K013331

NOV 3 0 2001

SECTION 7 - SUMMARY OF SAFETY AND EFFECTIVENESS

1. Applicant

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Corresponding Official:

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2. Device Name

Device trade or proprietary name:	Lympha Press Plus device
Common Name:	Compressible Sleeve Limb device
Classification Name:	Compressible Sleeve Limb, Class II, 870.5800

3. Predicate Devices

The Lympha Press Plus device is substantially equivalent to a combination of the Lympha Press device (manufactured by Mego Afek and subject of 510(k) document no. K810338), the Jobst Extremity Pump (manufactured by Jobst, Inc. and subject of 510(k) document no. K882683) and the Sequential Circulator device (manufactured by Bio Compression Systems, Inc., a Pre-Amendment Device).

4. Intended Use

The Lympha Press Plus device is intended for treatment of lymphatic disorders, venous disorders, post- mastectomy lymph-edema and dysfunction of the "Muscle Pump".

5. Description of the Device

The Lympha Press Plus Device is a programmable sequential compression therapy device with compression garments for the treatment of lymphatic and venous disorders. The Lympha Press Plus device consists of a main console and compression garments. The main console contains an air compressor that is regulated by a mechanical air pressure regulator. The regulated compressed air is transferred via an air distributor through a series of hoses to the sleeve garments containing up to 12 overlapping pressure cells. The sleeve fits on the affected limb and can be easily adjusted to any limb size within the sleeve tolerance.

5. Technological Characteristics Compared to Predicate Device

The technological characteristics, e.g., overall design, materials, mechanism of action, mode of operation, performance characteristics, etc., and the intended use of the Lympha Press Plus device are substantially equivalent to the predicate devices cited above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Ahava M. Stein
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c/o A Stein Regulatory Affairs Consulting
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Kfar Saba,
Israel

Re: K013331
Trade Name: Lympha Press Plus
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible limb sleeve
Regulatory Class: II
Product Code: JOW
Dated: September 30, 2001
Received: October 5, 2001

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. 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). 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,

for 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 STATEMENT

510(k) Number (if known): K013331

Device Name: Lympha Press Plus

Indications for use: Treatment of Lymphatic Disorders, Venous Disorders, Post-mastectomy Lymphedema and Dysfunction of the "Muscle Pump".

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (Per 21 C.F.R. 801.109) OR Over-The-Counter Use____ (Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K013331