

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: K131420.

1. **Submitter's Identification:**

MEGO AFEK LTD.
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NOV 01 2013

Date Summary Prepared: May 13, 2013

2. **Name of the Device:**

Proprietary name: Petite Basic System 701 ELT

Common Name: Compressible Limb Sleeve

3. **Common or Usual Name/Classification:**

Common name: Compressible Limb Sleeve
Classification name: Compressible Limb Sleeve
Regulation: 21 CFR 870.5800
Product Code: JOW

4. **Predicate Device Information:**

Lympha Press 201Max
Previously cleared 510(k) number: k100677

5. **Description:**

The Petite Basic System™ is a sequential pneumatic compression therapy system for treatment of lymphedema, venous insufficiency, venous stasis ulcers and dysfunction of the "muscle pump".

The Petite Basic System™ consists of:

- **The pressure control unit** (sometimes called "compressor" or "pump"), supplies air at regulated pressure to a compression garment that is worn over the area to be treated.

- **Hoses** that transfer the air from the pressure control unit to each of the cells in the compression garment.
- **The compression garment** (sometimes called a "sleeve"), fastened around the area to be treated. Each garment contains 4 overlapping air cells. These air cells are filled with air from the pressure control unit in sequence, applying a compressive massage. Once the entire area has been compressed, the Petite Basic System™ pressure control unit releases the pressure, and there is a brief pause. Then the process starts over again, and is repeated until the treatment session is complete.

The compress-and-release massage action of Petite Basic System™ stimulates lymphatic vessels in the treated area to take up and transport lymphatic fluid. The directional massage action encourages transport of the fluid towards the torso for collection by healthy lymphatics and return to the blood circulation. The directional compressive massage also helps reduce venous edema and stimulates venous return.

6. Intended Use:

- Primary lymphedema
- Secondary lymphedema
- Venous insufficiency
- Venous stasis ulcers
- Dysfunction of the "muscle pump"

7. Technological Characteristics

The technological characteristics of the Petite Basic System 701ELT are substantially equivalent to the predicate device. Both systems have the same specifications -

Comparison to Predicate Device

Item	Lympha-Press 201 Max	Petite Basic System 701ELT	Comments
Air Distribution method	rotating disc which distributes air in a predefined sequence	diaphragm which distributes air in a predefined sequence	Both devices provide the same output. No impact on safety & effectiveness as demonstrated by verification/validation testing performed
Accessories	4 - 12 cell garments	4 cell garments	Treated body areas are equivalent. Output is equivalent.
Cycle time	30 seconds full cycle, of which: 24 sec Inflation (2 sec per cell) 2 sec Hold 4 sec Deflation	Minimum Cycle Time: 20 seconds. Determined by pressure and pause settings, depending on garment size	The 701ELT allows the physician to predefine the pressure level & pause time. 201Max allows the physician to predefine the pressure level.
Display	LCD	Dial Selector	Both display pressure values.
Software/firmware	Proprietary	Proprietary	Changes were made to remove the digital display feature, add overpressure timeout.

8. Performance Data:

Non-clinical: As required by the risk analysis, verification, validation and testing activities were conducted to establish that the changes made to the device perform as designed. The following standards were included as part of the testing: IEC60601-1, IEC60601-2 and IEC TR-60721-2. The device passed all of the tests based on pre-determined Pass/Fail criteria.

9. Conclusions:

The data from consensus standard testing and comparison to the predicate device show that the Petite Basic System 701ELT is as safe and effective as the legally marketed predicate device.

Therefore Mego Afek, Ltd. conclude that the Petite Basic System 701ELT is substantially equivalent to the predicate device.



November 1, 2013

MEGO AFEK LTD.
Ms. Maria F. Griffin
mdi Consultants, Inc.
55 Northern Blvd., Suite 200
Great Neck, NY 11021

Re: K131420

Trade/Device Name: Petite Basic System 701 ELT
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: June 12, 2013
Received: June 14, 2013

Dear Ms. Griffin:

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 contact 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>. 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 -S

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

Enclosure

Indications for Use

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510(k) Number (if known): K131420

Device Name Petite Basic System 701ELT

Indications For Use:

- Primary lymphedema
- Secondary lymphedema
- Venous insufficiency
- Venous stasis ulcers
- Dysfunction of the "muscle pump"

Prescription Use X
(Per 21 CFR 801 Subpart D)

OR

Over-The Counter Use _____
(21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Bram D. Zuckerman -S

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