SECTION 6: 510(k) SUMMARY

AUG 20 2012

Date of Preparation: July 20, 2012

Company Name / Contact:

Company: Compression Therapy Concepts, Inc.
555 Industrial Way West
Eatontown, NJ 07724-2298

Contact: Leonard Nass
Phone: (732) 544-0800
Fax: (732) 544-0850
LNass@ctcdvt.com

Establishment Registration Number: 2249552

Device Identification:

Proprietary Name:	VasoPress DVT Garment (sterile)
Common Used Name:	Compressible Limb Sleeve
Classification Reference:	21 CFR § 870.5800
Classification Panel:	Cardiovascular
Device Product Code:	JOW
Proposed Regulatory Class:	Class II

Predicate Device:

The VasoPress DVT Garments (sterile) are substantially equivalent to devices in commercial distribution by Compression Therapy Concepts, Inc., 555 Industrial Way West, Eatontown, NJ 07724. Specifically the VasoPress DVT Leg Garments VP 501 (K991038, K112838) and VasoPress DVT Foot Garments VP 520 (K003828, K112838).

Device Description:

The VasoPress DVT Leg Garment (sterile) consists of a brushed nylon outer material bonded to a foam inner liner bonded to an inner lining. An inflatable polyvinylchloride (PVC) pressure bag is encapsulated between an additional nylon/foam material. The VasoPress DVT Foot Garment has the same outer shell with a polyurethane (PU) pressure bag inside. An exit tube leads out from the pressure bag for connection to the VasoPress Pump. The device is automatically inflated by a pneumatic pump. The patient contact material is tricot over polyurethane foam. The devices are terminally sterilized with Ethylene Oxide (EO) gas.

Intended Use:

The DVT Garment is an external pneumatic compression device intended to lower the risk of deep vein thrombosis (DVT) and resulting pulmonary embolism (PE) in patients who may be at risk for thrombosis formation.
This is the same intended use as previously cleared for the VasoPress DVT Garments under K991038, K003828, and K112838.

Technological Characteristics:
The sterile VasoPress DVT Garments have the same technological characteristics as the predicate devices. The materials used in the garments are identical and the mode of operation is unchanged.

PerformanceTesting:
The sterile VasoPress DVT Garments have the same performance testing requirements as the predicate devices. This includes 100% verification of bladder integrity via leak test where the bladders are pressurized to 120 mmHg and allowed to dwell for thirty (30) seconds without a drop in pressure above 20 mmHg. EO sterilization is performed at temperatures and pressures which will not impact bladder integrity.

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

AUG 20 2012

Compression Therapy Concepts, Inc.
c/o Mr. Leonard Nass
35 James Way
Eatontown, NJ 07724-2272

Re: K122179
Trade/Device Name: VasoPress DVT Garment (Sterile)
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: July 20, 2012
Received: July 23, 2012

Dear Mr. Nass:

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,

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

Enclosure

K122179

SECTION 5: DEVICE INDICATIONS FOR USE

510(k) Number (if known): K122179

Device Name: VasoPress DVT Garment (Sterile)

Indications for Use:

The DVT Garment is an external pneumatic compression device intended to lower the risk of deep vein thrombosis (DVT) and resulting pulmonary embolism (PE) in patients who may be at risk for thrombosis formation.

Prescription Use ___X___ (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)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K122179