K090308

Section 05 510(k) Summary

Submitter:	Stortford Medical LLC
Address:	295 Princeton Hightstown Road, Unit 321, West Windsor, NJ 08550 USA
Phone number:	609-235-9292
Fax number:	609-228-4320
Contact person:	Chris Daughtery
Date prepared:	4 February 2009
Establishment number:	Awaiting 510(k) Approval (Ref Steve Nagy – FDA Registrations and Listing 1-240-276-0145)

Trade Name:	Restep DVT System
Model number:	RSP-101
Common name:	Intermittent Pneumatic Compression device
Classification name:	Compressible Limb Sleeve
Class:	II
Product code:	JOW
Regulation number:	870.5800

Substantial Equivalent claimed to:

Flowtron Universal AC600, Huntleigh Healthcare (510k number K010744), in the basis that both systems use intermittent pneumatic compression to simulate muscle contractions in the legs aiding the return of venous flow. Compression is achieved by air delivery, through flexible plastic tubing, to single chamber inflatable bladders that are wrapped around the limb. Both devices can operate whilst connected to 110 VAC mains or on battery power and are controlled by software driven microprocessor. Both systems operate on a similar applied pressure and time cycle to the leg and can be used in dual leg or single leg mode. Both systems have leg and foot garments. Indications for use are similar.

Vasopress DVT System, VP500, CTC (was Britt Corp Inc.) (510k number K991038), in the basis that both systems use intermittent pneumatic compression to simulate muscle contractions in the legs aiding the return of venous flow. Compression is achieved by air delivery, through flexible plastic tubing, to single chamber inflatable bladders that are wrapped around the limb. The air delivery is controlled by a pneumatic pump and valve system. Both devices can operate whilst connected to 110 VAC mains. Both systems operate on a similar pressure and time cycle to the leg and foot, and can be used in dual leg or single leg mode. Both systems have leg and foot garments. Indications for use are similar.

Device Description:

The Restep DVT System consists of the Restep pump and compatible leg and foot compression garments. The system is a lightweight, portable, prescriptive pneumatic compression device that helps to stimulate blood flow in the deep veins of the legs through the use of pneumatically controlled single chamber pressure cuffs, actuated by an electronically controlled pump unit and solenoid valves.

Intended Use:

The Restep DVT System is a prescriptive device that helps stimulate blood flow in the deep veins of the legs and is intended for use in:-

- Preventing Deep Vein Thrombosis due to the presence of risk factors for thrombus formation during orthopedic, trauma, neurology, urologic, critical care, general medicine obstetrics and general surgery.

Contraindications:

The Restep DVT system should NOT be used in the following conditions:

- Severe arteriosclerosis or active infection.
- Suspected or known acute DVT.
- Severe congestive cardiac failure or where an increase of fluid to the heart may be detrimental.
- Existing pulmonary edema.
- Local skin or tissue conditions in which the garments would interfere.

Technological Characteristics:

The Restep DVT System is similar to the predicate devices listed above in function and operating principles to achieve similar results, however the Restep DVT system possesses a combination of features that each of the predicate devices incorporate individually. The Restep DVT system combines these features to offer greater flexibility in portability, whilst retaining the same clinical benefits.

All systems use a pneumatic pump to deliver pressurized air to bladders that are attached to the patient's lower legs, using a cycle of approx. 12 seconds inflated and 48 seconds deflated. The pressure delivered is 40mmHg nominal for leg garments and 80mmHg nominal for foot garments.

The system provide safety features to protect the patient, including high pressure alarm, low pressure alarm, no garment alarm, garment not deflating alarm and pump fault alarm. Additionally garments have a controlled leak to deflate the garment to a safe pressure in

the event of the exhaust being blocked to ensure that they cannot provide a tourniquet effect on the patient.

The garments are made from similar materials, a RF welded plastic bladder connected to a polyester or nylon material that provides the loop component of a hook and loop closure system, which allows the garments to be wrapped and fastened around a limb.

Performance Data:

No performance standards have been established for such devices under Section 514 of the Federal Food, Drug and Cosmetic Act.

The Restep DVT System has been tested to the following standards:-

Restep Pump:-

The Restep pump is undergoing electrical safety and electromagnetic testing to the following standards:-

- UL60101-1
- CSA22.2 No 601-1
- IEC60601-1
- IEC60601-2
- EN60601-1

The Restep pump has also had the following bench testing:-

- Software verification and validation.
- Performance testing of the output parameters and profiles

Restep Garments:-

The Restep garments have completed the following biocompatibility testing:-

- Cytotoxicity testing to ISO10993-5, results indicate the material is non-cytotoxic.
- Sensitization testing to ISO10993-10, results indicate the material does not elicit s sensitization response.
- Primary skin Irritation testing to ISO10993-10, results indicate the material is a non-irritant.

The results indicate that the material used will have negligible effects on the patient.

Restep DVT System

No clinical testing was performed on the Restep DVT System, however test results of the predicate devices and the Restep DVT System have been done for pressure/cycle profile, and blood flow augmentation on test subjects. Theses have shown that the Retsep DVT System produces a similar pressure and time profile whilst squeezing a patients limb and

this results in similar level of blood flow velocity augmentation, as measured in the femoral vein.

Equivalency Conclusion:

Based on the information provided in the accompanying 510(k), Stortford Medical LLC believes that the Restep DVT System is substantially equivalent to the predicate devices listed above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 1 2009

Stortford Medical LLC
c/o Mr. Chris Daughtery
President and CEO
295 Princeton Highstown Road, Unit 321
West Windsor, NJ 08550

Re: K090308
Restep DVT System
Regulation Number: 21 CFR 870.5800
Regulation Name: Sleeve, Limb, Compressible
Regulatory Class: Class II
Product Code: JOW
Dated: February 4, 2009
Received: February 6, 2009

Dear Mr. Daughtery:

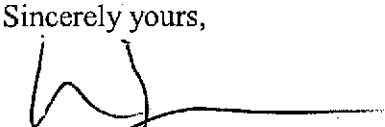
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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.
Division Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 04 Indications for Use Statement

Indications for Use

510(k) Number: K090308

Device Name: Restep DVT System

Indications For Use:

The Restep DVT System is a prescriptive device that helps stimulate blood flow in the deep veins of the legs and is intended for use in:-

- Preventing Deep Vein Thrombosis due to the presence of risk factors for thrombus formation during orthopedic, trauma, neurology, urologic, critical care, general medicine obstetrics and general surgery.

Contraindications:

The Restep DVT system should NOT be used in the following conditions:

- Severe arteriosclerosis or active infection.
- Suspected or known acute DVT.
- Severe congestive cardiac failure or where an increase of fluid to the heart may be detrimental.
- Existing pulmonary edema.
- Local skin or tissue conditions in which the garments would interfere.

Prescription Use_____X_____ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart D)

(PLEASE DO NOT WRITE BLOW THIS 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 K090308