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JAN 2 6 2011

Section 5: 510(k) Summary

Date Prepared: October 26, 2010

510(k) Number: K 103187

Sponsor

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Device Name

Trade Name: TriplePlay-VT Vascular Therapy System (including leg wrap cuffs)
Model Number: TPVT-01 (with accessory cuffs model TP-3333)
Common or Usual Name: Compressible Limb Sleeve Device
Classification Name: Compressible Limb Sleeve Device
Class II
Product Code: JOW
Regulation Number: 21 CFR 870.5800

Identification of Predicate Devices

ThermoTek, Inc., NanoTherm and VascuTherm	K061866
Doctor's Orders, Inc., DVTCare CA5	K061125
Medical Compression Systems, LTD, WizAir DVT	K023573
Dynamic Air, Inc., TravelAir Portable Compression System	K022340
Microtek Medical, Inc., Venodyne DVT Advantage Plus	K011318

Device Description

The TriplePlay-VT Vascular Therapy System is a lightweight, portable, rechargeable battery powered **prescriptive device** that is intended to be used by or under the direction of a medical professional to help stimulate blood flow as an aid in the prevention of deep vein thrombosis (DVT).

The system utilizes pneumatically controlled, single chamber cuffs actuated by an electronically controlled air pump unit and solenoid valves. All pump, battery and control components are protectively housed in a plastic case. A mylar control panel overlays 4 tactile touch control switches, an LED display for monitoring pressure, LED "selected function", "low battery" and "charging" indicators. There is also a port for connecting the battery charger/AC adapter plug.

The leg wrap (cuff), model TP-3333, consists of a Polyvinyl Chloride (PVC) air bladder encased inside a soft, non-woven medical fabric made from common kitchen sponge material, which is adhered to the PVC air bladder. The cuffs are supplied clean, non-sterile, packaged in pairs. One set of cuffs are supplied with the TPVT-01 system, and are also available as accessory items.

In operation, the user selects either 1 of 5 different output modes (leg 1, leg 2, auxiliary, or a combination of leg 1 + auxiliary or leg 1 + leg 2 + auxiliary). An LED corresponding to each output indicates the selected modes. Appropriate single user "cuffs" containing air bladders are connected to the unit via externally accessible plastic quick-disconnect air ports. The control unit then fills the cuffs to a pre-determined pressure (50 mmHg for the leg cuffs, with the auxiliary cuff setting being adjustable between 20 and 50 mmHg - default setting of 35 mmHg is preset for the auxiliary function). The LED that corresponds to the activated cuff flashes slowly while that cuff is being filled with air. Cuff pressure is monitored by an integrated pressure transducer and system software. Once the pressure reaches the proper level, the pump is turned OFF for a predetermined "rest" period, and the cuff deflates to ambient pressure through a valve inside the plastic case. After the "rest" period, the next cuff is sequenced, and so on. This cycle repeats until the unit is turned off.

The "rest" period is internally preset to allow each cuff approximately 60 seconds between inflations in order to insure adequate relaxation time between compressions. When multiple cuff modes are selected, only one cuff is inflated at a time.

Intended Use

The TriplePlay-VT, model TPVT-01 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 (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 of: stasis dermatitis, venous stasis ulcers, arterial and diabetic leg ulcers, chronic venous insufficiency and reduction of edema in the lower limbs;
- As a prophylaxis for DVT by persons expecting to be stationary for long periods of time.

Contraindications

The TriplePlay-VT, model TPVT-01 ***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, congestive heart failure, thrombophlebitis or 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;

Comparison of Indications

The Indications for Use for the TriplePlay-VT Vascular Therapy system are the same as those for the predicate devices listed on the previous page.

Substantial Equivalence of Technological Characteristics

The TriplePlay-VT Vascular Therapy system is equivalent to the predicate devices listed in function and operating principals to achieve identical results. All systems (*VascuTherm-K061866, DVTCare CA5-K061125, WizAir DVT-K023573, TravelAir-K022340 and Venodyne DVT Advantage-K011318)* utilize microprocessor controlled pumps 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 / 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. If more than one wrap is being used, the additional bladders are cycled during the rest period of the first bladder, keeping a constant cycle time of approximately 60 seconds for each.

