April 3, 2020

Inova Labs
% Rafael Aguila
Responsible Third-Party Official
Accelerated Device Approval Services, LLC
6800 S.W. 40th Street, Ste. 444
Ludlum, Florida 33155-3708

Re: K200564
Trade/Device Name: Aria System
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible limb sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: March 3, 2020
Received: March 4, 2020

Dear Rafael Aguila:

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)*
K200564

Device Name

Aria™ System

Indications for Use *(Describe)*

The Aria sequential circulator is a programmable sequential, pneumatic compression device intended for use by medical professionals and patients at home, for the treatment of the following conditions:

- Chronic edema
- Lymphedema
- Venous insufficiency
- Wound healing

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
Inova Labs Aria System

Date Prepared	April 3, 2020
Submitter	Inova Labs 7581 Convoy Court, San Diego CA 92111
Official Contact	Reuben Lawson Regulatory Affairs Consultant reuben.lawson@gmail.com
Product Codes	JOW
Class	Class II
Classification Reference	21 CFR 870.5800
Common/Usual Name	Sleeve, Limb, Compressible
Proprietary Name	Aria
Predicate Device(s)	Tactile Systems Technology Inc, Entre Model PD08-U (K143185)
Reason for submission	New Device

Indication for Use
The Aria sequential circulator is a programmable sequential, pneumatic compression device intended for use by medical professionals and patients at home, for the treatment of the following conditions:
• Chronic edema
• Lymphedema
• Venous insufficiency
• Wound healing

Device Description
The Aria system consists of two main components: A flow generator and a garment. The garment is to be wrapped around the limb, providing a comfortable fit. The garment has seven (7) chambers that are filled with air by the flow generator to provide compression on the extremity. The Aria system uses a compress-and-release massage action, similar to the predicate, in order to stimulate lymphatic vessels in the treated area and encourage fluid clearance.

The Aria system retains similar hardware and performance features of the predicate device. Key features include flow generator, valves, A/C plug pack, lower limb garment, tubing, no-LCD User Interface and ON/OFF button. The Aria System contains a microprocessor-controlled flow generator/blower system that generates pressure from 0-45 mmHG to provide for effective treatment of the conditions described in the IFU.

The Aria flow generator has no control settings and delivers one pre-programmed therapy mode.

Characteristics between predicate and new device

Characteristic	Predicate Device Entre Model PD08-U (K143185)	New device: Aria System
Indication for use	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	The Aria sequential circulator is a programmable sequential, pneumatic compression device intended for use by medical professionals and patients at home, for the treatment of the following conditions: • Chronic edema • Lymphedema • Venous insufficiency • Wound healing
Pressure range	0-45 mmHG (at 'moderate' setting)	0-45 mmHG
Cycle Time	65 seconds	56 seconds
Total Therapy Time	Approx. 60 minutes	Approx. 60 minutes
Modes of operation	Sequential gradient compression therapy	Sequential gradient compression therapy
System Components	• Flow generator • Valves • Tubing • Garment	• Flow generator • Valves • Tubing • Garment
Flow Generator operating system	Microcontroller	Microcontroller
Garment Air Chambers	8	7

Characteristic	Predicate Device Entre Model PD08-U (K143185)	New device Aria System
Tubing	Entre Tubing (2m length)	Aria tubing (1.8m length)
User Interface	On/Off Button Pressure Low/Med/High Button Start Therapy/Pause	On/Off (Start/Stop Therapy) Button
Connectivity	None	Bluetooth classic to allow export of system data to a paired app.
Motor type	Compressor	Brush-less low voltage DC
Power supply	100-240V, 50-60Hz	100-240V, 50-60Hz
Weight	2.5lb	0.65lb
Dimensions H x W x D (inches)	11 x 6 x 8	Flow generator unit: 2 x 3.3 x 5.3
IEC 60601-1 (electrical safety)	Yes	Yes
IEC 60601-1-2 (EMC)	Yes	Yes
IEC 60601-1-6 (Usability)	Yes	Yes
IEC 60601-1-11 (Home medical)	Yes	Yes
ISO 10993-1	Not referenced in 510(k) summary	Yes

Substantial Equivalence
The new device has the following similarities to the previously cleared predicate devices.

- Same intended use
- Similar operating principle
- Similar technology

As a result of the Risk Analysis review and design input requirements, non-clinical verification activities were performed on the Aria System. The results demonstrate that the Aria system raises no new safety or effectiveness concerns and is substantially equivalent to the predicate device. The Aria System complies with the applicable requirements referenced in the FDA guidance documents:

- FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 11, 2005)
- FDA Guidance for Industry and FDA Staff - Design Considerations for Devices Intended for Home Use- Document Issued on: Nov 24, 2014
- FDA Guidance for Industry and FDA Staff - Radio Frequency Wireless Technology in Medical Devices - Document Issued on: August 14, 2013

Non-Clinical Testing:
Side-by-Side bench testing was performed to verify that the Aria System met the requirements of the Aria System Specification when compared to the predicate device.

The bench testing included performance comparisons to the predicate device and covered:

- Pressure stability
- Sleeve burst test
- Sleeve leakage test
- Sleeve integrity test
- Pressure accuracy test
- Chamber filling cycle time testing
- Total therapy time

The Aria system has been tested to appropriate standards and other applicable requirements:

- IEC 60601-1:2005 A1:2015 Ed. 3.1, Medical electrical equipment - Part 1: General requirements for safety Medical electrical equipment – General requirements for basic safety and essential performance
- IEC 60601-1-2:2013 Ed. 4.0 Medical Electrical Equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 60601-1-11:2015 Ed 2.0 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.
- FDA guidance on software development for medical devices
- ISO 10993-1 Biological evaluation of medical devices
- IEC 60601-1-6 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

Clinical Testing:
As with the predicate system, clinical testing was not conducted for Aria system. The technology used in JOW devices is well known and understood. Bench testing, as well as testing against recognized consensus standards, is sufficient to demonstrate no new risk.

Conclusion
The Aria System is substantially equivalent the predicate device Entre PD08-U (K143185) and is as safe and as effective as the predicate device.