September 8, 2021

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

Re: K211235
Trade/Device Name: CIRCUL8 Luxe DVT Prevention Device
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: August 4, 2021
Received: August 9, 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,

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.

510(k) Number *(if known)*
K211235

Device Name
CIRCUL8 Luxe DVT Prevention Device

Indications for Use *(Describe)*
CIRCUL8 Luxe, 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 (simulating 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.

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ORTHO8™ **Ortho8, Inc.**
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510(k) Summary Preparation Date: 07 Sep 2021

Contact Details		21 CFR 807.92(a)(1)
Applicant Name	Ortho8, Inc.	
Applicant Address	2217 Plaza Drive, Rocklin, CA 95765	
Applicant Telephone Number	1-916-289-4002	
Applicant Contact	Taylor Nordeen	
Applicant Contact Email	taylor@pmpmed.com	
Correspondent Name	MedTech Review, LLC	
Correspondent Address	257 Garnet Garden Street, Henderson, NV, 89015, US	
Correspondent Telephone Number	1-612-889-5168	
Correspondent Contact	Mr. John Beasley, RAC (US)	
Correspondent Contact Email	john@medtechreview.com	
Device Name		21 CFR 807.92(a)(2)
Device Trade Name	Circul8 Luxe DVT Prevention Device	
Common Name	Intermittent Compression Sleeve	
Classification Name	Sleeve, Limb, Compressible	
Regulation Number	870.5800	
Product Code	JOW	

Legally Marketed Predicate Devices		21 CFR 807.92(a)(3)
Predicate [510(k)] #	Predicate Trade Name	Product Code
K160318	PlasmaFlow Vascular Therapy System	JOW

Device Description Summary — 21 CFR 807.92(a)(4)

The CIRCUL8 Luxe DVT Prevention Device is an ambulatory, portable, light weight, prescriptive intermittent pneumatic compression system intended to provide sequential compression therapy to a patient's lower limbs. The purpose of the CIRCUL8 Luxe is to aid in the prevention of Deep Vein Thrombosis (DVT) by helping to stimulate blood flow in the legs. This is accomplished by an electronically controlled pump delivering a set amount of air to the leg cuffs that, in turn, compress the calf or calves to aid blood flow out of the lower extremities. The pump will inflate each leg cuff to a pre-set pressure of 60mmHg (± 5 mmHg) and deflate once the pressure is reached. The cycles are repeated on each unit until the power is turned off. Internal rechargeable batteries (Li ion) allow the CIRCUL8 Luxe to be completely portable, thus preventing interruptions in treatment.

Intended Use/Indications for Use — 21 CFR 807.92(a)(5)

CIRCUL8 Luxe, 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 (simulating 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)
Other than the difference in the name of the device, there are no differences in the indications for use of the subject device when compared to the predicate device.	
Technological Comparison	21 CFR 807.92(a)(6)

The CIRCUL8 Luxe DVT Prevention Device is substantially equivalent to the PlasmaFlow (predicate) device in function and operating principles to achieve identical results.

- CIRCUL8 Luxe system utilizes microprocessor-controlled pumps to deliver approximately 60mmHg of pressure air to bladders, using a cycle time of 60 seconds and pressure tolerance of 8%. Similarly, PlasmaFlow delivers 55mmHg and has 5% of pressure tolerance. The administered pressure and cycle time on both devices deliver a safe amount of pressure over an acceptable period of time to be effective in DVT prevention.
- Each cycle consists of inflation of the bladder, followed by a hold period and a rest period during which the bladder deflates, and the cuff relaxes.
- The cuffs of both devices are comprised of single bladder PVC chambers encased in a covering of soft, non-latex, non-woven medical fabric for increased patient comfort and biocompatibility compliance.
- Both devices use visual and audible alarms to indicate low battery error and pressure error. The CIRCUL8 Luxe also includes an adapter error alarm. Unattended alarms result in device shutdown, with CIRCUL8 Luxe powering off after 30 seconds, giving sufficient time to become aware of a problem and taking action, and PlasmaFlow powering off after 10 seconds.
- The PlasmaFlow has two different modes: Mode 1 in which the pressure will inflate to 55mmHg and deflate; and Mode 2 in which the pressure will increase by 10mmHg increments until it reaches 55mmHg and then deflate in the same descending increments. CIRCUL8 Luxe has one fixed default operating mode, which operates the same as PlasmaFlow's Mode 1.
- Both devices use 3.7V Lithium-ion batteries in each cuff.
- Verification testing included electrical safety, EMC, mechanical integrity, environmental and life cycle testing. Results demonstrate the CIRCUL8 Luxe has performance characteristics substantially equivalent to the predicate device.

