September 7, 2023

Sun Scientific Inc
Allan Alward
Vice President Regulatory
145 Palisade Street
Ste: LL11
Dobbs Ferry, New York 10522

Re: K222823
Trade/Device Name: AeroDVx™ Arm System
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: August 7, 2023
Received: August 8, 2023

Dear Allan Alward:

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

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)*

k222823

Device Name

AeroDVx™ Arm System

Indications for Use *(Describe)*

The AeroDVx™ Arm System is comprised of a gradient compression sleeve, portable intermittent pneumatic pump and hand pump designed to provide static or intermittent pneumatic compression to the bicep and forearm, in both a clinical and outpatient setting. It is intended to provide treatment for:

- Enhancement of blood circulation
- Reduction of post-operative pain and swelling
- Reduction of edema
- Lymphedema
- Post immobilization edema
- Post mastectomy edema
- Edema following trauma and sports injuries
- Reducing wound healing time
- Lipedema

The AeroDVx Arm system is designed as a wearable compression system, designed to provide mobility for patients

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.

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510(k) Summary

(As Required by 21 CFR 807.92)

1. **Date Prepared [21 CFR 807.92(a)(1)]**

   September 6, 2023

2. **Submitter's Information [21 CFR 807.92(a)(1)]**

Company Name: Sun Scientific Inc.
Company Address: 145 Palisade Street STE: LL11
Dobbs Ferry, New York 10522
Registration# 3008773774
Contact Person: Allan Alward
Phone: 914.479.5108
Email: aalward@sun-scientific.com
Submission Correspondent: Allan Alward
Email: aalward@sun-scientific.com
Tel: 914.479.5108

3. **Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]**

Trade Name: AeroDVx ™ Arm System
Classification Name: Sleeve, limb, compressible, pump, intermittent, portable
Common Name: Compression sleeve, compressible limb sleeve, portable intermittent pneumatic pump
Product Code: JOW
Regulation Number: 21 CFR 870.5800
Device Class: II
FDA 510 (k) #: K222823

4. **Identification of Predicate Devices(s) [21 CFR 807.92(a)(3)]**

Primary predicate device
Manufacturer: Koya Medical, Inc.
Trade Name: Dayspring system
FDA 510 (k) #: K210885
Common Name: compressible limb sleeve
Product Code: JOW
Classification Name: Sleeve, limb, compressible
Regulation Number: 21 CFR 870.5800
Classification: Class II

Reference device

Manufacturer:	Sun Scientific
Trade Name:	AeroDVx System
FDA 510 (k) #:	K183349
Common Name:	compressible limb sleeve
Product Code:	JOW
Classification Name:	Sleeve, limb, compressible
Regulation Number:	21 CFR 870.5800
Classification:	Class II

5. Description of the Device [21 CFR 807.92(a)(4)]

The AeroDVx ™ Arm System is comprised of a compression sleeve, electronic intermittent pneumatic pump for intermittent pneumatic compression therapy or DVT Prophylaxis. The AeroDVx™ Arm compression sleeves are composed of a family of non-sterile single patient use medical devices. The AeroDVx ™ Arm compression sleeves contain a single bladder with a built-in gradient profile and inelastic Velcro straps to affix it to the patient's arm. The AeroDVx ™ Compression Sleeve for the Arms are available in three sizes, small, medium and large. The sleeves are composed of two polyurethane laminates that are sealed together creating an internal bladder system. The Arm Sleeves were developed on a technology platform that allows the sleeves to be wearable, which is designed to provide mobility for patients during use. The bladder system contains circular and bar welds that were engineered with their spacing and location to provide a gradient compression profile when worn and inflated. An inflation source is attached to the inflation valve on the sleeve. The insertion of the inflation source into the check valve, opens the luer valve so that the bladder can be inflated or deflated based on the direction of airflow. There is an inflation source provided: a portable, battery-operated intermittent pneumatic pump, the AeroDVx™ Pump (cleared under k183349), to provide intermittent pneumatic compression and a hand pump for static inflation. The system is intended for clinical and outpatient use. The AeroDVx Arm system is developed on a wearable compression technology platform, which is designed to provide mobility for patients.

