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

July 13, 2016

Medical Compression Systems (DBN) Ltd.
% Orly Maor
Regulatory Consultant
25 Sirkin Street
Kfar Saba, 44421 Israel

Re: K160431
Trade/Device Name: ActiveCare@Home
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: May 23, 2016
Received: June 1, 2016

Dear Orly Maor:

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,

for

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K160431

Device Name
ActiveCare@Home

Indications for Use *(Describe)*
The ActiveCare+SFT®and ActiveCare+DTx® Systems are portable, ambulatory, sequential, intermittent pneumatic compression devices (IPCDs) prescribed by health care 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 orthopaedic 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+SFT® 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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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**510(k) SUMMARY**
**Medical Compression Systems (DBN)**
**ActiveCare@Home Device**
**K160431**

## I. SUBMITTER

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**Date Prepared: May 23, 2016**

## II. DEVICE

**Device:**

| | |
|---|---|
| Name of Device: | ActiveCare@Home |
| Common or Usual Name: | ActiveCare@Home |
| Classification: | Sleeve, Limb, Compressible |
| Product Code: | JOW |
| Regulation No.: | 870.5800 |
| Class: | II |
| Panel: | Cardiovascular |

## III. PREDICATE DEVICE

The predicate device is the ActiveCare@Home, cleared under K151377.

## IV. DEVICE DESCRIPTION

The ActiveCare 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.

## V. INDICATIONS FOR USE

The ActiveCare 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.

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## VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The modified ActiveCare@Home has the same intended use and indications, principles of operation, and technological characteristics as the cleared ActiveCare@Home. The minor differences do not raise any new questions of safety or effectiveness. Performance data demonstrates that the modified ActiveCare@Home is as safe and effective as the cleared ActiveCare@Home. Thus, the ActiveCare@Home is substantially equivalent to its predicate device.

The modified ActiveCare@Home is different from the cleared device in the following:

1. The modified ActiveCare@Home was equipped with hardware Bluetooth Module.

2. Two new Software Blocks were added to its original Software, which were designed to:
   - Establish a communication between the ActiveCare main processor and the Bluetooth module **(Bluetooth Communication**)
   - Collect and reprocess data already being measured by the device in order to detect the number of the patient's steps generated during the treatment period (hereinafter referred to in this document as "**Patient's Activity Index**").

3. Three minor modifications were added to the ActiveCare@Home device GUI:
   - Reduction of the battery icon size in order to generate space for displaying the Activity Index graph mentioned above.
   - Displaying under the battery icon an estimation of the remained battery life time (appears only when the ActiveCare@Home device is powered by the internal battery).
   - Adding a 2D barcode icon to the Archives screen, this will include digital information, in addition to the same data which is displayed on the LCD screen verbally – for logistic.

## VII. PERFORMANCE DATA

The following tests were performed and they are the same as those submitted in the original submissions:

- **Risk analysis** per ISO 14971:2012
- **Software validation**

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Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for

Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "Moderate" level of concern. The level of concern is Moderate if a failure or latent design flaw could directly result in minor injury to the patient or operator. The level of concern is also "Moderate" if a failure or latent flaw could indirectly result in minor injury to the patient or operator through incorrect or delayed information or through the action of a care provider.

- **Electromagnetic compatibility (EMC)**
  Electromagnetic compatibility (EMC) per IEC 60601-1-2was conducted on the ActiveCare@Home device

- **Performance Testing**
  Performance testing simulated use for the patient activity index, and monitoring functionalities

## VIII. CONCLUSIONS

The modified ActiveCare@Home device has the same intended use compared to the predicate device. The principal features of the device that were described show that the minor differences in device characteristics between the subject and predicate device do not raise any new questions of safety or effectiveness.
Performance data and software validation has been provided, establishing that the ActiveCare@Home device performs as intended and in a manner that is substantially equivalent to the predicate.
Therefore, the device may be found substantially equivalent.