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Characteristics / Features	CIRCUL8 Luxe Subject Device	PlasmaFlow Predicate Device (K160318)	Comments
	COMPARISON OF GENERAL INFORMATION / USES AND INDICATIONS		
FDA Device Description	Compressible Limb Sleeve, 21 CFR 870.5800	Compressible Limb Sleeve, 21 CFR 870.5800	Same.
FDA Product Code	JOW	JOW	Same.
Function	Aids venous return by using cyclic, intermittent, pneumatic pressure application (inflation followed by deflation) to compress the lower limb(s).	Aids venous return by using cyclic, intermittent, pneumatic pressure application (inflation followed by deflation) to compress the lower limb(s).	Same.
Intended Use	CIRCUL8 Luxe, 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 (simulating 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.	The PlasmaFlow, model PF0001, 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 (simulating 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.	Same.
Contraindication(s)	The Circul8 Luxe DVT Prevention Device must not be used to treat the following conditions: ● Severe arteriosclerosis or other ischemic vascular diseases	The PlasmaFlow must not be used to treat the following conditions: Persons with suspected, active or untreated: deep vein thrombosis, ischemic vascular disease, severe arteriosclerosis, pulmonary edema, severe congestive heart failure, thrombophlebitis or	Same.

Characteristics / Features	CIRCUL8 Luxe Subject Device	PlasmaFlow Predicate Device (K160318)	Comments
	● Acute or active deep vein thrombosis ● Existing pulmonary edema, pulmonary embolisms, and/or congestive cardiac failure ● On patients with neuropathy, active infections, and/or thrombophlebitis ● On extremities that are extremely deformed, insensitive to pain, or where increased venous or lymphatic return is undesirable ● Any local skin or tissue condition in which the garments would interfere including but not limited to: o Vein ligation o Recent skin graft o Gangrene o Dermatitis o Open wounds o Massive edema	an active infection; On a leg where cuffs would interfere with the following conditions: vein ligation, gangrene, dermatitis, open wounds, a recent skin graft, massive edema or extreme deformity of the leg; On patients with neuropathy; On extremities that are insensitive to pain; Where increased venous or lymphatic return is undesirable	
Target Population / Intended Users	Patients who need venous return.	Patients who need venous return.	Same.
Where Used	Home, Hospital, Surgery Center, Altitude travel, areas of limited mobility.	Home, Hospital, Surgery Center, Altitude travel, areas of limited mobility.	Same.
Application	Non-invasive / external	Non-invasive / external	Same.
Portability	Portable, ambulant	Portable, ambulant	Same.
Basis of operation	Aids venous return by using cyclic, intermittent, pneumatic pressure application (inflation followed by deflation) to compress the lower limb(s).	Aids venous return by using cyclic, intermittent, pneumatic pressure application (inflation followed by deflation) to compress the lower limb(s).	Same.

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Characteristics / Features	CIRCUL8 Luxe Subject Device	PlasmaFlow Predicate Device (K160318)	Comments
Anatomical Site / Location of treatment application	Lower limb(s) (Calf)	Lower limb(s) (Calf)	Same.
System management	Electronic, microprocessor controlled	Electronic, microprocessor controlled	Same.
Pressure Source	Micro pump controlled by electronic processor	Micro pump controlled by electronic processor	Same.
Operating Modes	Mode 1	Mode 1 Mode 2	Similar; predicate device has a Mode 2. Mode 1 of both devices have the same functionalities.
Working Pressure	Mode one (default) is preset at 60 mmHg Pressure tolerance ±5mmHG or ~8%	Mode one and Mode two are preset at 55 mmHg	Similar; Circul8 Luxe has a tolerance of ±5mmHG from 60mmHG which equals 55mmHG to 65mmHG. The predicate's working pressure falls within the same range.
Cycle Time	60 seconds	60 seconds	Same.
System indicators	- Battery: BLUE=On and fully operational/RED=low voltage; connect charger required. - Pressure: numerical pressure display mmHg.	- Battery: BLUE=On and fully operational / RED=low voltage; connect charger required. - Pressure: numerical pressure display mmHg.	Same.
System alarms	- Low Battery Error: flashing red light + alarm for 30 sec.; unit turns off. - Pressure Error: flashing red light + alarm for 30 sec.; unit turns off.	- Battery Critical: RED=battery charge below critical level; cycling stops; alarm sounds for 10 sec.; unit turns off. - Low Pressure or Leak: Flashing red/blue and error code E1 displayed if pressure limit is not	Similar; appropriate alarms to mitigate risks are provided in both devices, however different terminology is used

