December 9, 2022

AIROS Medical, Inc
Darren Behuniak
Vice President, Operations and Marketing
2501 Monroe Blvd. Suite 1200
Audubon, Pennsylvania 19403

Re: K223193
Trade/Device Name: AIROS 8P Sequential Compression Device
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: October 12, 2022
Received: October 13, 2022

Dear Darren Behuniak:

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,

Eric E. Richardson -S 2022.12.09 16:00:05 -05'00'

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

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)*
K223193

Device Name
AIROS 8P Sequential Compression Device

Indications for Use *(Describe)*
The AIROS 8P Sequential Compression Device 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.

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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510(k) Summary
October 12, 2022

Submitter:
AIROS Medical, Inc.
2501 Monroe Blvd, Suite 1200
Audubon, PA 19403

Contact Person:
Darren Behuniak, VP Operations & Marketing
Email: dbehuniak@airosmedical.com
Phone: 866-991-6956

Common Classification & Proprietary Names
Trade Name: AIROS 8P Sequential Compression Device
Common Name: Sequential Compression Device

Classification

Classification Name	21 CFR Regulation	Product Code	Class
Compressible Limb Sleeve	870.5800	JOW	II

Primary Predicate Device and Reference Device
The AIROS 8P Sequential Compression Device is substantially equivalent to the primary predicate, AIROS 8 Sequential Device, and the reference device, Mego Afek Lympha Press Optimal.

	Primary Predicate AIROS 8 Sequential Compression Device	Reference Device Mego Afek Lympha Press Optimal
510(k)	K193068	K182003
21 CFR Regulation Number	870.5800	870.5800
Product Code	JOW	JOW
Classification	II	II

Device Description
AIROS 8P Sequential Compression Device is a pneumatic compression device used for treatment and management of venous or lymphatic disorders. The application of compression is effective by increasing blood flow and encouraging extracellular fluid clearance. The device consists of the mechanical device that is used to set the treatment options and supplies cycles of air to the compression garments. There are three primary treatment modes, Gradient Mode, Pressure Mode, and Peristaltic Mode. The air is supplied at adjustable pressures and sequences and inflates the compression garments from the distal to proximal areas of the body. The

compression garments are supplied in various sizes for the upper and lower extremity areas of the body.

Indication for Use

The AIROS 8P Sequential Compression Device 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.

Technological Characteristics

The manufacturer believes that the technological characteristics of the AIROS 8P are substantially equivalent to those of the primary predicate device and reference device. The AIROS 8P has similar components to its primary predicate and reference devices and has similar operating principles to the primary predicate and reference devices. The digitally controlled device consists of an electrically generated source of compressed air, tubing to convey the pressurized air to the sleeve, and like the primary predicate and reference devices, pressure is applied cyclically for a specified period of time, according to the physician's prescription. Three primary operating modes, Gradient, Pressure, and Peristaltic are available to the user and multiple size garments are available for the upper extremities, lower extremities, and trunk of the body. The AIROS 8P is identical to the AIROS 8 except for minor component changes that do not affect safety and efficacy of the device and the addition of new models of compression garments. The addition of the Peristaltic Mode is substantially equivalent to the reference device, the Mego Afek Lympha Press Optimal.

Functional Performance Testing

Testing was performed and to ensure that the system meets its specifications. The manufacturer believes that the technological characteristics of the AIROS 8P are substantially equivalent to those of the primary predicate and reference devices. The functional performance testing includes the following tests:

- Error Indicator Testing
- Noise Testing
- Cycle Time Accuracy
- Pressure Time Accuracy
- Therapeutic Performance
- Therapy Time Accuracy
- Garment Integrity

Standards

- ISO 14971:2019 Medical Devices – Application of Risk Management to Medical Devices
- ISTA 3A:2018 Packaged - Products for Parcel Delivery System Shipment
- ES 60601-1: 2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 - Medical electrical equipment- Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2: 2014 + AMD1:2020 CSV - Medical electrical equipment- Part 1-2: General requirements for basic safety and essential performance- Collateral Standard: Electromagnetic disturbances- Requirements and tests
- IEC 61000-3-2: 2018 A1: 2020 EMC – Part 3-2: Limits – Limits for harmonic current emissions (Equipment input current 16A per phase)
- IEC 61000-3-3: 2013 A1: 2017 EMC – Part 3-3: Limits – Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems for equipment with rated current ≤ 16 A per phase and not subject to conditional connections
- IEC 60601-1-6: 2010/AMD1: 2013 Medical electrical equipment- Part 1-6: General requirements for basic safety and essential performance- Collateral Standard: Usability
- IEC 60601-1-11: 2015 - Medical electrical equipment- Part 1-11: General requirements for basic safety and essential performance- Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

Statement of Substantial Equivalence

The AIROS 8P is substantially equivalent in technology, function, operating parameters, and indications to the AIROS 8 primary predicate device and the Lympha Press Optimal reference device. There are no new risks introduced with the AIROS 8P.

Conclusion

In accordance with the Federal Food, Drug and Cosmetic Act and 21 CFR Part 807, and based on the information provided in this pre-market notification, AIROS Medical, Inc., believes that the AIROS 8P is substantially equivalent to the primary predicate device and the reference device.