K071763

June 29, 2007

MAR - 7 2008

Section 5: 510(K) SUMMARY

Applicant: ConvaTec
A Division of E.R. Squibb and Sons, LLC
200 Headquarters Park Drive
Skillman, NJ 08558

Contact: Marilyn Konicky
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Device: AMADEUS Adaptive Compression Therapy

Classification Name: Compressible limb sleeve (21 CFR §870.5800)

Common Name: Adaptive Compression Therapy

Product Code: JOW

Device Class: Class II

PREDICATE DEVICES WITH WHICH SUBSTANTIAL EQUIVALENCE IS CLAIMED

Device Name: Wiz-Air® DVT

Company: Medical Compression Systems (DBN) Ltd.

510(k) Number: K012994

Classification: Compressible limb sleeve (21 CFR §870.5800)

Device Name: Extremity Pump® 7500

Company: Jobst Institute

510(k) Number: K882683

Classification: Compressible limb sleeve (21 CFR §870.5800)

Device Name: Model SC-3008 Sequential Circulator

Company: Bio Compression Systems, Inc.

510(k) Number: K043423

Classification: Compressible limb sleeve (21 CFR §870.5800)

In addition, a modified version of the Wiz-Air® DVT system (now marketed under the tradename ActiveCare DVT®) has been filed and cleared as ActiveCare ++ device (K060146, cleared March 8, 2006). Labeling was unavailable for the ActiveCare++ device; therefore this submission concentrates on the original Wiz-Air® (marketed as ActiveCare DVT in the U.S.) device.

DEVICE DESCRIPTION

AMADEUS Adaptive Compression Therapy has been designed to provide accurate, continuously monitored levels of graduated compression to the foot, ankle and leg.

AMADEUS Adaptive Compression Therapy consists of 4 main parts:

- The compression sleeve consists of 4 chambers that inflate with air to apply compression to the foot, ankle and leg. Its simple wrap-around design with hook and loop fasteners means the compression sleeve can be fitted to many different shaped legs and can be applied and removed with ease.
- The control unit is a small, compact and portable device that fits into the compression sleeve making the system ideal for ambulant use. The control unit continuously measures and precisely adjusts the delivery of pneumatic sustained graduated compression and intermittent pneumatic compression according to the physical status of the lower limb.
- The sock is designed to absorb perspiration and moisture away from the skin and has additional padding in key areas to provide additional comfort. The sock also aids in the support and positioning of the compression sleeve.
- The AC/DC power adaptor/charger is used to power the device directly (in IPC mode) and to recharge the control unit for ambulant use.

The device has 2 modes of operation: Sustained Compression mode and Intermittent Pneumatic Compression (IPC) mode. Sustained compression mode enables the control unit to provide accurate and continuously monitored compression levels to the lower limb. Intermittent Pneumatic Compression mode enables a programmed sequence of cyclical pressures to be applied to the lower limb.

AMADEUS Adaptive Compression Therapy features a compliance monitoring feature. An LCD screen is present on the control unit which displays the number of hours the device has been operational in both Sustained and IPC modes.

INTENDED USE OF THE DEVICE

AMADEUS Adaptive Compression Therapy provides optimized graduated compression in both sustained and intermittent settings for use in:

- Enhancing venous return
- Reducing venous leg ulcer healing time
- Treatment and promotion of healing of stasis dermatitis and venous stasis ulcers
- Treatment of chronic venous insufficiency
- Reducing edema due to venous stasis

The intended uses and indications of predicate devices and AMADEUS Adaptive Compression Therapy are substantially equivalent.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS

AMADEUS Adaptive Compression Therapy consists of a control unit, compression sleeve, socks, medical grade power adaptor/charger and a User Manual. AMADEUS Adaptive Compression Therapy can be powered by the on-board battery for mobile use and the supplied AC/DC power adaptor for IPC use (when non-ambulatory). AMADEUS Adaptive Compression Therapy has two built-in safety mechanisms: software controlled pressure monitoring and control and automatic hardware controlled shutdown and deflation.

AMADEUS Adaptive Compression Therapy is substantially equivalent to predicate devices and exempt traditional compression devices in terms of intended use, modes of operation and performance characteristics.

AMADEUS Adaptive Compression Therapy has been designed with the following features:

- dual graduated compression modality (Sustained and IPC modes – are substantially equivalent to the modes of operation of predicate devices and exempt traditional compression devices),
- a chamber in the compression sleeve to provide compression to ankle region
- the tubing (air hosing) is internal to the compression sleeve,
- the compression sleeve has an integral housing for the control unit,
- there are two automatic shutdown features in the unlikely event of a fault

SUBSTANTIAL EQUIVALENCE BASED ON CLINICAL AND NON-CLINICAL PERFORMANCE DATA

No comparative testing has been performed with either the AMADEUS Adaptive Compression Therapy, Wiz-Air® DVT, Extremity Pump® 7500 or Model SC-3008 Sequential Circulator (as per 807.92(b)(1), (2) & (3)). AMADEUS Adaptive Compression Therapy is substantially equivalent to predicate devices and exempt traditional compression devices in terms of intended use, modes of operation and performance characteristics.

A series of laboratory based tests and clinical investigations, with healthy volunteers and subjects with venous insufficiency, were performed with the AMADEUS Adaptive Compression Therapy to demonstrate that there were no safety concerns.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 7 2008

ConvaTec
c/o Ms. Marilyn Konicky
Associate Director, Regulatory Affairs
200 Headquarters Park Dr.
Skillman, NJ 08558

Re: K071763
AMADEUS Compression Therapy
Regulation Number: 21 CFR 870.5800
Regulation Name: Compression limb sleeve
Regulatory Class: Class II (two)
Product Code: JOW
Dated: February 8, 2008
Received: February 12, 2008

Dear Ms. Konicky:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

SECTION 4: INDICATIONS FOR USE STATEMENT

510(k) Number (if known): ~~Not Known~~ → K071763

Device Name: AMADEUS Adaptive Compression Therapy

Indications for Use:

Amadeus Adaptive Compression Therapy provides optimized graduated compression in both sustained and intermittent settings for use in::

- Enhancing venous return
- Reducing venous leg ulcer healing time
- Treatment and promotion of healing of stasis dermatitis and venous stasis ulcers
- Treatment of chronic venous insufficiency
- Reducing edema due to venous stasis

Prescription Use X (Per 21CFR 801.109) OR Over the Counter Use __ (Optimal Format 2-96)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vachuska
(Division Sign-Off)
Division of Cardiovascular Devices
510(K) Number K071763