July 2, 2020

Vena Group, LLC
Bill Dai
Consultant
14271 Jeffrey Rd. #246
Irvine, California 92620

Re: K200285
Trade/Device Name: VenaOne
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: June 1, 2020
Received: June 4, 2020

Dear Bill Dai:

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)*
K200285

Device Name
VenaOne

Indications for Use *(Describe)*
VenaOne is an easy to use system prescribed by healthcare professionals for stimulating blood flow in the legs (simulating muscle contractions) that aids in the prevention of DVT, enhances blood circulation, diminishes post-operative pain and swelling, reduces wound healing time, and aids 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.

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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510(k) Summary

1. Submitter's Information

Submitter: Vena Group, LLC
Address: 10 Westelm Gardens
San Antonio, TX 78230
Contact Person: Kasey Vukson
Tel: 210-422-4613
Date of Preparation: 01/16/2020

2. Subject Device

Trade/Device Name: VenaOne
Common Name: Compressible Limb Sleeve
Regulation Medical Specialty: Cardiovascular
Review Panel: Cardiovascular
Product Code: JOW
Regulation Number: 21 CFR 870.5800
Device Class: II
Use: Prescription

3. Predicate device

Primary Predicate Device: DVTCare CA5
510(k) Number: K130174
Clearance Date: May 2, 2013
Submitter: Ossur Americas Inc.

Predicate/Reference Device: Cirona 6400 Disposable Deep Vein Thrombosis Prevention System
510(k) Number: K161209
Clearance Date: May 31, 2016
Submitter: Devon Medical Products

4. Description of Subject Device

The VenaOne is a lightweight, portable, rechargeable battery powered prescriptive device. It is intended for stimulating blood flow in the legs (simulating muscle contractions) that helps stimulate blood flow as an aid in the prevention of deep vein thrombosis (DVT). Its portable design allows patients to wear the unit during many clinical related activities, such as physical therapy sessions, wheel chair transportation, cafeteria sittings, and during general mobility throughout the clinic.

As an easy to use system, VenaOne utilizes the pneumatically controlled chamber cuff actuated by an electronically controlled air pump unit and solenoid valve. All the pump and control components are protectively housed in a plastic case of the control unit that is permanently attached to an inflatable air bladder. An ON/OFF button, a display, and a battery icon provide for user interface. There is also a charging port for connecting the battery charger/AC adapter plug, and a USB cable port for connecting the VenaOne device to the computer for tracking patient device use time. The detachable rechargeable battery could be mounted on the control unit or on the separate charging station for charging. Prior to use, the cut-resistant air bladder and control unit are placed inside a disposable medical fabric or equivalent medical material. The VenaOne devices are supplied clean and non-sterile.

In operation, the device could be powered on via the single ON/OFF button. The control unit then fills

the air bladder to a pre-determined pressure (55 mmHg). The pressure of the air bladder is monitored by an internal pressure switch and system software. Once the pressure reaches the proper level, the pump is turned off, and the air bladder deflates to the ambient pressure through a valve inside the plastic case of the control unit. After the "rest" period of approximately 50 seconds, the cycle repeats until the unit is turned off.

5. Indications for Use

Prescription Use:

VenaOne is an easy to use system prescribed by healthcare professionals for stimulating blood flow in the legs (simulating muscle contractions) that aids in the prevention of DVT, enhances blood circulation, diminishes post-operative pain and swelling, reduces wound healing time, and aids 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.

6. Summary of Substantial Equivalence

The following comparison Table 1 summarizes the comparison between the subject device and the predicate device, indicating the intended use and technical characteristics of the subject device are substantially equivalent to those of the predicate device.

Table 1. Comparison between the subject device and the predicate device

	Subject Device	**Primary Predicate Device**	**Predicate/Reference Device**	**Equivalence**
510(k) Number	K200285	K130174	K161209	N/A
Submitter	Vena Group, LLC	Ossur Americas Inc.	Devon Medical Products	N/A
Device Name/Model	VenaOne	DVTCare CA5	Cirona 6400 Disposable Deep Vein Thrombosis Prevention System	N/A
Intended Use	VenaOne is an easy to use system prescribed by healthcare professionals for stimulating blood flow in the legs (simulating muscle contractions) that aids in the prevention of DVT, enhances blood circulation, diminishes post-operative pain and swelling, reduces wound healing time, and aids 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 DVTcare CA5 is intended to be a portable system that is prescribed by healthcare professionals to help prevent the onset of DVT in patients, by stimulating blood flow in the legs (simulating muscle contractions). Furthermore, the unit can be used as an aid in the prophylaxis for DVT by persons traveling, or those expecting to be stationary for long periods of time (> 4 hours). This device can also be used to: aid in the prevention of DVT, enhance blood circulation, diminish post-operative pain and swelling, reduce wound healing time, and 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 Cirona 6400 disposable deep vein thrombosis prevention system is intended to be an easy to use portable system, prescribed by a physician, to help prevent the onset of DVT in patients by stimulating blood flow in the extremities (stimulating muscle contractions). This device can be used in the home or clinical setting 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	Identical

