

FEB 13 1998

HEALTHCARE SERVICE AND SUPPLY  
510(k) SUMMARY  
ALP® (Alternating Leg Pressure) Pump and Garments

K974318

**I. NAME OF SUBMITTER**

Healthcare Service and Supply  
P.O. Box 1788  
Tustin, CA 92681  
Phone: (714) 669-8803

Contact person: Rick Roeder  
Establishment Registration Number: 2030561

**II. DEVICE NAME AND CLASSIFICATION**

Proprietary Name: Healthcare Service and Supply ALP® Alternating Leg  
Pressure Pump and Garments for the Limb  
Common or Usual Name: Compression Sleeve, Limb  
Classification: Class II; CV JOW 870.5800

**III. PREDICATE DEVICES**

The Healthcare Service and Supply ALP® Pump and Limb Garments are substantially equivalent to devices in commercial distribution by the following companies:

- Healthcare Service and Supply ALP® 501 Pump System, Tustin, CA 992681; K955853
- Huntleigh Technology DVT System AC500, L501 Garment, Manalapan, NJ, 07726; K881632

**IV. DESCRIPTION**

The ALP consists of an electrically-operated pump and controller with inflatable limb garments (or limb compression sleeves). The ALP® 501 pump, when used in connection with the Limb Garments, supplies a measured, intermittent, fully adjustable pressure into the limb garments worn by the patient. The pump and controller rhythmically squeeze the limb in a simulation of normal muscle contraction, by pumping air into the air bladder garments wrapped around the leg.

The ALP® Pump and Limb Garments are provided non-sterile.

## **V. INTENDED USE**

The intended use of this device, as well as the predicate devices, is to provide for external limb compression in order to artificially imitate the pumping action of the leg muscles. This provides the muscle contraction required by the venous return system, thereby helping to prevent venous stasis and subsequent thrombosis and embolism. The cyclic and alternating inflation and deflation of the garments closely simulates the normal healthy pumping action of the limb muscles to stimulate deep venous blood flow and the reactivation or increase in the body's fibrinolytic system.

This submission is intended to demonstrate equivalence in the use of the ALP<sup>®</sup> limb garments with the Huntleigh Healthcare Flowtron<sup>®</sup> DVT AC500 pump. The ALP<sup>®</sup> limb garments, when used with either the ALP<sup>®</sup> 501 pump or the Huntleigh AC500 pump, are safe and effective for their intended use for reducing the incidence of deep vein thrombosis and resulting pulmonary embolism, and increasing the circulation of blood in patients with restricted mobility through the use of external intermittent limb compression.

## **VI. TECHNOLOGICAL CHARACTERISTICS**

The ALP<sup>®</sup> Pump and Limb Garments has the same technological characteristics as its predicate devices. The materials used in the limb garments are the same and the operation of the pumps and the garments is also the same.

No new technology is being introduced in the design of the ALP<sup>®</sup> Pump and Limb Garments. The limb garments are to be used as part of an external compression pump system, where intermittent pneumatic compression is provided through the use of a pump/controller and limb garment system. The two referenced pumps are equivalent in specifications and in performance, and the performance of the compression garments with either pump is the same. Healthcare Service and Supply has performed a variety of tests which demonstrate that the use of the Healthcare Service and Supply compression garments with the Huntleigh pump is equivalent in effectiveness and safety to the use of these garments with the ALP<sup>®</sup> 501 pump.



FEB 13 1998

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850Mr. Rick Roeder  
President  
Healthcare Service and Supply  
P.O. Box 1788  
Tustin, CA 92681Re: K974318  
ALP® Alternating Leg Pressure) Pump and Garments  
Regulatory Class: II (Two)  
Product Code: JOW  
Dated: November 17, 1997  
Received: November 17, 1997

Dear Mr. Rick Roeder:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Pre-market Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 - Mr. Rick Roeder

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>."

Sincerely yours,



Thomas J. Callahan, Ph.D.

Director

Division of Cardiovascular, Respiratory,  
and Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Include the following "Indications For Use" page that contains the applicant's name, name of the device and the intended use of the device. The information, data and labeling claims in the entire the 510(k) submission must support and agree with the "indications for use" statement.

\*For a new submission, do NOT fill in the 510(k) number blank.

### INDICATIONS FOR USE

Applicant: **Healthcare Service and Supply**

510(k) Number (if known): N/A\*

Device Name: **ALP® (Alternating Leg Pressure) Pump and Garments**

Indications For Use:

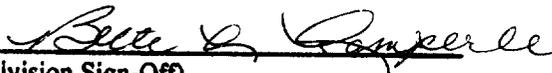
The Healthcare Service and Supply ALP® 501 Pump and Limb Garments are recommended for use in patients for whom external compression therapy using the ALTERNATING LEG PRESSURE SYSTEM® (ALP®) is indicated to reduce the incidence of deep vein thrombosis and resulting pulmonary embolism due to the presence of risk factors for thrombosis formation.

The Healthcare Service and Supply garments are attachable to the ALP® Pump as well as to the Huntleigh Flowtron® pump.

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

---

Concurrence of CDRH Office of Device Evaluation (ODE)

  
(Division Sign-Off)  
Division of Cardiovascular, Respiratory,  
and Neurological Devices

510(k) Number     K974318    

Prescription Use     ✓      
Per 21 CFR 801.109

OR

Over-the-Counter