



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

Medical Compressions System (DBN) Ltd.
Adely Levy
RA & QA General Manager
12 Ha'ilan Street, PO Box 75
Or - Akiva, Israel 30600

Re: K151377

Trade/Device Name: ActiveCare+S.F.T.; ActiveCare+S.F.T. Homecare; ActiveCare+DTx ;
ActiveCare+DTx Homecare

Regulation Number: 21 CFR 870.5800

Regulation Name: Compressible Limb Sleeve

Regulatory Class: Class II

Product Code: JOW

Dated: May 19, 2015

Received: May 22, 2015

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,

A handwritten signature in black ink, appearing to read "M. D. Zuckerman". The signature is written in a cursive style and is positioned above the typed name.

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): K151377

Device Name: ActiveCare+S.F.T.[®] and ActiveCare+DTx[®] Systems

The ActiveCare+S.F.T.[®] and ActiveCare+DTx[®] Systems are portable, ambulatory, sequential, intermittent pneumatic compression devices (IPCDs) prescribed by healthcare professionals. The systems include a rechargeable battery powered option allowing patient mobility and ease of use. These devices simulate muscle contractions in order to treat or enhance blood flow velocity in individuals experiencing venous impairment or reduced pulsatility (dysfunction of the muscle pump) when blood flow may become challenged or compromised, such as during and after major orthopedic surgery procedures e.g total joint (hip and knee) arthroplasty. They are intended for use in the clinical setting or home environment and can be provided directly to the patient for home use.

These devices are indicated for use in:

- Preventing Deep Vein Thrombosis (DVT)
- Diminishing post-operative pain and swelling
- Reducing wound healing time
- Patients at risk for deep vein thrombosis (DVT) and related pulmonary embolism (PE) (Venous Thromboembolism (VTE))
- Treatment of venous stasis
- Treatment and assistance in healing: Stasis dermatitis, venous stasis ulcers, arterial and diabetic leg ulcers
- Enhancing blood circulation
- Treatment of chronic venous insufficiency
- Reducing edema

The ActiveCare+S.F.T.[®] and ActiveCare+DTx[®] Systems are intended to provide external compression in synchrony with the specific patient's natural venous blood flow return profile in order to achieve a high pulsatile venous blood flow.

In addition, the ActiveCare+DTx[®] System can detect hemodynamic changes in venous blood flow.

Prescription Use X
(Per 21 C.F.R. 801 Subpart D)

AND/OR

Over-The-Counter Use
(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)

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5. 510(K) SUMMARY

Medical Compression Systems (DBN) Ltd's ActiveCare+S.F.T.® and ActiveCare+DTx® Systems

Date Prepared: May 18, 2015

Submitter and Manufacturer	Contact Person
Medical Compression Systems (DBN) Ltd. 12 Ha'ilan Street, PO Box 75 Or Akiva 30600, Israel Tel: +972 (4) 6266630 Fax: +972 (4) 6266640 E-mail: adely@mcsmed.com Manufacturer Registration Number: 9616558	Adely Levy 12 Ha'ilan Street, P.O. Box 75 Or Akiva 30600, Israel Telephone: +972 (4) 6266630 Fax: +972 (4) 6266640 E-mail: adely@mcsmed.com

Name of Device

Trade Names: ActiveCare+S.F.T.® and ActiveCare+DTx® Systems
ActiveCare+S.F.T.® HomeCare and ActiveCare+DTx® HomeCare
Common Names: Pneumatic Compression System
Classification Name: Compressible Limb Sleeve

Device Classification/FDA Reviewing Branch

The Division of Cardiovascular Devices has classified Compressible Limb Sleeves as Class II devices pursuant to 21 C.F.R. § 870.5800 (JOW).

Predicate Device Information

Predicate Device Name	510(k)	Manufacturer
ActiveCare+S.F.T. and ActiveCare+DTx Systems	K142728	Medical Compression Systems

Intended Use/Indications

The ActiveCare+S.F.T. and ActiveCare+DTx Systems are portable, ambulatory, sequential, intermittent pneumatic compression devices (IPCDs) prescribed by healthcare professionals. The systems include a rechargeable battery powered option allowing patient mobility and ease of use. These devices simulate muscle contractions in order to treat or enhance blood flow velocity in individuals experiencing venous impairment or reduced pulsatility (dysfunction of the muscle pump) when blood flow may become challenged or compromised such as during and after major orthopedic surgery procedures e.g total joint

(hip and knee) arthroplasty. They are intended for use in the clinical setting or home environment, and can be provided directly to the patient for home use.

These devices are indicated for use in:

- Preventing Deep Vein Thrombosis (DVT)
- Diminishing post-operative pain and swelling
- Reducing wound healing time
- Patients at risk for deep vein thrombosis (DVT) and related pulmonary embolism (PE) (Venous Thromboembolism (VTE))
- Treatment of venous stasis
- Treatment and assistance in healing: Stasis dermatitis, venous stasis ulcers, arterial and diabetic leg ulcers
- Enhancing blood circulation
- Treatment of chronic venous insufficiency
- Reducing edema

The ActiveCare+S.F.T. and ActiveCare+DTx Systems are intended to provide external compression in synchrony with the specific patient's natural venous blood flow return profile in order to achieve a high pulsatile venous blood flow.

In addition, the ActiveCare+DTx System can detect hemodynamic changes in venous blood flow.

Device Description/Technological Characteristics

The ActiveCare+S.F.T. and ActiveCare+DTx Systems are prescriptive, portable, sequential, intermittent pneumatic compression devices designed to apply sequential compression to the lower limb. The systems include a rechargeable battery powered option (in addition to an AC/DC adapter) allowing full patient mobility and ease of use. 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.

The ActiveCare+S.F.T. and ActiveCare+DTx Systems are intended to provide continuous monitoring of each patient's venous phasic blood flow on a real time basis so that the timing of external compression is in synchrony with the specific patient's natural venous blood flow return profile in order to achieve a high pulsatile venous blood flow.

In addition, the ActiveCare+DTx System can detect hemodynamic changes that may be indicative of the development of a venous blood flow obstruction event in the treated patient's limbs. The ActiveCare+DTx is not a diagnostic tool.

Performance Data

A Human Factors and Usability Study was conducted to validate usability of the ActiveCare Systems for Direct to Home use. The results substantiated the acceptability of the risks identified during the risk assessment activities.

Additional Testing/Reports referenced in support of this submission includes: Electrical Safety, Electromagnetic Compatibility, Usability/Environmental, Software Validation, Internal testing and Risk Analysis.

Substantial Equivalence

The ActiveCare+S.F.T. and ActiveCare+DTx Systems are substantially equivalent in intended use and technological characteristics to the commercially available Medical Compression Systems ActiveCare+S.F.T. and ActiveCare+DTx Systems, previously cleared under K142728, and raises no new safety or effectiveness issues.