



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

DM Systems, Incorporated
C/O Mr. Michael Zmuda
Z-Technologie, S.P.
1105 Buchbrush Drive
Folsom, California 95630

JAN 13 2011

Re: K101614
Trade/Device Name: HeelSafe™ DVT Hose
Regulation Number: 21 CFR 880.5780
Regulation Name: Medical Support Stocking
Regulatory Class: II
Product Code: DWL
Dated: December 30, 2010
Received: January 3, 2011

Dear Mr. Zmuda:

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

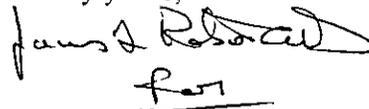
<http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding 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,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT (Amendment)

510(k) Number: K101614

Device Common Name: Medical Support Stocking

Device Proprietary Name: HeelSafe™ DVT Hose

Indications for Use: To prevent the pooling of blood and deep vein thrombosis in the legs.

Intended Uses: For patients at risk of developing compromised or inadequate venous return from the legs as a result of both medical and non-medical circumstances.

The HeelSafe DVT Hose are designed to aid and prevent deep vein thrombosis in the recumbent patient with limited mobility. Progressive compression from foot to knee aids in improving venous return and avoiding clot formation.

The HeelSafe DVT Hose open heel aids in preventing pressure on the heel that could be caused by the additional 15-18 mm Hg of pressure of other compression stockings. The HeelSafe DVT Hose open heel allows for easy visualization and palpation of the heel at all times.

Prescription Use? NO
(21 CFR 801 Subpart D)

Over-the-Counter Use? YES
(21 CFR 801 Subpart C)

Rob C. Chagnon 1/12/11
(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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