DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

April 04, 2016

Huntleigh Healthcare Ltd
Greg Baily
Technical Director
35 Portmanmoor Road
Cardiff, CF24 5HN United Kingdom

Re: K152228
Trade/Device Name: Hydroven 12 Pump and Garments
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: February 22, 2016
Received: February 24, 2016

Dear Greg Baily:

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 Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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,

for

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

Enclosure

510(k) Number: K152228

Device Name: **Hydroven 12 Pump and Garments.**

Indications for Use:

To enhance fluid flow into and along the vascular and lymphatic vessels. As a treatment for venous and lymphatic disorders.
As an effective in the treatment of the following clinical conditions, when combined with an individualized monitoring programme:

- Lymphedema.
  - Primary and secondary (including post-surgery, radio or chemotherapy).
- Chronic Edema of Venous Origin
- Chronic venous insufficiency.
- Acute and chronic wounds including venous leg ulcers and post- surgical wounds.

IPC may also be beneficial in the management of:

- Lipoedema.
- Varicose veins
- Postoperative Venous Ligation or Stripping
- Sports injuries
- Post Traumatic Edema
- Lymphatic Filariasis

Prescription Use		Over-The-Counter Use
YES	AND/OR	**NO**
(Part 21 CFR 801 Subpart D)		(Part 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)

HUNTLEIGH

510K Summary
Hydroven 12 Pump and Garments

Name & Address: Huntleigh Healthcare Ltd
Diagnostic Products Division
35 Portmanmoor Road
Cardiff, UK
CF24 5HN

Telephone: +(44) 2920 485885

Fax: +(44) 2920 447142

Prepared: July 2015

Contact: Greg Baily – Technical Director

Device Name: Hydroven 12 Pump and Garments

Common Name: Compressible Limb Sleeve

Classification:

Class	Product Code	Classification Regulation
II	JOW	870.5800

Classification Name: Sleeve, Limb, Compressible

Predicate Device: Lympha Press Plus and compression Garments (K013331) manufactured by Mego Afek AC Ltd. Kibbutz Afek, 30042, Israel

Indications for Use:

Indications for Use:

To enhance fluid flow into and along the vascular and lymphatic vessels. As a treatment for venous and lymphatic disorders.
As an effective in the treatment of the following clinical conditions, when combined with an individualized monitoring programme:

- Lymphedema.
  - Primary and secondary (including post-surgery, radio or chemotherapy).
- Chronic Edema of Venous Origin
- Chronic venous insufficiency.
- Acute and chronic wounds including venous leg ulcers and post-surgical wounds.

IPC may also be beneficial in the management of:

- Lipoedema.
- Varicose veins
- Postoperative Venous Ligation or Stripping
- Sports injuries
- Post Traumatic Edema
- Lymphatic Filariasis

Description : The Hydroven 12 system comprises of a range of inflatable sleeves,

inserts and a compatible air pump.
The sleeves fit around patients' upper and lower limbs. The sleeves contain separate but overlapping air chambers that intermittently compress the limbs in a specific sequence.
The resultant pressure on the patient's limb tissues promotes the transport of fluids and proteins.
The inflatable inserts can be added to allow large circumference limbs to be treated.
The pump provides the compressed air to the sleeves with user selected pressures and sequence of operation.

Models:

Model REF	Device	Features
316003US	Hydroven 12	AC powered pump
316A68, 316A78, 316AI68, 316AI78, 316L76S, 316L76W, 316L84S, 316L84W, 315LI76, 316LI84	Hydroven 12 garments.	Sequential inflation providing active compression.

Comparison of Technological Characteristics with Predicate Device

Intermittent Pneumatic Compression Therapy is the technological principle for both the subject and predicate devices. It is based on a pump and pneumatic garment combination. Whereby a garment with multiple internal air chambers is applied to the limb requiring therapy, the pump supplies air to inflate and deflate the garment chambers in sequence which compresses the limb. Applying a sequential compression to a limb takes over the permanently missing function of compromised lymphatics by squeezing edema tissue fluid to regions with normal lymphatic drainage.

The subject and predicate are based on the following same technological elements:

- An internal air source (air compressor)
- An electronic pressure control system
- A valve system to route air to the appropriate garment chamber
- A multiway pneumatic 'garment to pump' connection system
- PU Coated Nylon Garments
- Limb Garments with Multiple internal chambers
- Limb Garments with Zipper closures
- Front panel display indicating device settings

The following technological difference exist between the subject and predicate devices

- Subject uses low voltage compressor – predicate uses AC line powered compressor
- Subject uses motor driven rotary air valve – predicate uses a series of solenoid driven air valves
- Subject uses multiple LED displays – predicate uses a single LCD display

Substantial Equivalence:

The Hydroven 12 Pump and Garments is substantially equivalent to cleared device Lympha Press Plus and compression garments (K013331). The Hydroven 12 pump provides equivalent pressure profiles. The Hydroven 12 garments have similar construction and deliver substantially equivalent therapy.

Testing to demonstrate equivalence included:

Testing conducted	Result
Full validation of pump software / hardware functionality, including - User Interface - Therapy delivery	Passed
Performance testing garments – Pressure cyclic test. with Leg garments with Arm garments	Passed
Electrical Testing to Standard ANSI/AAMI ES60601-1:2005/(R)2012, C1:2009/(R)2012 and A2:2010/(R)2012	Complies with Standard
EMC testing to Standard IEC 60601-1-2, 2007	Complies with Standard
Environmental Stability testing. -Storage / Distribution Test. -Operational Temperature /Humidity Test.	Passed

Technologies Summary:

The Hydroven 12 pump consists of an air compressor, distribution valve and a microcontroller based control and monitoring system, all housed in a portable enclosure.
Options of pressure settings and cycle sequences can be selected by the user.
The system is powered by standard 60Hz AC line supply. The monitoring system can alert the user to faults.

The Hydroven 12 garments comprise of 12 separate air bladders constructed from RF welded polyurethane sheet material.
The cells are located in between the inner and outer covers, which are made from woven nylon/PU laminate materials.
The sleeve is fastened around the patient's limb by a zipper.
The cells overlap, in order to apply a continuous area of force along the limb.

Conclusion:

The data detailed within this submission demonstrates that the device is substantially equivalent to the legally marketed predicate device, identified in this summary.