			• As a prophylaxis for DVT by persons expecting to be stationary for long periods of time	
Prescription or OTC	Prescription	Prescription	Prescription	Identical
Power Source(s)	Rechargeable battery	Rechargeable battery	Rechargeable battery	Identical
Battery Specifications	3.7V rechargeable battery	7.4V rechargeable battery	3.7V rechargeable battery	Identical or similar. The voltage difference of batteries will not raise any new issue of the safety or effectiveness.
Battery Charge	Takes approximately 4 hours (from depleted state).	Takes approximately 3 - 5 hours (from depleted state).	Takes approximately 3 hours (from depleted state).	Similar. The difference of charging time does not change the product performance or parameters, which will not raise any new issue of the safety or effectiveness.
Power Supply	Input: 100 - 240 Vac, 50 - 60 Hz, Output: 12 Vdc @ 2 Amp)	Input: 100 - 240 Vac, 50 - 60 Hz, Output: 10 Vdc @ 1.1 Amp)	Input: 100 - 240 Vac, 50 - 60 Hz, Output: 5 Vdc @ 2 Amp)	Similar. The voltage difference of power supply used does not change the product performance or parameters, which will not raise any new issue of the safety or effectiveness.
Internal rechargeable batteries	Yes	Yes	Yes	Identical
Compliance with Voluntary Standards?	Yes	Yes	Yes	Identical
Electrical Safety Mechanical Safety Chemical Safety Thermal Safety Radiation Safety?	Yes	Yes	Yes	Identical
Functions and design	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).	Aids venous return by using cyclic, intermittent, pneumatic pressure application (inflation followed by deflation) to compress the lower limb(s).	Identical
Contraindication(s)	The VenaOne 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 an active infection. On the legs 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 any neuropathy.	The DVTCare CA5 System should not be used by persons with the following conditions: suspected, active or untreated deep vein thrombosis, ischemic vascular disease, severe arteriosclerosis, pulmonary edema, severe congestive heart failure, thrombophlebitis, or an active infection. Not recommended for use on a leg where the 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.	The Cirona® 6400 series system should NOT be used in the following conditions: • Severe arteriosclerosis or other ischemic vascular diseases • 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	Identical

	On extremities that are insensitive to pain. Where increased venous or lymphatic return is undesirable.	Not for use with patines with neuropathy. Do not use on extremities that are insensitive to pain. Do not use where increased venous or lymphatic return is undesirable. Leg cuffs may cause irritation when used in direct contact with skin.	increased venous or lymphatic return is undesirable • Any local skin or tissue condition in which the garments would interfere including but not limited to: Vein ligation, Recent skin graft, Gangrene, Dermatitis, Open wounds, Massive edema	
Target Population / Intended Users	Patients who need venous return.	Patients who need venous return.	Patients who need venous return.	Identical
Where Used	Hospital, Surgery Center, Altitude travel, areas of limited mobility	Home, Hospital, Surgery Center, Altitude travel, areas of limited mobility	Home, Hospital, Surgery Center, Altitude travel, areas of limited mobility	Identical or Similar
Application	Non-invasive / external	Non-invasive / external	Non-invasive / external	Identical
Portability	Portable, ambulant	Portable, ambulant	Portable, ambulant	Identical
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).	Aids venous return by using cyclic, intermittent, pneumatic pressure application (inflation followed by deflation) to compress the lower limb(s).	Identical
Anatomical Site / Location of treatment application	Lower limb(s) (Calf)	Lower limb(s) (Calf)	Lower limb(s) (Calf)	Identical
System management	Electronic, microprocessor controlled	Electronic, microprocessor controlled	Electronic, microprocessor controlled	Identical
Pressure Source	Micro pump controlled by electronic processor	Micro pump controlled by electronic processor	Micro pump controlled by electronic processor	Identical
Operating Modes	Default mode one	'Single leg' mode 'Double leg' mode	Default mode one	Identical or similar
Working Pressure	Preset at 55 mmHg	Preset at 50 mmHg, and adjustable 20 – 65 mmHg	preset at 40 mmHg	Identical or similar
Cycle Time	Approximately 60 seconds	Approximately 60 seconds	Approximately 60 seconds	Identical
System diagnostics	Audible and visual alarms prompt recognition of system faults	Audible and visual alarms prompt recognition of system faults	Audible and visual alarms prompt recognition of system faults	Identical
Modes	1 Modality	2 Modality	1 Modality	Identical or similar
Air delivery from pump to cuff bladder	Via flexible plastic tube(s) connected directly to the air bladder.	Via flexible plastic tube(s) connected directly to the air bladder.	Via flexible plastic tube(s) connected directly to the air bladder.	Identical
Sterility	Clean / non-sterile	Clean / non-sterile	Clean / non-sterile	Identical
Leg cuff usage	Single Patient Use	Single Patient Use	Single Patient Use	Identical
Material Used	A single air bladder encased in a covering of soft, nonlatex, non-woven medical fabric or equivalent medical material for increased patient comfort and biocompatibility compliance.	A single air bladder encased in a covering of soft, nonlatex, non-woven medical fabric or equivalent medical material for increased patient comfort and biocompatibility compliance.	A single air bladder encased in a covering of soft, nonlatex, non-woven medical fabric or equivalent medical material for increased patient comfort and biocompatibility compliance.	Identical or similar
Biocompatibility	Biocompatible	Biocompatible	Biocompatible	Identical
Software	Moderate	Moderate	Moderate	Identical
Dimensions	190x44x36.3 mm	150x99x41mm	130x70x30mm	Identical of similar

