

K993758

**MAY 1 9 2000**

**510(K) SUMMARY**

***ProAir 3000* Compression System**

**510(k) Number K\_\_\_\_\_**

**Applicant's Name:**

Medical Compression Systems (DBN) Ltd.  
9 Harugei Malhut st.  
Tel-Aviv 69714, Israel  
Tel.: 972-3-647-1615  
Fax: 972-3-647-0293

**Contact Person:**

Shoshana Friedman, RAC  
Push-med Ltd.  
117 Ahuzah St.  
Ra'anana 43373, Israel  
Tel: 972-9- 7718130  
Fax: 972-9-7718131

**Date Prepared:**

October, 1999

**Trade Name:**

*ProAir 3000* Compression System

**Classification Name:**

Compressible Limb Sleeve

**Classification:**

The FDA has classified compressible limb sleeves as class II devices (product code JOW, Regulation No. 870.5800) and they are reviewed by the Cardiovascular Panel.

**Predicate Device:**

- Kendall Model 6325 SCD Sequel Compression System (Kendall Co.), cleared under K942664
- Talley TM300 Sequential Multicom Compression System (Progressive Medical Technology, Inc.) cleared under K915092
- Jobst Extremity Pump System 7500 (Jobst Institute, Inc.) cleared under K921562
- Cowboy XV [PlexiPulse®] (KCI New Technologies, Inc.) cleared under K981311

**Performance Standards:**

No performance standards have been established for such device under Section 514 of the Federal Food, Drug, and Cosmetic Act. However, the *ProAir 3000* complies with the following voluntary standards: IEC 60601-1 (and amendments), IEC 60601-1-2, EN-1441, and applicable parts of Mil-Std-810E.

**Indications:**

The *ProAir 3000* is a prescriptive device that induces controlled compression of the calf, the foot or combined compression of both.

The *ProAir 3000* is intended for use by patients and medical professionals in treating many conditions, such as:

- prevention of deep vein thrombosis (DVT)
- enhancement of blood circulation
- reduction of post-operative pain and swelling
- reduction of wound-healing time
- stasis dermatitis
- treatment and assist healing of cutaneous ulceration
- venous stasis ulcers
- leg ulcers
- chronic venous insufficiencies
- reduction of edema

**Contraindications:**

The *ProAir 3000* compression system should not be used in the following cases: Gangrene, recent skin graft, severe arteriosclerosis or other ischemic vascular disease, congestive cardiac failure, massive edema, pulmonary edema, existing DVT, acute thrombophlebitis, acute infections, and during episodes of pulmonary embolism.

**Device Description:**

The *ProAir 3000* is a prescriptive, pneumatic compression device designed to apply sequential compression to the lower limb. The device is composed of four components:

- Portable pneumatic control unit
- Pair of cuffs (calf and/or foot-ware)
- Pneumatic connecting tubes.
- Electrical transformer

During the compression cycle the solenoid valves are activated to insert air into one cuff and then other valves are activated for the other cuff. After inflating the cells in one cuff, the solenoid valves are deactivated and, simultaneously, the second cuff is inflated. Following a complete cycle for both legs there is a relaxation period. A software-based protection limits the pressure in all cuff cells using pressure sensors. In addition, a mechanical valve has been included in the air system for releasing air in case of over pressure in one of the cells. The *ProAir 3000* has three operation modes: calf cuff mode, foot cuff mode and combined mode.

**Substantial Equivalence:**

Based on a series of safety and performance testing including a comparative study, Medical Compression Systems (DBN) Ltd. believes that the *ProAir 3000* is substantially equivalent to its predicate devices cited above without raising new safety and/or effectiveness issues.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAY 19 2000

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Shoshana Friedman  
Medical Compression Systems Ltd.  
C/O Push-med Ltd.  
117 Ahuza Street  
Ra'ananna 43373  
Israel

Re: K993758  
ProAir 3000 Compression System  
Regulatory Class: II  
Product Code: JOW  
Dated: March 5, 2000  
Received: March 7, 2000

Dear Ms. Friedman:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Pre-market Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your pre-market notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

  
James E. Dillard III  
Director  
Division of Cardiovascular and  
Respiratory Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K993758

Device Name: *ProAir 3000* Compression System

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

  
**(Division Sign-Off)**  
**Division of Cardiovascular, Respiratory,**  
**and Neurological Devices**  
510(k) Number K993758