July 19, 2019

Sun Scientific Inc
Allan Alward
Vice President Regulatory and R&D
145 Palisade Street
Dobbs Ferry, New York 10522

Re: K183349
Trade/Device Name: AeroDVx System
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: March 14, 2019
Received: March 22, 2019

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,

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)*

K183349

Device Name

AeroDVx ™ System

Indications for Use *(Describe)*

The AeroDVx ™ 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 calf and foot, in both the hospital and outpatient setting. It is intended to provide treatment for:

1. DVT Prophylaxis
2. Enhancement of blood circulation
3. Reduction of post-operative pain and swelling
4. Reduction of wound-healing time
5. Stasis dermatitis
6. Treatment and assistance of healing cutaneous ulceration
7. Venous stasis ulcers
8. Leg ulcers
9. Chronic venous insufficiency
10. Reduction of edema
11. Lymphedema

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.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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*PRAStaff@fda.hhs.gov*

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

Sun Scientific

As specified by 21 CFR 807.92)
Prepared November 20, 2018

**Device Name:** AeroDVx ™ System

**Intended Use:**
The AeroDVx ™ 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 calf and foot, in both the hospital and outpatient setting. It is intended to provide treatment for:

1. DVT Prophylaxis
2. Enhancement of blood circulation
3. Reduction of post-operative pain and swelling
4. Reduction of wound-healing time
5. Stasis dermatitis
6. Treatment and assistance of healing cutaneous ulceration
7. Venous stasis ulcers
8. Leg ulcers
9. Chronic venous insufficiency
10. Reduction of edema
11. Lymphedema

**No Previous NSE Decision:**

This device has not been the subject of a previous NSE decision nor has there been submission or communication to the FDA regarding this device.

**Establishment Registration Number:**

Regulatory Contact
Allan Alward
145 Palisade Street
Dobbs Ferry, NY 10522
Tel: 914-479-5108

Sponsor/Manufacturer
Sun Scientific Inc.
145 Palisade Street
Dobbs Ferry, NY 10522
Tel: 914-479-5108

**Device Trade or Proprietary Names:**

The device trade names are: AeroDVx ™ System

**Device Common, Usual or Classification Names:**

Gradient compression sleeve, Compressible limb sleeve
Portable intermittent pneumatic pump

**Classification Panel:**

Classification of this device falls under the responsibility of the Division of Cardiovascular Devices, Office of Device Evaluation

**Class:**

Class II device under the following product codes/regulations:

- JOW, 21 CFR 870.5800, sleeve, limb, compressible

**Applicable Standards:**

**Compliance with Section 514 of the Food, Drug and Cosmetic Act**

None, Section 514 has not established performance standards for this device.

**Device Description:**

**Summary of the function of the device and its major components:**

The AeroDVx ™ System is comprised of a gradient compression sleeve, electronic intermittent pneumatic pump and hand pump to provide static and/or intermittent pneumatic compression for compression therapy or DVT Prophylaxis.
The AeroDVx™ gradient compression sleeve is composed of a family of non-sterile single patient use medical devices.
The AeroDVx ™ Gradient Compression Sleeve contains a single bladder with a built-in gradient profile and inelastic straps to affix it to the patient's leg. The AeroDVx ™ Gradient Compression Sleeve is available in four sizes and two different lengths (standard and short). The wrap is composed of two polyurethane laminates that are sealed together creating an internal bladder system. The bladder system contains circular and bar welds that were engineered with their spacing and location to provide 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 onto the check valve of pressure opens the leur valve so that the bladder can be inflated or deflated based on the direction of airflow.
There will be two inflation sources provided: a portable, battery-operated intermittent pneumatic pump, the AeroDVx™ Pump, to provide intermittent pneumatic compression and a hand pump to provide static compression.

The system is intended for hospital and outpatient use.

**Patient Contact Materials:**

The device is composed of biocompatible materials including the patient contact components that are used in medical devices and have been tested per ISO 10993 and have successfully passed the requirements for surface contact per ISO 10993.

**Cleaning, Disinfection, Sterilization and Pyrogenicity:**

N/A – Non-sterile, single patient use.

**510(k) Summary of Safety and Efficacy:**

We believe that the AeroDVx™ System is substantially equivalent to the predicate devices and other technologies cleared by the FDA. The AeroWrap™ was previously cleared under k070457, which has been on the market for years and has had no safety issues. The Venera 508 DVT Prevention Therapy System has been FDA approved under k180389, and has had no safety issues.

**Technological Characteristics:**

Sun Scientific believes that the subject device is substantially equivalent to other devices that have previously received FDA 510(k) clearance including the predicate devices listed below.