Characteristics / Features	CIRCUL8 Luxe Subject Device	PlasmaFlow Predicate Device (K160318)	Comments
	- Adapter Error: intermittent flashing red/blue light +alarm for 5 sec; unit turns off.	reached within 30 sec. Cycling stops; alarm sounds for 10 sec.; unit turns off.	(battery critical vs low battery error).
System diagnostics	Visual indicators prompt recognitions of systems faults	Audible and visual alarms prompt recognition of system faults	Similar; both devices have alarms. The execution differs from audible and visual by the predicate and only visual for Circul8 Luxe. Patients are properly warned with a visual indicator that satisfies risk mitigation.
Battery Specifications	Rating Voltage: 7.4V Li-ion battery pack rechargeable (one 3.7V Li-ion in each cuff)	Rating Voltage: 7.4V Li-ion battery pack rechargeable (one 3.7V Li-ion in each cuff)	Same.
Internal rechargeable batteries	Yes	Yes	Same.
Air delivery from pump to cuff bladder	Via flexible plastic (PVC) tube(s) connected directly to the air bladder.	Via flexible plastic (PVC) tube(s) connected directly to the air bladder.	Same.
Sterility	Clean / non-sterile	Clean / non-sterile	Same.
Leg cuff usage	Single Patient Use	Single Patient Use	Same.
Material Used	Single bladder PVC chambers encased in a covering of soft, non- latex, non-woven medical fabric (a Polyester blend) or equivalent medical material for increased patient comfort and biocompatibility compliance. Grey colored, stitched, and thick.	Single bladder PVC chambers encased in a covering of soft, non- latex, non-woven medical fabric (a Polyester blend) or equivalent medical material for increased patient comfort and biocompatibility compliance. Grey colored, stitched, and thick.	Same.

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Characteristics / Features	CIRCUL8 Luxe Subject Device	PlasmaFlow Predicate Device (K160318)	Comments
	Material does not raise any question of safety or effectiveness.	Material does not raise any question of safety or effectiveness.	
	COMPARISON OF APPLICABLE STANDARDS		
Biocompatibility:	Passed; biocompatible.	Passed or N/A	Similar; testing results and facilities not available for predicate but standards for device are similar and it is determined predicate had same testing standards; therefore, substantially equivalent.
Software	Moderate	N/A	Similar; testing results and facilities not available for predicate but standards for device are similar and it is determined predicate had same testing standards; therefore, substantially equivalent.
Electrical Safety and EMC	Equivalent to predicate confirming with outside testing results. Safety also confirmed in our risk assessment and usability document.	Passed or N/A	Similar; testing results and facilities not available for predicate but standards for device are similar and it is determined predicate had same testing standards; therefore, substantially equivalent.

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Characteristics / Features	CIRCUL8 Luxe Subject Device	PlasmaFlow Predicate Device (K160318)	Comments
Labeling, Packaging, and sterilization Standards.	Substantial Equivalent	Substantial Equivalent	Similar; design of documents and word choice; does not pose a danger to device safety or effectiveness; therefore substantially equivalent.
TECHNICAL DATA			
Dimensions	23.3'' x 11.3'' (59.3 x 28.7 cm)	23" x 10.25" x 1.5" (58cm x 26cm x 4cm)	Similar; Circul8 Luxe is 0.3" wider and 1.05" shorter in length compared to the predicate, therefore dimensions are similar.
Weight: Approx.	0.66 lbs (0.3 kg)	1.43 lb (.65 kg)	Similar; weight determined differently - PlasmaFlow weight pertains to both units and the sleeves, whereas, Circul8 Luxe weighted only the main control unit, weights are similar.
Source of Power	Inner Battery (single cell, 3.7-volt Li-ion battery), per cuff	Inner Battery (single cell, 3.7-volt Li-ion battery), per cuff	Same
Power Supply (Adapter)	Class II, input: 100 – 240Va.c., 50-60 Hz output: 5Vd.c. @ 2A	Class II, input: 100 - 240Va.c., 50-60Hz output: 8.4Vd.c @ 1A	Similar; each device uses a different charger with different voltage capacity,

