K072372

510(K) SUMMARY

PHLEBOPRESS DVT MODEL 601A

COMPRESSIBLE LIMB SLEEVE DEVICE

510(k) Number K_____

Applicant's Name: Mego Afek Ltd.
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NOV 2 1 2007

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Date Prepared: August 2007

Trade Name: Model 601A Compression Therapy Device

Device Common or Usual Names: Compressible Limb Sleeve

Classification Name: CFR Classification section 870.5800 (Product code JOW)

Classification: Class II medical Device

Predicate Device: The Model 601A Compression Therapy Device is substantially equivalent to a combination of the following predicate devices:

- PhleboPress Model 701A (K060220) manufactured also by Mego Afek, Ltd (Israel). PhleboPress Model 701A is a compressible

limb sleeve, similar to the Model 601 Compression Therapy Device.

- Flowtron Excel Model AC550 (K961166), manufactured by Huntleigh Healthcare Inc.
- Flowtron Universal Model AC600 (K010744), manufactured by Huntleigh Healthcare Inc.

Device Description: Mego Afek's Model 601 Compression Therapy Device utilizes a software controlled air compression pump, which sequentially inflates and deflates cells within a compression garment (sleeve) that is put around a limb. This helps to push excessive interstitial fluid in the treated limb, back into the venous and lymphatic systems; improve limb circulation; and thus treat the symptoms of a variety of venous disorders and dysfunction of the "muscle pump". The device consists of a main console and compression garments. The main console contains an air compressor that is regulated by an electro-mechanical mechanism, including pressure sensors and solenoid valves. The regulated compressed air is transferred via an air distributor through a series of hoses to the sleeve garments. In the Model 601 device, each garment contains up to 4 overlapping pressure cells. The sleeve fits on the affected limb and can be easily adjusted to any limb size within the sleeve tolerance.

Intended Use / Indication for Use: Prevention of Deep Vein Thrombosis (DVT) in susceptible patients; Reduction of pain and swelling after injury and surgery; Enhancement of venous and arterial circulation; Prevention of venous stasis; Assist healing of cutaneous ulcers; Reduction of compartmental pressures.

Performance Standards:

There are no performance standards under the Federal Food, Drug and Cosmetic Act, for a compressible limb sleeve device.

Test Data: The Model 601A Compression Therapy device has been subjected to extensive safety, performance testing, and validation before release. Final testing of the Model 601A Compression Therapy device included various performance tests and software validation tests, designed to ensure that the device met all its functional specifications. Tests have been performed to ensure the device complies with industry and safety standards.

Substantial Equivalence: The Model 601A Compression Therapy device is similar to currently distributed Compression Therapy devices intended for treatment of venous and lymphatic disorders, dysfunction of the "muscle pump" and prevention of deep venous thrombosis. The device uses sequential inflation and deflation of cells within compression sleeves put around a limb. Inflation/ Deflation pressures and sequences are similar to those of predicate devices. Operating modes are similar to those of predicate devices. All of the above features are similar to these features in the predicate devices.

Conclusions: The conclusions drawn from the above Performance Testing and comparison to predicate devices is that the Model 601A compression therapy device is substantially equivalent in safety and efficacy to the predicate devices listed above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 1 2007

MEGO AFEK
c/o Ms. Ahava Stein
Regulatory Affairs Counseling
Beit Hapa'Amon (Box 124)
20 Hata'As St.
Kfar Saba,
Israel 44425

Re: K072372
Phlebopress Model 601A Compression Therapy Device
Regulation Number: 21 CFR 870. 5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II (two)
Product Code: JOW
Dated: August 17, 2007
Received: August 23, 2007

Dear Ms. Stein:

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 (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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Bochner

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

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K072372

Device Name: Model 601A Compression Therapy device

Indications for Use:

Prevention of Deep Vein Thrombosis (DVT) in susceptible patients.

Reduction of pain and swelling after injury and surgery.

Enhancement of venous and arterial circulation.

Prevention of venous stasis.

Assist healing of cutaneous ulcers.

Reduction of compartmental pressures.

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

OR

Over-The-Counter Use___ (Optional Format 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. Lechner

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K072372