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Device Characteristic	Proposed Device	Koya Medical, Inc. Primary Predicate Device (K210885)	Reference Device (K183349)	Comparison
Product Name	AeroDVx System Arm	Dayspring	AeroDVx System Legs	N/A
Classification	II	II	II	SE
Regulation Number	21 CFR 870.5800	21 CFR 870.5800	21 CFR 870.5800	SE
Product Code	JOW	JOW	JOW	SE
Intended Use	The AeroDVx™ Arm System is comprised of a gradient compression sleeve, portable intermittent pneumatic pump and hand pump designed to provide static or intermittent pneumatic compression to the bicep and forearm, in both a clinical and outpatient setting. It is intended to provide treatment for: •Enhancement of blood circulation •Reduction of post-operative pain and swelling •Reduction of edema •Lymphedema •Post immobilization edema •Post mastectomy edema •Edema following trauma and sports injuries •Reducing wound healing time •Lipedema The AeroDVx Arm system is designed as a wearable compression system, designed to provide mobility for patients.	The Dayspring system is a prescription only wearable compression system that is intended for use in a clinic or home setting 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 injuries • Post immobilization edema • Venous insufficiency • Reducing wound healing time • Treatment and assistance in healing stasis dermatitis, venous stasis ulcers, or arterial and diabetic leg ulcers • Lipedema • Phlebolymphedema The Dayspring system is developed on a wearable compression technology platform, which is designed to provide mobility for patients.	AeroDVx ™ Gradient Compression Sleeve when coupled with an inflation source provides intermittent and/or static pneumatic compression to the calf and foot, and is intended to provide treatment for: • DVT Prophylaxis • Enhancement of blood circulation • Reduction of post-operative pain and swelling • Reduction of wound-healing time • Stasis dermatitis • Treatment and assistance of healing cutaneous ulceration • Venous stasis ulcers • Chronic venous insufficiency • Reduction of edema • Lymphedema • ·Leg ulcers	SE
Anatomy where used:	Arms	Arm, Knee / Lower Leg / Foot	SE	SE

Main Components principle of operation	Lithium-ion battery Powered pneumatic pump inflates gradient arm sleeve with air, the pressure is sequential from the wrist to the shoulder	Lithium-ion battery powered with integrated shape memory alloy channels creating Compressive pressure as exertion of sequential pressure to affected area	SE, Identical type battery powered, the pump is the same as K183349,	SE
Sleeve Material	Nylon fabric, Velcro fabric Straps	Nylon Fabric with Velcro fabric Straps	Identical material	SE
Biocompatibility	Material passed ISO 10993-1, -5-10-11-23	Passed	Passed	SE
Electrical Safety Test	Electrical Safety Test (AAMI / ANSI ES60601-1:2005/(R)2012 and A1:2012, EMC completed under k183349	Passed	Identical pump	SE
Output	Gradient pneumatic pressure with a cycle time and pressure preset to 106mm/hg output for 10secs then release and repeat every 60 seconds	Sequential calibrated mechanical gradient Pressure capable of delivering 0-100 mmHg compression pressures.	SE	SE
User interface	On Off switch	Pushbutton, along with mobile applications	SE	SE

6. Indications for Use [21 CFR 807.92(a)(5)]

The AeroDVx™ Arm System is comprised of a gradient compression sleeve, portable intermittent pneumatic pump and hand pump designed to provide static or intermittent pneumatic compression to the bicep and forearm, in both a clinical and outpatient setting. It is intended to provide treatment for:

- Enhancement of blood circulation
- Reduction of post-operative pain and swelling
- Reduction of edema
- Lymphedema
- Post immobilization edema
- Post mastectomy edema
- Edema following trauma and sports injuries
- Reducing wound healing time
- Lipedema

The AeroDVx Arm system is designed as a wearable compression system, designed to provide mobility for patients

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7. Substantial Equivalence [21 CFR 807.92(b)(1) and 807.92(b)(2)]

The subject and the primary predicate device share the same intended uses and apply similar technologies. The main difference between the two is the Dayspring utilizes mechanical compression whereas the AeroDVx systems utilizes pneumatic compression. They all automate manual lymphatic drainage and are used to reduce edema by compressing parts of the body to move lymphatic fluid. Compared to the primary predicate other than the differences in type of compression (mechanical versus pneumatic) both products have similar rechargeable energy sources. Both Products utilize similar materials of construction (nylon fabric with Velcro straps). There have been no changes to the materials, design, energy source or other features of the subject device that raise different questions of safety or effectiveness. The Arm Sleeves agrees with predicate device labeling and does not change the intended use when compared to the predicate devices. Therefore, we believe the subject device is substantially equivalent.

