K060146

MAR 8 2006

510(K) SUMMARY

Medical Compression Systems (DBN) Ltd

ActiveCare®++ System

7.1.1 Applicant's Name:

Medical Compression Systems (DBN) Ltd.
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Or Akiva 30600, Israel
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7.1.2 Contact Person:

Dorit Winitz, Ph. D
Biomedical Strategy (2004) Ltd.
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Ramat Gan 52520, Israel
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dorit@ebms.co.il

7.1.3 Date Prepared:

January, 2006

7.1.4 Trade Name:

ActiveCare®++ System

7.1.5 Classification Name:

Sleeve, Limb, Compressible

7.1.6 Classification:

Class II; Product Code JOW;
Regulation No. 870.5800
Panel: Cardiovascular

7.1.7 Predicate Devices

Medical Compression Systems (DBN) Ltd. Systems (ActiveCare® System, previously named WizAir Compression System, Wizair DVT or ProAir 3000), cleared under K023573, K012994, K002287 and K993758.

7.1.8 Device Description:

The ActiveCare®++ is a prescriptive, pneumatic compression device designed to apply sequential compression to the lower limb. The control unit of the ActiveCare®++ is light and compact, thus making it a portable ambulant system. The ActiveCare®++ provides the user with an option of battery operation in addition to the operation from the mains option. The ActiveCare®++ is easy to use and provides the user with several treatment options: compression of the foot – single or double (either regular foot or foot booster), 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 sequential intermittent pressure pulse application to a single celled foot sleeve. The calf and thigh compression program is a sequential intermittent gradient application of a pressure to a three-celled calf sleeve.

7.1.9 Intended Use:

The ActiveCare®++ System is a prescriptive device that induces Continuous Enhanced Circulation Therapy of the lower limbs.
The ActiveCare®++ System is 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.

7.1.10 Contraindications:

The ActiveCare®++ System should not be used in the following cases: fresh pre-existing DVT, pulmonary embolism, leg gangrene, recent skin graft, acute thrombophlebitis and in medical situations where increased venous and lymphatic return is undesirable

8.11 Performance Standards:

No performance standards have been established for such device under Section 514 of the Federal Food, Drug, and Cosmetic Act. However, the ActiveCare®++ System complies with the voluntary standards such as IEC 60601-1, IEC 60601-2 and AAMI / ISO 14971-1.

8.11 Performance Data & Substantial Equivalence

The ActiveCare®++ System is substantially equivalent in all aspects, e.g., technological characteristics, mode of operation, performance characteristics, intended use, etc., to the commercially available Medical Compression Systems (DBN) Ltd.'s Systems (ActiveCare® System, previously named WizAir Compression System, Wizair DVT or ProAir 3000), cleared under K023573, K012994, K002287 and K993758.

The principle changes between the devices include:

- The software programming language was changed from Assembler to ANSI C.
- A capability to synchronize the compression cycles with the respiratory related, natural phasic venous flow, was added
- The user interface of the Control Unit was modified to include a Liquid Crystal Display (LCD).
- A Compliance status indicator was added.
- A new calf sleeve, the TripleActive, was added.

A series of safety and performance testing, including bench testing and clinical comparison in healthy volunteers, were performed to demonstrate that the modified ActiveCare®++ System does not raise any new questions of safety and efficacy. These tests include:

- Electrical and electromagnetic testing
- Software verification and validation
- Performance testing of the output parameters and pressure profile

Based on these tests results, Medical Compression Systems (DBN) Ltd. believes that the modified ActiveCare®++ System is substantially equivalent to the cleared ActiveCare® Systems (WizAir Compression System, Wizair DVT or ProAir 3000 Systems), without raising new safety and/or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 8 2006

BioMedical Strategy (2004) Ltd.
c/o Dorit Winitz, Ph.D.
Company Consultant
Moshe Aviv Street, 34th Floor
7 Jabotinsky Street
Ramat Gan 52520, Israel

Re: K060146
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II (Two)
Product Code: JOW
Dated: January 16, 2006
Received: January 19, 2006

Dear Dr. Winitz:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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

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); 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.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address

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Sincerely yours,

Donna R. Vuchmes

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): K060146

Device Name: ActiveCare®++ System

Indications for Use:
The ActiveCare®++ System is a prescriptive device that induces Continuous Enhanced Circulation Therapy of the lower limbs.
The ActiveCare®++ System is intended for use in:

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- Enhancing blood circulation.
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- Treatment of chronic venous insufficiency.
- Reducing edema.

Prescription Use __√__ (Part 21 C.F.R. 801 Subpart D)

AND/OR

Over-The-Counter Use____ (Part 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)

Donna R. Vachney

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K060146