October 11, 2024

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

Re: K240499
Trade/Device Name: ARTAIRA Arterial Compression Device (AACD01)
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: September 16, 2024
Received: September 17, 2024

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 (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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K240499

Device Name
ARTAIRA Arterial Compression Device

Indications for Use *(Describe)*
The ARTAIRA Arterial Compression Device's is an intermittent pneumatic compression device intended for treatment of patients with the following conditions:
• Intermittent claudication
• Rest pain
• Diabetic Foot
• Ischemic neuritis
• Arterial ulcers
• Gangrene
• Poor runoff.

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
September 9, 2024

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: ARTAIRA Arterial Compression Device

Classification

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

Predicate Device
The ARTAIRA Arterial Compression Device is substantially equivalent to the predicate device, the ArtAssist Device.

	Predicate ArtAssist Device
510(k)	K131146
21 CFR Regulation Number	870.5800
Product Code	JOW
Classification	II

Device Description
The AIROS ARTAIRA Arterial Compression Device is an intermittent pneumatic compression device intended to increase blood flow and increase circulation in the lower extremities by providing timed compression to the foot/ankle and calf. The device consists of a hard casing with an air pump, a set of air valves, an air reservoir controlled by the device software to deliver a rapid burst of pneumatic pressure to the treatment area. The device connects through air tubing to a pair of compression garments (left and right leg), each with two air chambers: one on the underfoot (Foot/Ankle chamber) and one on the calf area (Calf Chamber). The device can either be used with one garment or two garments. The system is intended to be used primarily at home settings according to a physician-prescribed therapy.

Indication for Use

The ARTAIRA Arterial Compression Device is an intermittent pneumatic compression device intended for treatment of patients with the following conditions:

- Intermittent claudication
- Rest pain
- Diabetic Foot
- Ischemic neuritis
- Arterial ulcers
- Gangrene
- Poor runoff.

Technological Characteristics

The manufacturer believes that the technological characteristics of the ARTAIRA are substantially equivalent to those of the predicate device. The ARTAIRA has the same pressure setting, as well as the same compression and non-compression timing sequences. Both devices are used with associated compression garments that feature air chambers in both the foot/ankle area and the underfoot. The garments can be used on one limb or two and the material is biocompatible. The device and grarment system provides cyclical air compression sequences intended to increase blood flow to the lower extremities.

The ARTAIRA also features a large color LCD screen that can be easily viewed by the user. The LCD screen displays pressure as well as a countdown timer so the user knows how much therapy time is left in the treatment session. Additional device features include LED lights to indicate device states and multiple error indicators that are triggered in the event of an error with the device.

Functional Performance Testing

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

- User Interface & Error Indicator Testing
- Noise Testing
- Compression Sequence Timing Accuracy Testing
- Pressure Accuracy Testing
- Therapy Time Accuracy Testing
- Garment Integrity Testing
- Air Leakage Testing

Standards

- ISO 14971:2019 Medical Devices – Application of Risk Management to Medical Devices
- ISO 10993-1 2018 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
- 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 ARTAIRA is substantially equivalent in technology, function, operating parameters, and indications to the ArtAssist predicate device There are no new risks introduced with the ARTAIRA.

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 ARTAIRA is substantially equivalent to the predicate device.