8. Technological Characteristics [21 CFR 807.92(a)(6)]

The AeroDVx Arm utilizes a rechargeable battery powered pump; the pump is the identical pump as approved under (k183349) all the original testing is still valid as no changes have occurred to the pump. The Arm sleeve is constructed of the same type of materials and gradient technology design as the primary predicate K210885 and the identical materials as the reference device k183349. There only difference between the subject device and the predicate is the predicate utilizes mechanical compression technology, whereas the AeroDVx utilizes pneumatic compression, there are no performance differences between the subject device and both the primary and secondary predicate devices. They are the same in terms of control mechanisms, operating principle, cleaning and disinfection, packaging. No design changes have been made since the AeroDVx 510(k) submission and clearance that would significantly affect the use and safety of the device as they share the intermittent pneumatic pump. The manufacturer's risk assessment has not identified any new or significantly modified risks related to design changes, to the arms for use. There have been no unexpected issues from verification testing, nor has clinical data been necessary to support any design changes. Similarly, there are no materials differences between the subject device and the primary predicate device. The manufacturer's risk assessment has not identified any new or increased biocompatibility concerns related to material changes. Thus, the subject device has no technological characteristics that raise different questions of safety or effectiveness compared to the primary predicate devices.

9. Performance Data

Non-Clinical Performance Test Conclusion

There is no FDA recognized performance standard for compressible sleeves.

Non-clinical tests were conducted per design control procedures to verify that the proposed device met the requirements of design control procedures and was Substantially Equivalent (SE) to the predicate device both in performance and Intended uses.

The testing was as follows:

- Visual Appearance found to be equivalent
- Risk assessment completed, F-08-1A, no new risks identified.
- Device safety identical no new safety issues identified
- Flexibility with same material, additional biocompatibility testing completed under protocol TR-0057
- Performance Pressure testing under protocol# TR-0050 equivalent to k183349 protocols TR-0035 and TR-0037.
    - Testing equipment is identical for all protocols.
    - The sample size determination is identical for all protocols.
- Pump and Brace, Sleeve Packaging was reviewed and found to be equivalent.
- TR-0058 was completed as verification and validation testing for mobility it was determined that the interface pressure did not significantly change when the unit was worn during movement of the body, (walking, rising from a sitting position, and stair climbing).
- During verification testing, all data met pre-defined criteria.

10. Clinical Testing:

None

11. Safety and Performance Data

Safety and performance data submitted for the previously cleared reference device AeroDVx system pump (k183349) supports the subject device as the pump used is identical. Bench top testing was performed to support substantial equivalence for the AeroDVx system with the Arm having similar pressure readings when used with the battery powered intermittent pneumatic pump when compared to the predicate device.

12. Substantial Equivalence Conclusion

The subject and the primary predicate devices share the same intended uses and apply similar technologies. The main difference between the two is the Dayspring utilizes sequential mechanical compression whereas the AeroDVx system utilizes gradient pneumatic compression identical to the reference device k183349. They all automate manual lymphatic drainage and are used to reduce edema by compressing parts of the body to move lymphatic fluid. Compared to the predicate other than the differences in type of compression (mechanical versus pneumatic) both products have similar rechargeable energy sources. Both Products utilize similar materials of construction (nylon) and Velcro for the arm wraps. The Arm Sleeves agrees with predicate device labeling and does not change the intended use compared to the predicate devices. Therefore, we believe the subject device is substantially equivalent.

13. Biocompatibility Testing:

The subject device is considered a surface contacting device with prolonged exposure duration considering potential cumulative use, but is not intended to have direct skin contact. The possible patient-contacting material consists of a Nylon with Velcro fabric straps and is commonly used for compression liner applications, such as blood pressure cuffs. The surface contacting material described has been evaluated for biocompatibility per ISO 10993-1, ISO 10993-5, and ISO 10993-10, ISO 10993-11, ISO 10993-23, USP pyrogen testing. Results demonstrated that the subject device was compliant to all applicable biocompatibility safety standards.

14. Sterilization & Shelf-life Testing

The subject device is non-sterile, and components are unlikely to deteriorate with age, and come with a 180-day warranty.

15. Electrical Safety and Electromagnetic Compatibility (EMC)

The subject device was evaluated based on the following applicable performance and safety standards: IEC 60601-1:2012, IEC 60601-1-11:2015 and IEC 60601-1-2:2014. Results demonstrated that the subject device was compliant to all applicable performance and safety standards.

16. Conclusion:

The data included in this submission demonstrate that the AeroDVx™ Arm is substantially equivalent to the cleared primary predicate device, the Koya Dayspring™(K210885).