The minor differences in design specifications do not present new or modified risks, and therefore, they do not raise different questions of safety and effectiveness.

Trade/Device Name	**Subject Device: PnueAira**	**Primary Predicate: AIROS 6P Sequential Compression Device**	**Reference Device: Lympha Press Optimal Plus**
Manufacturer	BioTAB, LLC	AIROS Medical, Inc	Mego Afek AC Ltd.
510(k) Number	Proposed Device	K223195	K182003
Regulation Number	21 CFR 870.5800	21 CFR 870.5800	21 CFR 870.5800
Regulation Name	Compressible Limb Sleeve	Compressible Limb Sleeve	Compressible Limb Sleeve
Regulatory Class	Class II	Class II	Class II
Product Code	JOW	JOW	JOW
Indications for Use	*The PNUEAIRA device and garments for legs*	*The AIROS 6P Sequential Compression Device*	*The device is intended for use by medical*

Trade/Device Name	Subject Device: PnueAira	Primary Predicate: AIROS 6P Sequential Compression Device	Reference Device: Lympha Press Optimal Plus
	and core are intended for use by medical professionals and patients who are under medical supervision to increase lymphatic flow in the treatment of many conditions such as: • *Lymphedema* • *Primary lymphedema* • *Post mastectomy edema* • *Edema following trauma and sports issues* • *Post immobilization edema* • *Venous insufficiency* • *Reducing wound healing time* • *Treatment and assistance in healing stasis dermatitis, venous stasis ulcers, arterial ulcers, and diabetic leg ulcers* • *Lipedema*	*utilizes gradient pneumatic compression, which is intended for treatment of patients with the following conditions:* *- Lymphedema* *- Venous stasis ulcers* *- Venous insufficiency* *- Peripheral edema* *The device is safe for both home and hospital use.*	*professionals and patients who are under medical supervision in treating many conditions such as:* *-Primary lymphedema* *-Secondary lymphedema* *-Venous insufficiency* *-Venous stasis ulcers* *-Dysfunction of the muscle pump* *-Post-mastectomy edema* *-Edema following trauma and sports issues* *-Post-immobilization edema* *-Reducing wound healing time* *-Reduction of pain and swelling after injury and surgery* *-The device may also be beneficial in the management of Lipoedema.* *The device is intended for hospital, home, and clinic use.*
Contraindications	*The PnueAira device should not be used if you have one or more of the following conditions:* • *Heart failure (acute pulmonary edema, decompensated acute heart failure)* • *Acute venous disease*	*Pneumatic compression IS NOT recommended for use in patients with the following conditions:* *• Known or suspected Deep Vein Thrombosis (DVT) or pulmonary embolism* *• Infections in the limb, including cellulitis*	*Use of Lympha Press is not recommended in the presence of one or more of the following conditions:* *-Known or suspected Deep vein thrombosis (DVT) or pulmonary embolus* *-During the inflammatory phlebitis process* *-Acute infection of the*

Trade/Device Name	Subject Device: PnueAira	Primary Predicate: AIROS 6P Sequential Compression Device	Reference Device: Lympha Press Optimal Plus
	• *Acute thrombophlebitis* • *Deep venous thrombosis* • *Pulmonary embolism* • *Severe peripheral artery disease (critical limb ischemia, including ischemic rest pain, arterial wounds, or gangrene)* • *Active skin or limb infection/inflammatory disease (acute cellulitis, other uncontrolled skin, or untreated inflammatory skin disease)* • *Any circumstance where increased lymphatic or venous return is undesirable.* • *The biocompatibility of PnueAira garments has only been evaluated for contact with intact skin and should not be used with an open wound. Wounds should be appropriately covered with an FDA-cleared dressing before the garment is applied for wound healing therapy in order to*	*• Presence of lymphangiosarcoma* *• Inflammatory phlebitis* *• Congestive Heart Failure (CHF)* *• Any local conditions in which garments would interfere, including: Untreated wounds, infected wounds, gangrene, recent skin graft, or dermatitis*	*affected limb* *-Decompensated cardiac failure* *-Severe arteriosclerosis or other ischemic vascular disease* *-Any circumstance where increased venous and lymphatic return is undesirable* *-Due to movement of fluids in the body when using the system, exercise caution when using on patients with heart disease.* *-High pressure is not recommended for patients who have peripheral occlusion disease. The abdominal area should not be treated during pregnancy.*