Multiple audible and visual safety alarms are built into the system, similar to those built into the *VascuTherm* and *DVTCare CA5*, including; High and low pressure alarms, low battery alarm and system malfunction overpressure safety via an internal safety vent switch with a release pressure of 2 psi (approximately 100 mmHg).

Cycle and maximum fill times are factory preset and cannot be changed. The default settings are similar to predicate devices in fill time, cycle time and pressure settings. Like the *DVTCare CA5,* the TriplePlay-VT includes provisions for an auxiliary third wrap to be used by physicians as may be needed in patient therapy. This third AUX outlet provides the same intermittent pneumatic compression as does the Leg 1 and Leg 2 outlets. Both units allow the pressure setting for the auxiliary wrap to be adjusted from 20 mmHg to 50 mmHg (default setting 35 mmHg) for maximum patient comfort. The default pressure setting for the leg wraps is factory preset at approximately 50 mmHg for both units. This default setting cannot be adjusted on the TriplePlay-VT system.

The TriplePlay-VT system uses similar means for pressure delivery to the cuffs as the predicate devices. Pressurized air is delivered by the pump to the cuffs via flexible, plastic air tubes connected to the plastic pump / control unit by means of locking, quick disconnect couplings. Like the *DVTCare CA5* and *VascuTherm*, the TriplePlay-VT cuffs, model TP-3333, are comprised of single bladder PVC chambers encased in a covering of soft, non-latex, non-woven medical fabric made from common kitchen sponge material for increased patient comfort and biocompatibility compliance.

As with the *WizAir DVT* and *TravelAir* systems, 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.

Non-Clinical Testing

Non-clinical validation, including electrical safety, EMC, mechanical integrity, environmental and life cycle testing have shown that the TriplePlay-VT Vascular Therapy System has performance characteristics substantially equivalent to or surpassing those of the listed predicate devices. In-house bench testing has verified equivalent pressure delivery, cuff (bladder) fill time, cycle time and overall system operation as the predicate devices listed.

Clinical Testing

No clinical testing was performed on the TriplePlay-VT Vascular Therapy System, however test results of some predicate devices have been compared in the following published clinical studies:

- Evaluation of Intermittant Pneumatic Compression Devices (Orthopedics 24(3):257-261, 2001);
- Venous hemodynamics after total knee arthroplasty: Evaluation of active dorsal to planar flexion and several mechanical compression devices (Journal of Bone and Joint Surgery, November 1998)

The summary conclusions of both studies state that the use of intermittent pneumatic compression devices is useful in decreasing the risk of postoperative DVT. The Venodyne model used in the studies produced a mean blood flow velocity of 76.2 +/- 23.77 using an average inflation pressure of 43 mmHg, a fill time of 11.6 seconds and a total cycle time of 60 seconds. In that these values are nearly identical to the corresponding default parameters used by the TriplePlay-VT Vascular Therapy System, and the methods of pressure delivery and operation are identical in both systems, substantial equivalence is concluded.

Summary Conclusion

Per the requirements of 21 CFR 807, surrogate clinical data, non-clinical validation testing and the information provided in the accompanying 510(k) submission, Wildcat Medical, Inc. concludes that the TriplePlay-VT model TPVT-01 (with accessory cuffs model TP-3333) is safe, effective and performs in a manner that is substantially equivalent to the predicate devices listed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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c/o Joe Adkins, Sr. Project Engineer
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Hinckley, Ohio 44233

JAN 26 2011

Re: K103187
TriplePlay – VT (TPVT-01) and leg cuff (TP-3333)
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: October 26, 2010
Received: October 28, 2010

Dear Mr. Adkins:

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.

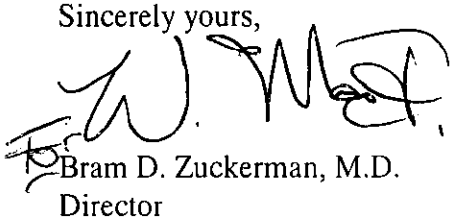
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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

Enclosure

K103187

Section 4: Indications for Use Statement

510(k) # K 103187

Indications for Use:

The TriplePlay-VT, model TPVT-01 (supplied with a pair of model TP-3333 "cuffs") 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 (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.

Prescription Use: X	**AND/OR**	**Over-The-Counter Use:**
(Part 21 CFR 801 Subpart D)		**(Part 21 CFR 807 Subpart C)**

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K103187