K965153

510(k) Summary

FP5000 System

JAN 26 1998

The FP5000 System is an external pneumatic compression system comprised of a pump which supplies compressed air to a pair of foot wrap garments. The garments alternately inflate to provide compression to the venous plantar plexus of the foot. Venous plantar plexus compression move blood out of the leg, and may be used to prevent deep vein thrombosis (DVT), and as part of the treatment regimen for venous and arterial conditions of the lower limbs.

The system is designed to provide therapy comparable to existing marketed devices such as the AV5000 system (Kendall) and the PlexiPulse system (NuTech/KCI). There are no changes to the claims, intended use, clinical applications, patient population, performance specifications, or method of operation. Laboratory evaluation on healthy subjects documented that the venous outflow velocity, as measured at the common femoral vein, is comparable between the FP5000 System and the two predicate systems.

There are no performance standards established for this category of medical device (Class II - Compressible Limb Sleeves). Voluntary standards met include UL listing and compliance with the European Medical Directive for electromagnetic compatability.

The FP5000 System raises no new safety or effectiveness concerns.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Audrey Witko
Director of Corporate Affairs
Huntleigh Healthcare Inc.
227 Route 33 East
Manalapan, NJ 07726

JAN 26 1998

Re: K965153
Huntleigh FP5000 System Model FP5000
Regulatory Class: II (Two)
Product Code: JOW
Dated: October 30, 1997
Received: October 31, 1997

Dear Ms. Witko:

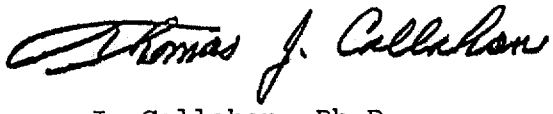
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 (Premarket 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.

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

510(k) Number (if known): K965153

Device Name: Huntleigh FP5000 System

Indications For Use:

1. Prevention of deep vein thrombosis
2. Enhancement of venous & arterial circulation
3. Preventionof venous stasis
4. Assist healing of cutaneous ulcers
5. Reduction of acute or chronic edema
6. Reduction of lower limb pain due to surgery or trauma
7. Reduction of compartmental pressures

(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 K965153

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)