October 12, 2018

Radial Medical, Inc.
% Mark Smutka
Consultant
Mark Smutka
10984 Northseal Square
Cupertino, California 95014

Re: K181651
Trade/Device Name: Radial Medical Compression System
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: June 19, 2018
Received: June 22, 2018

Dear Mark Smutka:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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)*

K181651

Device Name
Radial Medical Compression System

Indications for Use *(Describe)*

The Radial Medical Compression System is indicated for use in:

- Preventing deep vein thrombosis (DVT)
- Enhancing blood circulation
- Diminishing post-operative pain and swelling
- Reducing wound healing time
- Treatment and assistance in healing: stasis dermatitis; venous stasis ulcers; arterial and diabetic leg ulcers
- Treatment of chronic venous insufficiency
- Reducing edema

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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# Premarket Notification 510(k) Summary

**510(k) Number:** K181651

**Applicant Information:**


| | |
|---|---|
| Date Prepared: | October 4, 2018 |
| Name: | Radial Medical, Inc.<br>Address: 2500 Grant Road<br>Mountain View, CA 94040 |
| Contact Person: | Mark Smutka, Consultant<br>msmutka@comcast.net |
| Mobile Number: | (408) 981-7531 |


**Device Information**:

| | |
|---|---|
| Trade Name: | Radial Medical Compression System |
| Common Names: | Compression Sleeve |
| Classification Name(s): | Compressible Limb Sleeve |
| Product Code/ Regulation: | JOW / 21 CFR 870.5800 |
| Classification: | Class II |

**Predicate Device**:

- Vasculaire Compression System – 510(k) #K122609

**Device Description:**

The Radial Medical Compression System (RMCS) is a light weight, mobile, sequential compression device (SCD) placed around the lower leg. The device is designed to provide sequential compression to the calf to augment blood flow. The system includes three components: the Cirvo sequential compression device, an inductive charging cradle and a smart device app (i.e. tablet or smartphone). The RMCS records the amount and duration of compression received during a therapy session as well as compliance with the prescribed therapy. Identified patient data, and compiled, de-identified data will be shared with the treating physician to facilitate clinical decision making.

The Cirvo uses a mechanical system to sequentially compress the leg utilizing four tension zones tensioned in series. A circumferential sleeve of polyester material is placed around the calf, held in place using hook and loop straps. During the compression cycle, a reduction in the effective circumference of the sleeve exerts a radially inward force on the calf. The device has a compression cycle time of 6 seconds and a physician-determined dwell time between compression cycles. The range of compression cycle pressures of the Cirvo is 40-60 mmHg.

**Indications for Use:**

The Radial Medical Compression System is indicated for use in:

- Preventing deep vein thrombosis (DVT)
- Enhancing blood circulation
- Diminishing post-operative pain and swelling
- Reducing wound healing time
- Treatment and assistance in healing: stasis dermatitis; venous stasis ulcers; arterial and diabetic leg ulcers
- Treatment of chronic venous insufficiency
- Reducing edema.

**Summary Comparison to Predicate:**

The following table provides a summary of substantial equivalence between the subject device and the cited predicate. The subject device has the same intended use as the predicate device. Although the subject device has different technological characteristics than the predicate device, the differences do not raise different questions of safety or effectiveness.

**Comparison to Predicate and Reference Devices**

| Key Attributes | Subject Device | Predicate Device |
|---|---|---|
| Name | Radial Medical Compression System | Vasculaire Compression System |
| K Number | K181651 | K122609 |
| Indication for Use | The Radial Medical Compression System is indicated for use in:<br>• Preventing deep vein thrombosis (DVT)<br>• Enhancing blood circulation<br>• Diminishing post-operative pain and swelling<br>• Reducing wound healing time<br>• Treatment and assistance in healing: stasis dermatitis; venous stasis ulcers; arterial and diabetic leg ulcers<br>• Treatment of chronic venous insufficiency<br>• Reducing edema | The Vasculaire Compression System is indicated for use in:<br>• Preventing deep vein thrombosis (DVT)<br>• Enhancing blood circulation<br>• Diminishing post-operative pain and swelling<br>• Reducing wound healing time<br>• Treatment and assistance in healing: stasis dermatitis; venous stasis ulcers; arterial and diabetic leg ulcers<br>• Treatment of chronic venous insufficiency<br>• Reducing edema |