Trade/Device Name	Subject Device: PnueAira	Primary Predicate: AIROS 6P Sequential Compression Device	Reference Device: Lympha Press Optimal Plus
	avoid any garment contact with the wound.		
Target Population	Patients 18 years and older	Patients 18 years and older	Patients 18 years and older
Use Environment	At-home and healthcare facilities	At-home and healthcare facilities	At-home and healthcare facilities
Electrical Requirements	100 - 240VAC, 50/60Hz	100 - 240VAC, 50/60Hz	100 - 240VAC, 50/60Hz
Enclosure Material	All plastic construction	All plastic construction	All plastic construction
Manifold Assembly	Plastic construction with integrated air channel	Plastic construction with integrated air channel	Plastic construction with integrated air channel
User Interface	Mechanical rotary knobs and buttons	Tactile Pushbuttons	Tactile Pushbuttons
Chambers	Up to 32, depending on garment size and type	Up to 12, depending on garment size and type	Up to 24, depending on garment size and type
Output Mode(s)	Peristaltic and Sequential gradient pressure	Peristaltic and Sequential	Sequential gradient pressure
Garment Chamber Pressure Control	Pressure Based Control	Pressure Based Control	Pressure Based Control
Treatment Time	30, 34, 60, and 90 minutes	15, 30, 45, or 60 minutes	Not Available
Pressure Range	0 - 80 mmHg (Core garment is limited to 50 mmHg)	Not Available	20-80 mmHg
Pressure Accuracy	±5 mmHg	Not Available	Not Available
Performance Testing (Standards)	• Electrical Safety: IEC 60601-1:2005/ AMD2:2020 • Usability: IEC 60601-6:2010/ AMD2:2020 • Home Use: IEC 60601-1-11:2015/ AMD1:2020 • EMC: IEC 60601-1-2:2014/ AMD1:2020 • FCC: 47 CFR FCC	• Electrical Safety: IEC 60601-1:2005/ AMD2:2020 • Usability: IEC 60601-6:2010/ AMD2:2020 • Home Use: IEC 60601-1-11:2015/ AMD1:2020 • ISO 14971:2019 Medical Devices – Application of Risk Management to	Not Available

Trade/Device Name	Subject Device: PnueAira	Primary Predicate: AIROS 6P Sequential Compression Device	Reference Device: Lympha Press Optimal Plus
	Part 15 Subpart B • Biocompatibility: ISO 10993-1:2018 (Cytotoxicity, Sensitization, and Irritation) • Transportation Shipping: ASTM D4169 • Firmware Testing: IEC 62304:2006 + A1:2015	Medical Devices • Biocompatibility: ISO 10993-1 (Cytotoxicity, Sensitization, and Irritation) • Transportation Shipping: ISTA 3A	

SUMMARY OF NON-CLINICAL TESTING

Electrical safety and EMC testing were performed to demonstrate conformity to IEC 60601-1 and IEC 60601-1-2 standards. The PnueAira device is categorized as a surface device with a prolonged contact duration with intact skin. All intact skin contacting materials used in the PnueAira device are listed in Section B of Annex G of the FDA Guidance Document Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process".

Functional Performance Testing

Testing was performed to ensure that the system meets its design specifications. The functional performance testing includes the following tests:

- Pressure Profile and Overpressure Testing
- Treatment Duration Testing
- Mechanical Connections and Integrity Testing
- Display and User Interface Testing
- Therapy Time Accuracy
- Garment Design and Garment Pressure Integrity Testing
- Data Integrity USB-C Security Testing
- Device Longevity Testing

Other tests completed, such as transportation and shipping (ASTM D1469), demonstrate that design outputs meet user needs and design inputs.

Firmware verification and validation testing were performed per IEC 62304:2015, and therefore, the methods are acceptable.

CONCLUSION

Based on the verification and validation testing performed in accordance with various recognized standards and bench testing, it can be concluded that the subject device does not raise new issues of safety or effectiveness compared to the predicate devices. The similar indications for use, technological characteristics, and performance characteristics for the proposed PnueAira device are demonstrated to be substantially equivalent to the primary predicate device.