November 15, 2021

Ortho8 Inc.
% John Beasley
Senior Consultant
MedTech Review, LLC
257 Garnet Garden Street
Henderson, Nevada 89015

Re: K212731
Trade/Device Name: Circul8 Pro Vascular Therapy System
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: October 15, 2021
Received: October 18, 2021

Dear John Beasley:

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 Nicole Gillette
Acting 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.

Submission Number *(if known)*

K212731

Device Name

Circul8 Pro Vascular Therapy System

Indications for Use *(Describe)*

The Circul8 Pro Vascular Therapy System is intended to be an easy to use portable system, prescribed by a physician, for use in the home or clinical setting to help prevent the onset of DVT in patients by stimulating blood flow in the extremities (stimulating muscle contractions). This device can be used to:

- Aid in the prevention of DVT;
- Enhance blood circulation;
- Diminish post-operative pain and swelling;
- Reduce wound healing time;
- Aid in the treatment and healing of stasis dermatitis, venous stasis ulcers, arterial and diabetic leg ulcers, chronic venous insufficiency and reduction of edema in the lower limbs.

The unit can also be used as an aid in the prophylaxis for DVT by persons expecting to be stationary for long periods of time.

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

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Ortho8 Inc.
Applicant Address	2217 Plaza Drive Rocklin CA 95765 United States
Applicant Contact Telephone	916-289-4002
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Correspondent Name	MedTech Review, LLC
Correspondent Address	257 Garnet Garden Street Henderson NV 89015 United States
Correspondent Contact Telephone	612-889-5168
Correspondent Contact	Mr. John Beasley
Correspondent Contact Email	john@medtechreview.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Circul8 Pro Vascular Therapy System
Common Name	Compressible Limb Sleeve
Classification Name	Compressible Limb Sleeve
Regulation Number	21 CFR 870.5800
Product Code	JOW

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K193020	Circul8 Pro Vascular Therapy System	JOW
K200285	VenaOne	JOW

Device Description Summary

21 CFR 807.92(a)(4)

The Circul8 Pro Vascular Therapy System is a lightweight, portable, rechargeable battery powered prescription device. The device is intended to be used in the home or clinical setting by or under the direction of a medical professional by any patient needing venous return due to an increased risk from blood clots.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The Circul8 Pro Vascular Therapy System is intended to be an easy to use portable system, prescribed by a physician, for use in the home or clinical setting to help prevent the onset of DVT in patients by stimulating blood flow in the extremities (stimulating muscle

contractions). This device can be used to:
• Aid in the prevention of DVT;
• Enhance blood circulation;
• Diminish post-operative pain and swelling;
• Reduce wound healing time;
• Aid in the treatment and healing of stasis dermatitis, venous stasis ulcers, arterial and diabetic leg ulcers, chronic venous insufficiency and reduction of edema in the lower limbs.
The unit can also be used as an aid in the prophylaxis for DVT by persons expecting to be stationary for long periods of time.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The indications for use of the predicate device and the subject device are the same.

Technological Comparison 21 CFR 807.92(a)(6)

The subject device is a modification of the predicate device in K193020, which includes:

- modification of the plastic housing enclosing the electronically controlled air pump unit and solenoid valve,
- relocation of the tactile touch control switch from the front of the housing to the top of the housing,
- introduction of LED display to replace the tricolored LED for ON, LOW BATTERY, CHARGING and CHARGE COMPLETED indications, and the blue LED for indicating a leak or low pressure alarm,
- removal of the micro USB port for obtaining usage (patient compliance) data,
- no longer labeling cuff as either left leg cuff or right leg cuff,
- cuffs are filled to 55 mmHg pressure
- introduces Night Mode, which minimizes light disturbances from the LEDs during patient resting times.
- increased battery life.

The subject device has the identical performance characteristics to the predicate device in K193020. The circuit board in the subject device is updated to fit within the newly designed plastic case, which does not change any product performance. Additionally, the circuit board is updated to accommodate the relocation of the I/O switch, the removal of the micro USB connector and the connection of the power adapter. The circuit board is also updated with a new charging circuit for the battery. Software is updated to accommodate the LED screen and Night Mode. None of these updates change the device performance. The differences between the modified (subject) device and the original (predicate) device do not raise any new issues of safety or efficacy.

The subject device is substantially equivalent to the predicate and reference device in function and operating principles to achieve identical results. The predicate device utilizes a microprocessor controlled pump to deliver approximately 50 mmHg of pressurized air to bladders that are attached to the patient's lower limbs, using a cycle time of approximately 60 seconds while the subject device is designed to deliver approximately 55 mmHg (reference device: VenaOne, K200285). Each cycle consists of inflation of a bladder, followed by a rest period during which the bladder deflates and the limb relaxes without any compression.

Both the subject device and predicate device utilize pneumatically controlled, single chamber cuffs actuated by an electronically controlled air pump unit and solenoid valve. All pump, battery and control components are protectively housed in a plastic case that is permanently attached to the inflatable cuff. The change in the shape of the protective plastic case do not raise any new issues of safety or effectiveness.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Ortho8 performed the following design verification testing on the modified Circul8 Pro (L10):

(a) Physical Requirements:
Test 1. Unit size to be no smaller than 140 X 70X 40 mm
Test 2. Unit weight to be no more than Less than 0.5 kg
Test 3. Housing material of construction confirmed to be ABS
Test 4. New location of On/Off is confirmed located on the top side the device
Test 5. LED screen correctly displays "LP" for low pressure alert, "HP" for high pressure alert, "55mmHg" for operating pressure, "_" during cycles, and battery status
Test 6. Device correctly displays usage hours when power on
Test 7. Leg wrap size, shape are identical (no distinctions between Left and Right cuffs)

Design verification test results demonstrate the estimate of the true mean (average) proportion, with a 5% margin of error and at the 90% confidence level, comply with Physical Requirements #1, #2, #3, #4, #5, #6, and #7.

(b) Performance Requirements:

Test 1: Inflation pressure accuracy of the pressure switch and software in the device correctly controls inflation of the wrap to 55 mmHg ± 10% (substantially the same preset pressure used by the predicate devices)

Test 2: Night mode performed as specified in the software design input

Design verification test results demonstrate the estimate of the true mean (average) proportion, with a 5% margin of error and at the 90% confidence level, comply with Performance Requirements #1, and #2.

(c) Electrical Requirements:

Test 1: Confirm 3.7V, 1800mAh battery and 100 - 240 Vac, 50 - 60 Hz, Output: 5Vdc @2.0 Amp power supply

Design verification test results demonstrate the estimate of the true mean (average) proportion, with a 5% margin of error and at the 90% confidence level, comply with Electrical Requirement #1.

Non-clinical tests were performed on the subject device in order to validate the design and to assure conformance with the following voluntary design standards in connection with medical device electrical safety, and electromagnetic compatibility.

(e) IEC 60601-1:2005+AMD1:2012+AMD2:2020, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance;

(f) IEC 60601-1-2:2014, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

(g) IEC 60601-1-11:2015+AMD1:2020, 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, and

(h) IEC 62133-2:2017+AMD1:2021, Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems

Design validation test results demonstrate the modified Circul8Pro (L10) device complies with general electrical safety requirements, electromagnetic compatibility requirements, requirements for use in home healthcare environment, and requirements for secondary lithium cells and batteries for use in portable applications.

The verification of software used in the modified Circul8Pro (L10) device has been carried out according to the FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.

These results demonstrate the modified Circul8Pro (L10) device is as safe, as effective, and performs as well as or better than the legally marketed device predicate.