| | | |
|---|---|---|
| Target Population | Patients requiring compression therapy. | Patients requiring compression therapy. |
| Where Used | Hospital, physician office, and home | Hospital, physician office, and home |
| Anatomical Site | Calf | Calf, or calf and foot |
| User | Physician and patient | Physician and patient |
| Sterility | Non-sterile | Non-sterile |
| Use | Single patient use | Single patient use |
| Power Source | Rechargeable battery | Rechargeable battery |
| Pressure Delivered | 40 – 60 mmHg | 50 – 150 mmHg |

The primary technical difference between the Cirvo and the predicate device is that the Cirvo uses a mechanical system to sequentially compress the leg using a system of pulleys and cables to tension four zones, tensioned in series, to apply pressure (**Figure 1**) and the Vasculaire uses a pneumatic pump to inflate a series of four bladder zones in series to apply pressure  The therapy delivery mode is the same for both devices, sequentially compressing the calf from caudal to cranial to augment venous flow.  The clinical effect of the Cirvo is similar to the effect of the predicate device.

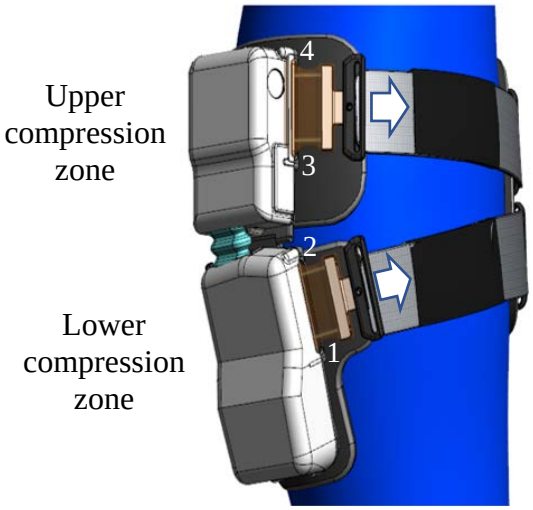


**Figure 1.** Sequential compression mechanism of operation.  Cirvo on lower leg. Four pulley zones tensioned in series from zone one to four (numbers) tension lower and upper compression zones via straps resulting in compression (arrows).

**Summary of Performance Testing**

Functional and performance testing was successfully completed on the subject device. In addition, the subject device has been investigated with respect to biocompatibility, electrical safety, software validation, human factors and clinical requirements. The Radial Medical Compression System has been tested for electromagnetic compatibility and electrical safety.

**Bench Testing**

The following testing was performed to verify the performance specifications of the Radial Medical Compression System:

- Device strap tensile test
- Device drive cord tensile test
- Device strap weld tensile test
- Device hook and loop tensile test
- D-ring chassis strap and T-bar breakaway release tensile test
- Device shin plate tensile test
- Simulated use and reliability test
- Packaging test

In addition, device simulation testing was performed to compare the performance of the Radial Medical Compression System to the predicate device. Bench testing demonstrated that the two devices deliver equivalent pressures.

**Biocompatibility**

Materials in contact with the patient include the following:

| Material | Description | Part# | Material Manufacturer |
|---|---|---|---|
| Velcro (inadvertent contact) | Velcro strap (nylon) | DG15BLTH-S | Hook-and-Loop |
| Polyester fabric (sealing the foam) | Tek Stretch 4 fabric | TS100BW/4W | Eastex Products, Inc. |

Biocompatibility was considered according to ISO 10993-1:2009, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (Biocompatibility). Cytotoxicity testing, irritation and sensitization testing were performed and successfully completed.

**Software**

Radial Medical followed the FDA Guidance Document, “General Principles of Software Validation; Final Guidance for Industry and FDA Staff” (January, 2002) to classify the software as a “moderate level of concern”. The software has been prepared in accordance with the FDA guidance document as well as IEC 62304.