**Predicate Device:**

The following devices have been identified as predicate devices:

- K180389 Suzhou Minhua Medical Apparatus Supplies Co., Ltd., Venera 508 (DVT) Prevention Therapy System

**Predicate Device Comparison:**

A comparison is presented in the table below:

| Company Name | **Sun Scientific** | **Suzhou Minhua Medical** |
|---|---|---|
| Model Name / Number | AeroDVx ™ System | Venera 508<br>(DVT) Prevention Therapy System |
| 510(k) | | K180389 |
| Device classification | Class 2 | Class 2 |
| SLEEVE | | |

| | | |
|---|---|---|
| Indications for use. | 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:<br>1. DVT Prophylaxis<br>2. Enhancement of blood circulation<br>3. Reduction of post-operative pain and swelling<br>4. Reduction of wound-healing time<br>5. Stasis dermatitis<br>6. Treatment and assistance of healing cutaneous ulceration<br>7. Venous stasis ulcers<br>8. Leg ulcers<br>9. Chronic venous insufficiency<br>10. Reduction of edema<br>11. Lymphedema | Intended for:<br>1. Prevention of DVT<br>2. Enhance blood circulation<br>3. Diminish postoperative pain and swelling<br>4. Reduce wound healing time<br>5. Aid in the treatment of: stasis dermatitis, venous stasis ulcers, arterial and diabetic leg ulcers, chronic venous insufficiency and reduction of edema in the lower limb |
| Anatomy | Knee / Lower Leg / Foot | Knee / Thigh<br>Knee |
| Fabric | Polyurethane film laminate, non-woven polyester | White, non-woven polyester, PVC outer, white nylon Velcro fabric |
| | **Sun Scientific** | **Suzhou Minhua Medical** |
| | AeroDVx ™ System | Venera 508<br>(DVT) Prevention Therapy System |
| PUMP | | |
| Weight | 0.66 lbs | 0.66 lbs |
| Dimensions | 6.1 x 2.2x 1.6 inches | 6.1 x 2.2x 1.6 inches |
| Power | 3.7 Volt Li-ion Battery (rechargeable) | 3.7 Volt Li-ion Battery (rechargeable) |
| Operating Time | | 12 hours |
| Charging Time | 5 hours | 5 hours |
| Pump Max Pressure | 106 mm Hg ± 10 mm Hg | 50 mmHg ± 5mm Hg |
| Cycle Time | 60 seconds | 60 seconds |
| Interface Pressure Range | 50 mm Hg ± 5mm Hg | 50 mmHg ± 5mm Hg |
| Mode of Operation | Continuous | Continuous |

**Discussion on Comparison:**

Similarities

The similarities between the AeroDVx™ System and the predicate device are:

- Connection to an inflation source for compression therapy.
- Similar methods of construction, materials and manufacturing.
- Similar indications for use.

Differences

The main differences between the AeroDVx ™ System and the predicate device listed above are:

- The AeroDVx ™ Sleeve is a combined lower leg and foot compression sleeve.
- The AeroDVx ™ System provides gradient pressure from the ankle to the upper calf whereas the predicate device provides a single pressure along the bladder.
- The AeroDVx™ System has a check-valve that engages when the inflation source is removed and maintains passive air loss / pressure, whereas the predicate devices do not have a check valve.
- The AeroDVx™ attaches to the inflation source through tubing whereasVenera 508 has an electronic pump source attached directly to the sleeve.
- The AeroDVx™ Sleeve can be used with the AeroDVx™ pump and a hand-held pump and is designed to provide both intermittent pneumatic compression as well as static pressure.

**Table of Contents:**

A table of contents is included at the beginning of this submission. The pages referred to in the contents correspond to the sequentially numbered pages of this premarket notification.

**Truthful and Accurate Statement:**

A "truthful and accurate" statement regarding all information provided in this premarket notification is included.

**Confidentiality:**

Sun Scientific, Inc. considers certain information in this premarket notification to be confidential business information and has taken measures to protect the release of this information. Sun Scientific, Inc. requests the FDA respect the confidentiality of this information to the extent possible under law. We expect the FDA will consult with Sun Scientific, Inc. prior to the release of any information in this premarket notification (outside the 510(k) summary) for any reason, including requests under the Freedom of Information Act.

**Performance Data [21 CFR 807.92(b) (1)]:**

The critical functions of the device have been tested for verification and have met the design inputs. All the components used in the manufacturing of the device are composed of biocompatible materials with a history of usage in the medical device industry and tested and passed the requirements of ISO 10993 for a surface device.

**Conclusion [21 CFR 807.92(b) (3)]:**

We believe the differences are minimal and conclude that the subject device is as safe and effective as the predicate devices.