SUMMARY OF SAFETY AND EFFECTIVENESS

K100521
(Premarket Notification [510(k)] Number)

Date: April 28, 2010

MAY 14 2010

1. Applicant

Mego Afek Ltd.
Kibbutz Afek
Post Afek
ISRAEL 30042
Tel: +972-4-8784277
Fax: +972-4-8784188

Corresponding Official:

Name: Ahava M. Stein, Consultant
Address: A. Stein - Regulatory Affairs Consulting
Beit Hapa'amon (Box 124)
20 Hata'as St.
44425 Kfar Saba
ISRAEL
Tel: +972-9-767 0002
Fax: +972-9-766 8534
Email: ahava@asteinrac.com

2. Device Name:	Compression Therapy Device
Device trade/proprietary name:	Compression Therapy Device sleeves: ComfySleeve 1-75; LymphaPod
Common Name:	Compression Therapy Device
Classification Name:	Compressible Limb Sleeve (product code JOW, Class II, 870.5800

3. Predicate Devices

The modified sleeves of the Compression Therapy devices are substantially equivalent to the original sleeves; and the combination of the modified sleeves with the original consoles is substantially equivalent to the combination of the original sleeves with the original consoles of the following devices:

Device	Manufacturer	510(k) No.
Lympha Press Optimal device	Mego Afek Ltd.	K082149
Lympha Press Plus device	Mego Afek Ltd.	K013331

4. Indications for Use

Lympha Press Optimal (Model 1201AP) Compression Therapy device:

- Primary Lymphedema (for example, congenital/ milroy's disease)
- Secondary Lymphedema (for example, post mastectomy, chronic edema, post-traumatic edema)
- Venous disorders (for example, venous insufficiency, varicose veins, venous static ulcers)
- Dysfunction of the muscle pump (for example, promotion of wound recovery, reduction of edema and lower limb pain following trauma and sports injuries)

The device is intended to be used by the patient at home, as well as by physicians at clinics or hospitals.

Lympha Press Plus:
Treatment of Lymphatic Disorders, Venous disorders, Post-mastectomy Lymphedema and Dysfunction of the "Muscle Pump".

5. Description of the Device

The Lympha Press Plus and Optimal Compression Therapy devices utilize a software controlled air compression pump, which sequentially inflates and deflates cells within a compression garment (sleeve) that is put around the area to be treated. This helps to move excessive interstitial fluid back into the venous and lymphatic systems; improve limb circulation; and thus treat the symptoms of lymphedema, a variety of venous disorders and dysfunction of the "muscle pump". The devices consist of a main control unit and compression garments. The main control unit 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. Additional garments include the ComfySleeve 1-75 (a jacket sleeve to treat the arm and thorax) and the LymphaPod (a pant sleeve to treat the legs and abdomen).

6. 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 Compression Therapy device with the modified sleeves are substantially equivalent to the predicate device cited above.

7. Performance Testing

The ComfySleeve 1-75 and the LymphaPress Pod garments were each tested with the LymphaPress Plus and with the Lympha Press Optimal devices. The garment pressure was measured and found comparable to the set pressure. The ComfySleeve I-75 was also tested for user comfort and to ensure that it does not cause any bruising or irritation during or after treatment. The ComfySleeve™ 1-75 garment was found suitable for the user and did not cause any bruising or irritation during or after treatment.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

MAY 14 2010

Mego Afek Ltd.
c/o Ms. Ahava Stein
Regulatory Consultant
Beit Hapa'amon Box 124
20 Hata'as Street
44425 Kfar Saba
Israel

Re: K100521
ComfySleeve 1-75 and LymphaPod Therapy devices
Regulation Number: 21 CFR 870.5800
Regulation Name: Sleeve, Limb, Compressible
Regulatory Class: Class II
Product Code: JOW
Dated: April 29, 2010
Received: May 4, 2010

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

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

510(k) Number (if known): K100521

Device Name: ComfySleeve 1-75 and LymphaPod garments for use with the Lympha Press Optimal (Model 1201AP) Compression Therapy device and with the Lympha Press Plus Compression Therapy Device.

Indications For Use:

- Primary lymphedema (for example congenital/ milroy's disease)
- Secondary lymphedema (for example post-mastectomy, chronic edema, post-traumatic edema)
- Venous disorders (for example venous insufficiency, varicose veins, venous stasis ulcers)
- Dysfunction of the muscle pump (for example promotion of wound recovery, reduction of edema and lower limb pain following trauma and sports injuries.)

The garments are intended to be used by the patient at home, as well as by physicians at clinics or hospitals.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 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. Vachuska

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K100521