**Electrical Safety Testing**

Electrical safety testing was performed to demonstrate compliance with the following standards:

- IEC 60601-1:2006, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance FDA recognition number:19-4
- IEC/EN 60601-1-2:2007, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (Edition 3). FDA recognition number: 19-2
- IEC 60601-1-6:2013, Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- IEC60601-1-11: 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
- FCC Part 15 and Part 18 FCC Part 15, Subpart C (15.209), FCC Part 15, Subpart C (15.207), RSS-210 Issue 9, FCC Part 18 (Consumer Device), FCC Part 15, Subpart B, and Industry Canada ICES-003 Issue 5

In addition, coexistence testing with intentional radiators was successfully completed.

**Human Factors Testing**

Radial Medical performed human factors testing for the Radial Medical Compression System. Testing operations were performed according to FDA Guidance Document "Applying Human Factors and Usability Engineering to Medical Devices" (Feb. 3, 2016). The usability of the device was also evaluated in compliance with IEC 60601-1-6.

A Use Failure Modes and Effects Analysis (FMEA) was performed to evaluate potential safety issues related to the use or misuse of the device. The analysis revealed that there are no serious safety events that are related to the use or misuse of the product. As part of design testing of the products, formative usability testing was performed to evaluate overall usability and related human factors. The testing evaluated the Radial Medical Compression System performance when used by the intended patient population. The testing shows that the Radial Medical Compression System meets the requirements and expected performance of the intended users. The results also were used as input into the device design.

The device was also shown to be compliant with IEC 60601-1-11 for use in the home healthcare environment.

**Clinical Performance Testing**

A feasibility study[1] was performed in which ten subjects with CEAP 3-6 venous insufficiency were recruited into an IRB approved study of venous flow augmentation. A baseline summary of subjects' demographics can be found below. Subjects underwent DVT screening and those

[1] Provisionally accepted for publication in the Journal of Vascular Surgery

who passed the DVT screen went on to have measurement of peak venous velocity in cm/s at the popliteal and femoral veins for the following conditions: (1) baseline (2) Radial device in low setting (3) Radial device in high setting. In 5 patients, an additional measurement of peak venous velocity in cm/s at the popliteal and femoral veins was completed while wearing a commercially available portable intermittent pneumatic compression (IPC) device (Tactile Actitouch). A minimum of 3 peak venous velocities were taken for each condition.

| **Demographic** | **Average (Range)** |
|---|---|
| Age | 56 (33-78) |
| Weight (lbs) | 170 (103-277) |
| BMI ($kg/m^2$) | 26.6 (19.3-40.9) |
| Height (inches) | 66 (61-69) |
| Gender | 63% female |

As shown below, both settings of the Radial device resulted in higher average peak venous velocities when compared to both baseline and the IPC device ($p<0.05$), with an average 3.5-fold femoral venous flow augmentation observed for the Radial device high setting. An average of three-fold increase (range 1 - 6.5-fold increase) in peak femoral venous velocities are reported in the literature for commercially available compression devices.[2] No Adverse Events or safety issues were reported in the course of the study.

| | Average and range of Peak Venous Flow Augmentation measured at Popliteal Vein (cm/s) | Average and range of Peak Venous Flow Augmentation measured at Femoral Vein (cm/s) |
|---|---|---|
| Baseline | 11.1 (1.0-17.5) | 13.5 (9.9-16.7) |
| IPC Device | 14.1 (4.5-18.1) | 19.2 (13.4-25.1) |
| Radial - low setting | 56.6 (41.1-67.3) | 45.5 (30.5-60.1) |
| Radial - high setting | 58.3 (42.9-77.4) | 47.1 (32.0-56.3) |

**Conclusion**

Testing described in this 510(k) consisted of verification of design input requirements and product specifications. Clinical input requirements were validated. Side by side bench testing demonstrated that the Radial Medical Compression System is substantially equivalent with respect to device performance. Clinical testing demonstrated that the device is clinically effective, and no safety events were reported in the study.

Based upon the intended use, product technical information, performance evaluation, and standards compliance provided in this premarket notification, the Radial Medical Compression System has been shown to be substantially equivalent to the legally-marketed predicate device.

2 Labropoulos N, Oh DS, Golts E, Kang SS, Mansour MA, Baker WH. Improved venous return by elliptical, sequential and seamless air-cell compression. Int Angiol.2003 Sep;22(3):317-21