

Section VIII

VIII.A 510(k) Summary

MAY 02 2013

510(k) Number K130174

Date: Mar 11 2013

Submitter:

Ossur Americas Inc.
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Foothill Ranch, CA 92610
Phone: 949-268-3185
Establishment Registration Number: 3003764610

Contact Person:

Ubaldo Anaya
Quality Assurance Manager

Device name and classification:

Trade Name / Model: DVTCare CA5
Common or usual name: Compressible Limb Sleeve Device
Classification Name: Compressible Limb Sleeve
Class: II
Product Code: JOW
Regulation Number: 21 CFR 870.5800

Predicate Devices:

- i. DVTCare CA5, Doctors Orders (K061125), Acquired by Össur Americas
- ii. TriplePlay-VT Vascular Therapy System TPVT-01, Wildcat Medical Inc (K103187)

Device Description:

The subject 'DVTCare CA5' is a light weight, portable, prescriptive device intended to aid in prevention of Deep Vein Thrombosis (DVT) by helping to stimulate blood flow in the legs. This functionality is accomplished through the use of electronically controlled pump unit delivering a set amount of air to the leg cuffs that, in turn, compresses the calf(s) to aid blood flow out of the lower extremities. The pump control unit components are protectively housed in a plastic shell except the outer membrane switch (needed for user interface), 2 locking, plastic quick disconnects for air tube connection, and an external power supply input jack. The device is provided with non-serviceable, rechargeable battery to allow user portability, and an external power supply for mains connection.

During device operation, the pump unit provides air to the cuff through flexible plastic tubing, inflating it to a specified pressure (set by user or healthcare provider), to compress the lower limb, thus aiding venous return. Air pressure and delivery are monitored by a pressure transducer and integrated system software contained in the plastic control unit. Immediately after the pressure transducer detects that the cuff has achieved the set pressure, the cuff deflates to ambient pressure. This allows the blood flow to return to the limb. The device software ensures the cycle time is a minimum of 60 seconds (the cycle time is the length of time for one complete cycle on one cuff including fill time, exhaust, and relaxation time). This is done to prevent excessive stimulation of the limb.

Intended Use / Indications for Use:

The subject 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.

Technological Characteristics and comparison with predicates:

The intended use of the subject ‘DVTCare CA5’ is same as the intended use of the predicates DVTCare CA5 (K061125) and TriplePlay-VT (K103187). The fundamental technology of the proposed device is also same as that of the predicates. A comparison of the main characteristics and features of these devices is provided as follows:

	DVTCare CA5	DVTCare CA5	TriplePlay-VT Vascular Therapy System, TPVT-01
	Subject Device (Ossur Americas, Inc.)	Predicate K061125 (Össur Americas)	Predicate K103187 (Wildcat Medical Inc.)
Characteristics / Features			
Application	Non-invasive / external	Non-invasive / external	Non-invasive / external
Portability	Portable, ambulant	Portable, ambulant	Portable, ambulant
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).

	DVTCare CA5	DVTCare CA5	TriplePlay-VT Vascular Therapy System, TPVT-01
	Subject Device (Ossur Americas, Inc.)	Predicate K061125 (Össur Americas)	Predicate K103187 (Wildcat Medical Inc.)
Characteristics / Features			
Location of treatment application	Lower limb(s) (Calf)	Lower limb(s) (Calf)	Lower limb(s) (Calf)
System management	Electronic, microprocessor controlled	Electronic, microprocessor controlled	Electronic, microprocessor controlled
Treatment delivery	Uses electronic microprocessor and pneumatics to inflate and deflate bladder cuffs to achieve compression therapy	Uses electronic microprocessor and pneumatics to inflate and deflate bladder cuffs to achieve compression therapy	Uses electronic microprocessor and pneumatics to inflate and deflate bladder cuffs to achieve compression therapy
Pressure Source	Micropump controlled by electronic processor	Micropump controlled by electronic processor	Micropump controlled by electronic processor
Outlet ports	Two	Two	Three
Outlet valves	Two 2-way valves with one vent valve	One three-way valve with two vent valves	Three 3-way valves
Operating Modes	<ul style="list-style-type: none"> • 'Single leg' mode • 'Double leg' mode 	<ul style="list-style-type: none"> • 'Single leg' mode • 'Double leg' mode 	<ul style="list-style-type: none"> • Leg 1 • Leg 2 • Auxiliary • Leg 1+auxiliary • Leg 2+auxiliary
Working Pressure	<p>Single and double leg modes are preset at 50mmHg; and adjustable by user between 20-50mmHg,</p> <p><u>Note:</u> The Healthcare Provider can adjust pressure range from 20-65mmHg for both modes, if so prescribed.</p>	<p>Single and double leg modes are preset at 40mmHg; and adjustable by user between 20-40mmHg.</p> <p><u>Note:</u> The Healthcare Provider can adjust pressure range from 20-65mmHg for both modes, if so prescribed.</p>	<p>Leg 1 and Leg 2 modes are preset at 50mmHg; and adjustable between 20-65mmHg</p> <p>Auxiliary modes are preset at 35mmHg; and adjustable between 20-50mmHg.</p>
Inflation time (average)	10 seconds	10 seconds	Not Specified

