JAN 12 2005

K042217

7-1 510(k) Summary

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510(K) SUMMARY

FlowMedic (USA) Inc.

510(k) Number K042217

Applicant's Name:

Flowmedic (USA) Inc.
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Contact Person:

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And/Or

Dorit Winitz Ph.D
Biomedical Strategy Ltd.
11 Menachem Begin Street.
Ramat Gan 52521, Israel
Tel: +972-3- 6123281
Fax: +972-3-6123282

Date Prepared:

July 2004

Trade Name:

FlowMedic™ FM220 System

Classification Name:

Sleeve, Limb, Compressible

Classification:

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

Predicate Devices:

- The ArterialFlow™ System (Aircast, Inc), cleared under K024019
- The ArtAssist® Model AA-1000 (ACI Medical, Inc.), cleared under K942530
- WizAir DVT™ (Medical Compression Systems (DBN) Ltd.), cleared under K012994

Performance Standards:

No performance standards have been established for such device under Section 514 of the Federal Food, Drug, and Cosmetic Act. However, the FlowMedic™ FM220 System complies with the following voluntary standards:

- IEC 60601-1 (1988) + A1 (1991) + A2 (1995)
- IEC/EN 60601-1-2 (2001)
- IEC 60601-1-4 (1996) + A1 (1999)
- EN 1441 (1997)
- ISO 14971 (2000)

Intended Use / Indication for Use:

The FlowMedic™ FM220 System is intended for the improvement of blood circulation in ,the lower extremities to help prevent and reduce complications of poor circulation.

Device Description:

The FlowMedic™ FM220 System is a small, battery operated, microprocessor controlled, portable and simple mechanical system, intended for the improvement of blood circulation in the lower extremities through the application of intermittent compression to the calf.

The FlowMedic™ FM220 System consists of the following basic components:

1. FlowMedic™ FM220 System Control Unit and Straps
2. FlowMedic™ FM220 System Disposable Sleeve
3. Charger

The anatomical concave-convex shaped Control Unit is directly mounted on a pre-positioned Sleeve on the calf. Upon Control Unit activation, the straps are periodically pulled into the Control Unit base and subsequently pull the underneath sleeve, generating an intermittent compressive pressure on the patient's limb.

Substantial Equivalence:

The FlowMedic™ FM220 System and its predicate devices share the same intended use and similar materials and design. In addition, the mode of operation and delivery of therapy is similar in all the devices. A comprehensive testing program was developed and performed in order to verify that the FlowMedic™ FM220 System does not raise any new safety and effectiveness issues in comparison to its predicate devices. This includes the following testing and activities:

- Electrical safety and electromagnetic compatibility testing according to IEC 60601-1 (and amendments), and IEC 60601-1-2 standards
- Software verification and validation testing
- A set of *in vitro* (bench) performance testing and side by side comparison to the predicate devices
- Hazard analysis including risk level and solutions performed in compliance with EN 1441 (1997) and AAMI/ISO 14971-1, 2000 for the entire system and for the software

Tests results indicated that the FlowMedic™ FM220 System performs according to its specifications and share very similar operational characteristics, including applied pressure output, pressure duration and frequency, with its predicate devices.

In conclusion, FlowMedic (USA) Inc. believes that the FlowMedic™ FM220 System is as safe and effective as its predicate devices for its intended use and is substantially equivalent to its predicate devices without raising any new safety and/or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 12 2005

FlowMedic (Israel) Ltd.
c/o Mr. Jonathan S. Kahan
Hogan & Hartson, LLP
555 13th Street, N.W.
Washington, DC 20004-1109

Re: K042217
FlowMedic™ FM220 System
Regulation Number: 21 CFR 868.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II (two)
Product Code: JOW
Dated: November 19, 2004
Received: November 19, 2004

Dear Mr. Kahan:

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 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); 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 (301) 594-4646. 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 Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained 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 http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

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): K042217

Device Name: FlowMedic™ FM220 System

Indications for Use:

The FlowMedic™ FM220 System is intended for the improvement of blood circulation in the lower extremities to help prevent and reduce complications of poor circulation.

Prescription Use √ AND/OR Over-The-Counter Use ____
(Part 21 C.F.R. 801 Subpart D) (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)

Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K042217