Characteristics / Features	CIRCUL8 Luxe Subject Device	PlasmaFlow Predicate Device (K160318)	Comments
			which does not affect safety or effectiveness.
Temperature	System Operating Environment: 10°C (50°F) to +35°C (95°F)	10°C (50°F) to +40°C (104°F)	Similar; Circul8 Luxe has a minor upper limit.
Humidity	Atmospheric: 45%-75%. Keep dry.	30%-75%. Keep dry.	Similar; Circul8 Luxe device has the lower limit 15% tighter. This does not impact safety or effectiveness.
Pressure Tolerances	Working Pressure: 8%	5%	Similar; Circul8 Luxe device claims to have a wider percentage of pressure tolerance.
Battery Charge	Approximately 6 hours	Approximately 4-5 hours	Similar; Circul8 Luxe does not have a tolerance stated on the battery charge because the word "Approximately" is stated.
Cleaning and Disinfecting	Inspect the device and follow the cleaning and disinfecting procedures prior to each use. Clean the outer surface of the pump unit using a soft cloth, moistened with 70% isopropyl alcohol. Air dry only. Clean the exterior of the cuffs using a damp cloth. Unit must be completely dry prior to use. To ensure that, leave the device in the OFF position and disconnected from the wall outlet for at least 30 minutes (and as long as necessary for the unit to dry completely) after cleaning or disinfecting.	Clean the outer surface of the pump unit using a soft cloth, moistened with soapy water or 70% isopropyl alcohol. Air dry only. Clean the exterior of the cuffs using a soft cloth, moistened with soapy water or 70% isopropyl alcohol. Unit must be completely dry prior to use. To ensure that, leave the device in the OFF position and disconnected from the wall outlet for at least 30 minutes (and if necessary, for the unit to dry completely) after cleaning or disinfecting. Do not remove the pump unit from the cuff. Do not place	Similar; both devices have appropriate cleaning and disinfection according to device design.

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Characteristics / Features	CIRCUL8 Luxe Subject Device	PlasmaFlow Predicate Device (K160318)	Comments
	Do not remove the pump unit from the cuff. Do not place cuffs in dryer or microwave. Do not use a hair dryer to accelerate drying. Do not place the device on top or in front of portable stationary radiators to accelerate drying. Do not use water, abrasive cleaners, oil, benzene gasoline and chemical agents to wash the pump unit or the cuffs. Otherwise, the life of the pump unit and cuffs will be shortened. Do not wash the cuffs, rub with cloth gently. Do not put the pump unit and cuffs near sharp things, such as stoves, needles, scissors and so on.	cuffs in dryer or microwave. Do not use a hair dryer to accelerate drying. Do not place the device on top or in front of portable stationary radiators to accelerate drying. Do not use abrasive cleaners.	
	DISPOSAL		
Disposal	This unit is an electromechanical device that includes printed circuit boards and rechargeable batteries. Do not discard in landfill. Consult local county requirements for proper disposal instructions. Pump control units contain rechargeable batteries. Do not discard the pump unit in regular waste. Bring the unit to your local recycling center or contact Ortho8 Inc.	This unit is an electromechanical device that includes printed circuit boards and rechargeable batteries. Do not discard in landfill. Consult local county requirements for proper disposal instructions. Pump control units contain rechargeable batteries. Do not discard the pump unit in regular waste. Bring the unit to your local recycle center or contact ManaMed.	Similar; both devices have proper disposal instructions in the IFU.

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

Non-Clinical Summary:

The results from nonclinical tests demonstrated that the proposed CIRCUL8 Luxe meets design, safety, and performance requirements; and does not raise any new concerns of safety and effectiveness.

Testing Item	Comments
Biocompatibility	CIRCUL8 Luxe device passed Cytotoxicity (ISO 10993-5), Sensitization and Irritation (ISO 10993-10) tests.
Electromagnetic Compatibility and Electrical Safety	CIRCUL8 Luxe passed - Electrical Safety (IEC 60601-1) - EMC (IEC 60601-1-2)
Battery (Li-ion)	Li-ion battery passed test requirements stated in IEC 62133-2
Software	Software verification and validation met software requirements specifications for moderate level of concern.
Performance	Device performance confirmed in bench testing for - Pressure delivery - average maximum pressure reached for the Circul8 Luxe was 62.03mmHg - Cycle time - average cycle time for the Circul8 Luxe device was 74.8 seconds - Leakage – average leakage test value for the Circul8 Luxe device was 58.2 - Burst - average burst pressure for Circul8 Luxe device was not less than 2x maximum operating pressure plus indicated tolerance.

Conclusion:

Based on device comparison information and non-clinical bench testing, the proposed device is substantially equivalent to the legally marketed predicate device (K160318).