Weight Approx.	0.33kg	0.43kg	0.33kg	Identical or similar
Temperature	Operate in a dry location between +10 ºC (50 ºF) and +40 ºC (104 ºF). Store in a dry location between -25 ºC (-13 ºF) and +70 ºC (158 ºF).	+10 ºC (50 ºF) to +40 ºC (104 ºF)	+5 ºC (41 ºF) to +40 ºC (104 ºF)	Identical or similar
Humidity	15%-93%	30%-75%	15%-93%	Identical or similar
Tolerances	± 5 mmHg	± 4 mmHg	± 5 mmHg	Identical or similar
Cleaning and Disinfecting	• Clean the outer surface of the pump unit using a soft cloth, moistened with soapy water or 70% isopropyl alcohol. • Do not use abrasive or volatile cleaners. • Do not place cuffs in dryer. • NEVER remove the unit from the cuff. • Hand wash the exterior of the cuffs using a soft cloth, moistened with soapy water or 70% isopropyl alcohol and let air dry. • To ensure the unit IS completely dry prior to use, leave unit in the OFF condition and disconnected from the wall outlet for 30 minutes after cleaning or disinfecting.	• Clean the outer surface of the pump unit using a soft cloth, moistened with soapy water or 70% isopropyl alcohol. • Do not use bleach on any item. • Do not use abrasive or volatile cleaners – display could become scratched and hard to read. • Do not place cuff or carry pouch in dryer, as the bladder could melt. • Hand wash exterior of cuff and carry pouch using a soft cloth moistened with soapy water or 70% isopropyl alcohol and let air dry. • To ensure product is completely dry prior to use, leave unit in the off condition and disconnected from power (wall outlet) for 30 minutes after cleaning or disinfecting.	SWITCH OFF AND DISCONNECT THE POWER CORD FROM THE MAIN SUPPLY BEFORE CLEANING AND INSPECTION. • The unit casing is made from plastic and can be cleaned using a soft damp cloth and a mild detergent free from harsh chemicals to avoid deterioration. • Sleeves are designed for single patient use and cleaning is not recommended.	Identical or similar
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.	This unit is an electromechanical device that includes printed circuit boards and rechargeable batteries. Do not discard in landfill. Consult local, state, federal and country requirements for proper disposal instructions. Cuffs may be discarded in US landfills.	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.	Identical or similar

7. Substantial Equivalence

As shown in the above table of comparison, the subject device in this submission has the identical performance and parameter to the predicate device. The updated and optimized circuit board in the subject device does not change any product performance. And the differences between the subject device and the predicate device do not raise any new issues of safety or effectiveness.

The subject device is substantially equivalent to the predicate devices listed in function and operating principals to achieve identical results. The predicate device utilizes microprocessor controlled pumps to deliver pressurized air to bladders that are attached to the patient's lower limbs, using a cycle time of

approximately 60 seconds/leg. 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.

Identical to the predicate device, the subject device has multiple audible and visual safety alarms built into the system, including low pressure alarms, low battery alarm and system malfunction overpressure safety alarm. In addition, the cuff is comprised of a single air bladder encased in a covering of soft, non-latex, non-woven medical fabric or equivalent medical material for increased patient comfort and biocompatibility compliance. The microprocessor and pump units are powered by internal rechargeable batteries, and can be connected to the main AC power line (through the battery charger / AC adaptor) while in use, allowing uninterrupted prolonged service.

The subject device is designed for the same intended use as the predicated device. The comparison of the specifications demonstrates the functional equivalence of the products, concluding that the subject device is substantially equivalent to the predicate device.

8. Non-Clinical Tests Performed

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.

(a) ANSI AAMI ES60601-1 "Medical Electrical Equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1)".

(b) IEC 60601-1-2 "Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral standard: Electromagnetic Compatibility - Requirements and Tests".

In addition to the compliance of voluntary standards, bench tests have been performed on the physical requirements, electrical requirement, and performance requirement; the verification of software used in the subject device has been carried out according to the FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.

9. Conclusion

The tests and comparison performed demonstrate the subject device is substantially equivalent to the predicate device. Therefore, the subject device is as safe and effective as the predicate device that has been legally marketed in the United States.