July 12, 2019

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

Re: K190976
Trade/Device Name: Cirvo Compression System
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: May 2, 2019
Received: June 14, 2019

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/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,

for 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)*
K190976

Device Name
Cirvo Compression System

Indications for Use *(Describe)*
The Radial Medical Cirvo 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: K190976

Applicant Information:

Date Prepared:	May 2, 2019
Name:	Radial Medical, Inc. Address: 2500 Grant Road Mountain View, CA 94040
Contact Person:	Mark Smutka, Consultant msmutka@comcast.net
Mobile Number:	(408) 981-7531

Device Information:

Trade Name:	Cirvo 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:

- Radial Medical Compression System – 510(k) #K181651

Device Description:

The Cirvo Compression System is a light-weight, mobile, sequential compression device (SCD) placed around the calf that sequentially compresses the calf to augment blood flow. SCD's are used in both the hospital and home setting, most commonly to prevent deep vein thrombosis (DVT), heal venous leg ulcers (VLU) and reduce swelling. The Cirvo Compression System includes three components: the Cirvo sequential compression device, an AC charger and a smart device app.

The Cirvo compression unit generates compression cycles using a small motor to sequentially cycle the compression unit on the calf. The Cirvo sequential compression device is placed around the lower leg using a detachable shin guard with self-aligning magnets, with the padded compression unit aligned on the calf. Proper fitting is achieved by adjusting a pair of hook and loop straps. The Cirvo compression system continuously monitors and maintains the prescribed compression therapy, records the duration of therapy session as well as compliance with the prescribed therapy. Therapy can be initiated and stopped using either the app interface on a smart device or using the capacitive touch sensor on the compression unit. Patients can track their progress with the app and can opt in to have text reminders sent to reinforce compliance with their therapy and notifications sent to their physician. All data is saved and transmitted using high-level, AES-128 encryption.

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 and substantially equivalent technological characteristics that do not raise different questions of safety or effectiveness.

Comparison to Predicate and Reference Devices

Key Attributes	Predicate Device	Subject Device
Name	Radial Medical Compression System	Cirvo Compression System
K Number	K181651	K190976
Indication 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	The Cirvo 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	• Treatment of chronic venous insufficiency • 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
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	40 – 60 mmHg
Mechanical Properties	2 servo motors	1 servo motor
Charging Method	Wireless inductive charging unit using 12V power adapter	Direct plug-in charging using 12V power adapter

Summary of Performance Testing

Functional and performance testing was successfully completed on the subject device using the same methods and similar equipment as the predicate device to evaluate the minor modifications to the Cirvo Compression System. All testing met pre-established acceptance criteria.

Bench Testing

The following testing was performed to verify the relevant performance specifications of the Cirvo Compression System:

- Device strap tensile test
- Device buckle to cord tensile test
- Simulated use testing
- Reliability testing
- Packaging test

Software Testing

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. Testing included:

- Battery power supervisor software testing
- Mobile application client software testing
- Signal board software testing
- Security verification testing

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
- 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.

Conclusion

Testing described in this 510(k) consisted of verification of design input requirements and product specifications. Based upon the intended use, product technical information, performance evaluation, and standards compliance provided in this premarket notification, the Cirvo Compression System has been shown to be substantially equivalent to the legally-marketed predicate device.