

**MAR - 3 2000**

**510(K) SUMMARY**

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***SlendAir 4000* Compression System**

**510(k) Number K 994057**

**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  
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**Date Prepared:**

November, 1999

**Trade Name:**

***SlendAir 4000* Compression System**

**Classification Name:**

Massager, Powered Inflatable Tube

**Classification:**

The FDA has classified compressible limb sleeves as class II devices (product code IRP, Regulation No. 890.5650) and they are reviewed by the Physical Medicine Panel.

**Predicate Device:**

- Talley TM300 Sequential Multicom Compression System (Progressive Medical Technology, Inc.), cleared under K915092;
- Talley TM500 Sequential Multicom Compression System (Progressive Medical Technology, Inc.) cleared under K915637.
- Talley Multipulse Sequential Compression Unit (Progressive Medical Technology, Inc.) cleared under K914774.

**Performance Standards:**

No performance standards have been established for such device under Section 514 of the Federal Food, Drug, and Cosmetic Act. However, the *SlendAir 4000* 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 *SlendAir 4000* is a prescriptive device that induces controlled compression of the leg or the arm.

The *SlendAir 4000* is intended for use by medical professionals and patients at home in treating many conditions, such as:

- Primary lymphoedema
- Post mastectomy edema
- X • Leg ulcers
- Edema following trauma and sport injuries
- Post immobilization edema
- Venous insufficiencies
- Lymphoedema

**Contraindications:**

The *SlendAir 4000* compression system should not be used in the following cases:

- Acute pulmonary edema
- Acute thrombophlebitis
- Acute congestive cardiac failure
- Deep vein thrombosis
- Episodes of pulmonary embolism
- Acute infections.

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### **Device Description:**

The *SlendAir 4000* is a prescriptive, pneumatic compression device designed to apply peristaltic compression to a limb. The device is composed of four components:

- Light and portable pneumatic control unit
- Calf, foot, full leg, or full arm cuff composes of 1-12 cells.
- Pneumatic connecting tubes.
- Electrical transformer

The *SlendAir* enables different treatment pressures (30-90mmHg) and treatment times (15-60 minutes) that should be used according to physician discretion. When activated, air flows into the cuff cells in a continuous, predetermined peristaltic waveform. A mechanical valve has been included in the air system for releasing air in case of over pressure in one of the compartments.

### **Substantial Equivalence:**

Based on a series of safety and performance testing ~~including a comparative study~~, Medical Compression Systems (DBN) Ltd. believes that the *SlendAir 4000* is substantially equivalent to its predicate devices cited above without raising new safety and/or effectiveness issues.

**MAR - 3 2000**Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Shoshana Friedman, RAC  
MCS Consultant  
Medical Compression Systems  
C/O Push-Med LTD.  
117 Ahuzah Street  
RA'ANANNA,  
Israel

Re: K994057/S1  
Trade Name: SlendAir 4000 Compression System  
Regulatory Class: II  
Product Code: IRP  
Dated: February 8, 2000  
Received: February 14, 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 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 (Premarket 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 requirement, 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 premarket 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.

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.

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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) 594-4595. 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" (21 CFR 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/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read "Neil P. Ogden", with a stylized flourish at the end.

James E. Dillard III  
Acting Director  
Division of General and  
Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