	DVTCare CA5	DVTCare CA5	TriplePlay-VT Vascular Therapy System, TPVT-01
	Subject Device (Ossur Americas, Inc.)	Predicate K061125 (Össur Americas)	Predicate K103187 (Wildcat Medical Inc.)
Characteristics / Features			
Hold Time	2 seconds	0 second	3.5 seconds (approximately) <i>Note: Although the TriplePlay-VT user manual does not specify the 'hold-time'; in-house testing by Ossur showed the hold-time as 3.5 seconds (approximately)</i>
Cycle time (One inflation and deflation per limb)	Preset at 60 seconds, Adjustable between 60-75 seconds	Preset at 60 seconds, Adjustable between 60 and 75 seconds.	Preset at 60 seconds. Adjustable between 60-70 seconds
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
Battery Specifications	7.4V, 1.8Ah, Li-Po rechargeable battery	6V, 1.8Ah, Ni-MH rechargeable battery	6V, 2.0 Ah, Ni-MH rechargeable battery
Power Requirement	Rechargeable battery and/or 110VAC	Rechargeable battery and/or 110VAC	Rechargeable battery and/or 110VAC
Air delivery from pump to cuff bladder	Via flexible plastic (PVC) tube(s) terminated with quick disconnect CPC fittings	Via flexible plastic (PVC) tube(s) terminated with quick disconnect CPC fittings	Via flexible plastic air tubes with locking / quick disconnect air ports
Leg cuffs (garments) material	PVC bladder covered with brushed Nylon	PVC bladder covered with brushed Nylon	PVC bladder encased in a soft, non-woven medical fabric made from common sponge material
Leg cuff Sterile / Not Sterile	Clean / non sterile	Clean / non sterile	Clean / non sterile
Leg cuff usage	Single patient use	Single patient use	Single patient use

Like the predicates, the subject device uses intermittent, pneumatic compression to simulate muscle contractions in the legs aiding the return of venous flow. The compression is achieved by air delivery, through flexible plastic tubing that are terminated with CPC quick lock connectors, to inflatable cuffs/bladders that are wrapped around the limb(s) to transmit the pneumatic force to the leg. The air delivery is controlled by a microprocessor controlled pump and valve system. The specifications of the proposed device (such as working pressure, cycle-

time and hold-time) are also comparable to the identified predicates. Like the predicates, the proposed 'DVT-Care CA5' includes audible and visual alarms for system monitoring and fault recognition. Like the predicates, the proposed device also incorporates rechargeable batteries enabling the unit to be portable; and is offered with an external power supply for connection to mains supply (for normal operation and battery recharging). The difference in type of battery between the subject device (Li-PO battery) and the predicate devices (Ni-MH battery), different configuration of outlet valves and slight difference in appearance do not raise any new concerns of safety or effectiveness.

Non-Clinical Testing

The 'DVT-Care CA5' has been subjected to extensive in-house bench testing for design, software and performance validation. Moreover, the device was also evaluated by third party test laboratories for compliance to Electrical safety (IEC/UL/CAN60601-1) and Electromagnetic Compatibility (IEC 60601-1-2) and Environmental testing. Being a portable unit, the DVT-Care CA5 was also tested to standard MIL-STD 810D, section 514.3-1 for Vibration integrity. The results from these non-clinical tests demonstrated that the proposed DVT-Care CA5 meets design, safety and performance requirements; and does not raise any new concerns of safety and effectiveness.

The list of Design Changes and the corresponding Validation Documents are listed below. The location of each Test Report can be found in this in the Cover Letter, Section IV.B.

Design Change	Validation Document
Upgrade from NiMH batteries to Lithium Ion batteries.	DVT Charge Parameters and Verification Report
	Globtek battery UN38 3 TEST REPORT
	EC DECLARATION EN62133 battery
	Software Functions Verification Report highlighted
	CA5 System Safety Testing Report
	CA5 System EMC test report
	CA5 Shelf Life Test
Changes in the external power supply.	CA5 PCB Verification Report
	UL REPORT GTM21089
	Software Functions Verification Report highlighted
	CA5 System Safety Testing Report
	CA5 System EMC test report
The single 3-way outlet valve with two vent valves has been replaced by two 2-way fill valves with one common vent valve.	Software Functions Verification Report highlighted
	CA5 System Safety Testing Report
Case material changed from ABS to ASA-PC.	CA5 System Safety Testing Report
	V0 material trans test 110512
	CA5 Crush Test
Software has been modified to provide control for the Lithium Ion battery.	Software Functional Requirements highlighted

	Software Functions Verification Report highlighted
Default pressure setting for both 'single-leg' and 'double-leg' modes has changed from 40mmHg to 50mmHg.	Software Functional Requirements highlighted
	Software Functions Verification Report highlighted
	CA5 Predicate Testing
The hold-time specification for both modes has changed from 0 seconds to 2 seconds before deflation.	Software Functional Requirements highlighted
	Software Functions Verification Report highlighted
	CA5 Predicate Testing
Self-diagnostic feature added to verify proper operation every half hour during use.	Software Functional Requirements highlighted
	Software Functions Verification Report highlighted
Resettable Compliance Counter added for provider use to record number of hours use by each patient.	Software Functional Requirements highlighted
	Software Functions Verification Report highlighted

Conclusion:

Based on validation testing, compliance to voluntary standards and non-clinical bench testing information provided in the submission; the proposed 'DVT-Care CA5' is substantially equivalent to the predicate devices, and does not raise any new concerns of safety or effectiveness. Therefore, the proposed device is substantially equivalent to the referenced predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G605
Silver Spring, MD 20993-0002

May 2, 2013

Ossur Americas Inc.
c/o Mr. Ubaldo Anaya
Quality Assurance Manager
27051 Towne Center Drive
Foothill Ranch, CA 92610

Re: K130174
Trade/Device Name: DVTCare CA5
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II (two)
Product Code: JOW
Dated: March 14, 2013
Received: March 15, 2013

Dear Mr. Anaya:

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. 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.

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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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Bram D. Zuckerman

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section VII

VII.C Indications for Use

510(k) Number (if known): K130174

Device Name: DVTCare CA5

Indications for Use:

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.

Prescription Use √
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Bram D. Zuckerman
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