MAY 0 8 2014

510(k) SUMMARY

Medical Compression Systems (DBN) Ltd.'s ActiveCare DVT, ActiveCare+SFT and ActiveCare+DTx Systems

Submitter's Name, Address, Telephone Number

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Date Prepared: March 24, 2014

Name of Device and Name/Address of Sponsor

ActiveCare DVT, ActiveCare+SFT and ActiveCare+DTx Systems

Common or Usual Name

Pneumatic Compression System

Classification Name

Compressible Limb Sleeve
Class II; Product Code: JOW
Regulation No. 870.5800
Panel: Cardiovascular Devices

Predicate Devices

Medical Compression Systems (DBN) Ltd. ActiveCare DVT (K113525)
Medical Compression Systems (DBN) Ltd. ActiveCare+SFT(K113525)
Medical Compression Systems (DBN) Ltd. ActiveCare+DTx (K110159)

Purpose of the Special 510(k) notice

This special 510(k).was submitted in order to clear minor modifications to the ActiveCare DVT, ActiveCare+SFT and ActiveCare+DTx Systems. Specifically, the following modifications were made to the cleared systems: addition of secondary sources hardware components, minor SW changes, minor hardware changes and minor labelling changes, and Electrical Testing updates per recognized Standards.

Intended Use

The ActiveCare DVT, ActiveCare+SFT and ActiveCare+DTx Systems are prescriptive devices that induce Continuous Enhanced Circulation Therapy of the lower limbs.

The Systems are intended for use in:

- Preventing Deep Vein Thrombosis (DVT).
- Enhancing blood circulation.
- Diminishing post-operative pain and swelling.
- Reducing wound-healing time.
- Treatment and assistance in healing: stasis dermatitis; venous stasis ulcers; arterial and diabetic leg ulcers.
- Treatment of chronic venous insufficiency.
- Reducing edema.

Technological Characteristics

The ActiveCare+DTx, ActiveCare+SFT and ActiveCare DVT Systems are prescriptive, pneumatic compression Systems designed to apply sequential compression to the lower limb. The control units of the Systems provide the user with several treatment options: compression of the foot – single or double, compression of the calf – single or double, compression of the thigh – single or double, and combined compression of any combination of two sleeves. The foot compression program is an intermittent pressure pulse application to a single celled foot sleeve. The calf and thigh compression program is a sequential intermittent application of a pressure to a three-celled cuff sleeve.

Performance Data

Testing, including risk analysis, electrical safety, software validation and internal testing were performed to demonstrate that the modified systems with the described modifications do not raise any new questions of safety and efficacy. Based on these tests results, Medical Compression Systems (DBN) Ltd. believes that the modified ActiveCare DVT, ActiveCare+SFT and ActiveCare+DTx Systems are substantially equivalent to the previously cleared ActiveCare DVT, ActiveCare+SFT and ActiveCare+DTx Systems without raising new safety and/or effectiveness issues.

Substantial Equivalence

The ActiveCare DVT, ActiveCare+SFT and ActiveCare+DTx systems have the same intended use and similar indications, principles of operation, and technological characteristics as the previously cleared systems. The minor differences in the hardware, software and labelling do not raise any new questions of safety or effectiveness. Performance data demonstrates that the ActiveCare DVT, ActiveCare+SFT and ActiveCare+DTx Systems are as safe and effective as their predicates. Thus, the ActiveCare DVT, ActiveCare+SFT and ActiveCare+DTx systems are substantially equivalent to their predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

May 8, 2014

Medical Compression Systems (D.B.N.) Ltd.
Adely Levy
RA/QA Manager
12 Ha'ilan Street, P.O. Box 75
Or Akiva 30600, Israel

Re: K140755
Trade/Device Name: ActiveCare DVT, ActiveCare+SFT and ActiveCare+DTx Systems
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible limb sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: April 7, 2014
Received: April 8, 2014

Dear Adely Levy,

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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

Kenneth J. Cavanaugh -S

for

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

Enclosure

Indications for Use Statement

510(k) Number (if known): K140755

Device Name: ActiveCare DVT, ActiveCare+SFT and ActiveCare+DTx Systems

Indications for Use:

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- The Systems are intended for use in:
- Preventing Deep Vein Thrombosis (DVT).
- Enhancing blood circulation.
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- Reducing wound-healing time.
- Treatment and assistance in healing: stasis dermatitis; venous stasis ulcers; arterial and diabetic leg ulcers.
- Treatment of chronic venous insufficiency.
- Reducing edema.

Prescription Use __X___ AND/OR Over-The-Counter Use____
(Per 21 C.F.R. 801 Subpart D) (Per 21 C.F.R. 807 Subpart C)

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

_____ Concurrence of CDRH, Office of Device Evaluation (ODE)

Kenneth J. Cavanaugh -S