December 4, 2019

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

Re: K193068
Trade/Device Name: AIROS 8 Sequential Compression Device
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible limb sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: November 1, 2019
Received: November 4, 2019

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,

Fernando Aguel
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K193068

Device Name
AIROS 8 Sequential Compression Device

Indications for Use *(Describe)*

The AIROS 8 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.

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

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510(k) SUMMARY

November 1, 2019

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 8 Sequential Compression Device
Common Names: Sequential Compression Device

Classification
The classification name, 21 CFR Part and Paragraph number, product code and classification of the AIROS 8 Sequential Compression Device.

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

Predicate Device:
The AIROS 8 Sequential Compression Device is substantially equivalent to the following.

Predicate Device	Manufacturer	510(k)#
AIROS 8 Sequential Compression Device	AIROS Medical, Inc.	K172779

Device Description
The AIROS 8 Sequential Compression Device is a gradient pneumatic compression device. The device is used for treatment and management of venous or lymphatic disorders. The application of gradient sequential compression increases blood flow and encourages extracellular fluid clearance.

The AIROS 8 system consists of the device and 8-chambered garments. The device provides cycles of compressed air and sequentially inflates the garments from distal to proximal.

Intended Use:
The AIROS 8 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 8 are substantially similar to those of the predicate device.

The AIROS 8 has similar components to its predicate device and has similar operating principles. 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 predicate, pressure is applied cyclically for a specified period of time, according to the physician's prescription.

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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 8 are substantially equivalent to those of the predicate device. The functional performance testing includes the following tests:

Test Description
Alarm Testing
LED/LCD Testing
Cycle Time Testing
Pressure Accuracy Testing
Therapy Time Testing
Therapeutic Performance Testing
Garment Integrity Testing
Pull Testing
Garment Printing Testing

Standards

The AIROS 8 conforms to the following standards:

- ISO 14971:2007 Medical Devices – Application of Risk Management to Medical Devices
- ISO 10993-5 Biological evaluation of medical devices - Part 1: Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10 Biological evaluation of medical devices -Part 10:Tests for irritation and delayed-type hypersensitivity

Statement of Substantial Equivalence

The AIROS 8 is substantially equivalent in technology, function, operating parameters, and indicated use to the predicate device that is currently commercially available and in distribution. The system does not raise any new risks when compared to the predicate product.

Conclusions

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 8 is substantially equivalent to the predicate device.

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