

510(k) Summary

Summary

Substantial Equivalence Summary for the Hygia Health Services Reprocessed Huntleigh Flowtron® DVT Compression Sleeves

In accordance with 21 CFR Part 807.92, this summary is submitted by:

Hygia Health Services, Inc.
2800 Milan Court
Suite 259
Birmingham, Alabama 35211

Date: July 31, 2001

1. Contact Person

Geoff M. Fatzinger
Director, Compliance and Regulatory Affairs
(205) 943-6670

2. Name of Device

Classification Name: Compressible Limb Sleeve
Common or Usual Name: Intermittent Pneumatic Compressible Limb Sleeve
Review Panel: Cardiovascular
Classification: Class II
Proprietary Name: Hygia Health Services Reprocessed Huntleigh Flowtron®
DVT Sleeve.

3. Predicate Device

Classification Name: Compressible Limb Sleeve
Common Name: Intermittent Pneumatic Compressible Limb Sleeve
Classification: Class II
Proprietary Name: Huntleigh Flowtron® DVT Garment

4. Statement of Substantial Equivalence

The Hygia Health Services Reprocessed Huntleigh Flowtron® DVT Sleeve employs no new technology other than the method used to reprocess the sleeve in order to allow the device to be utilized more than once. The Hygia Health Services Reprocessed Huntleigh Flowtron® DVT Sleeve is substantially equivalent to the Huntleigh Flowtron® DVT in that the basis of operation for both of the devices is the intermittent inflation of a single bladder, which is placed around the patient's lower limbs. The sleeves are then connected to a controller via a set of connecting tubes that range from 60-inches in length to 120-inches in length. Inflation of the sleeve is accomplished using ambient air and a controller cycle that functions to alternately inflate and deflate the sleeves in a predetermined manner and interval.

The Hygia Health Services Reprocessed Huntleigh Flowtron® DVT Sleeve is substantially equivalent in function, operating parameters, and intended use to the Huntleigh Flowtron® DVT sleeve that is currently commercially available and in distribution. There is no significant change in the device, the predicate Huntleigh Flowtron® DVT sleeve is marked for "single-patient use" only. Hygia Health Services reprocess the sleeve via thermal high-level disinfection (HLD) so as to make the sleeve able to be reused. The Hygia Health Services HLD protocol does not alter the device's efficacy, safety, composition, or intended use.

5. Description of the Device

The Hygia Health Services Reprocessed Huntleigh Flowtron® DVT sleeve is a compressible limb device that, when attached to an approved controller, provides intermittent pneumatic compression. The sleeve is constructed out of brushed nylon with a polyester foam lining. The single bladder is constructed of poly vinyl chloride (PVC), as is the inflation/deflation tube. The binding is a polyester/cotton blend, and the hook fasteners are made of polyethylene. The tube terminates in a snap lock connector. The sleeves are placed around the leg and secured with a hook and loop fastener. As the sleeves compress the leg, veins collapse, increasing the venous pressure thus ejecting the blood upward toward the heart. After compression, the sleeves deflate allowing the veins to refill and bring oxygenated blood to the lower limbs. The controller predetermines the inflation

and deflation sequence. The pressure of compression is determined by the controller and is adjusted by altering the readout on the controller.

6. Intended Use of Device

The Hygia Health Services Reprocessed Huntleigh Flowtron® DVT Sleeve is designed to operate in the identical manner as the predicate device, the Huntleigh Flowtron® DVT. It is designed to apply compression to a patient's lower limbs for the prevention of deep vein thrombosis (DVT) as well as the treatment of edema secondary to venous insufficiency. The device is used in both the home and institutional settings on patient populations for which this device applicable.

7. Technological Characteristics

The technological characteristics of the Hygia Health Services Reprocessed Huntleigh Flowtron® DVT sleeve are identical to the original Huntleigh Flowtron® DVT in overall design, materials, energy source, mode of operation, and performance characteristics.

8. Performance Data

Nonclinical Tests- Comparative bench testing was utilized to assess and prove similarity of function between the Hygia Health Services Reprocessed Huntleigh Flowtron® DVT sleeve and the predicate device, the Huntleigh Flowtron® DVT. All tests found that functional and operational performance characteristics including compression, pressure control, timing sequence, and both safety and operational parameters used when connected to a controller were substantially equivalent.

Clinical Tests- Clinical tests were summarized in support of the premarket notification submission.

Test Conclusions- Clinical and nonclinical test results of the Hygia Health Services Reprocessed Huntleigh Flowtron® DVT Sleeve indicated substantial equivalence in all aspects to the predicate device, the Huntleigh Flowtron® DVT Garment.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 12 2002

Mr. Geoff M. Fatzinger, BS MS
Director, Compliance and Regulatory Affairs
c/o Hygia Health Services, Inc.
2800 Milan Court, Suite 259
Birmingham, AL 35211

Re: K012654
Trade Name: Hygia Health Services Reprocessed Huntleigh Flowtron® DVT Sleeve
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II (two)
Product Code: JOW
Dated: February 7, 2002
Received: February 8, 2002

Dear Mr. Fatzinger:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), 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 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); 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.

This letter will allow you to begin marketing your device as described in your Section 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 21 CFR Part 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Donna-Bea Tillman, Ph.D.

Acting Director

Division of Cardiovascular
and Respiratory Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

P1/2

INDICATIONS FOR USE

Applicant: Hygia Health Services, Inc.

510(k) Number: K012654

Device Name: Hygia Health Services Reprocessed Huntleigh Flowtron® Single

Pulse DVT Sleeve

COPY

Indications For Use:

The Hygia Health Services Reprocessed Huntleigh Flowtron® Single Pulse DVT Sleeve is used as a non-invasive therapeutic method to prevent deep vein thrombosis, and treat venous leg ulcers and edema that result from venous insufficiency.

PRECAUTIONS AND CONTRAINDICATIONS

Contraindications:

Sleeves may not be recommended for patients with the following:

1. Any local leg condition in which sleeves would interfere such as dermatitis, gangrene, recent skin graft, untreated infected wounds, or vein ligation (immediate postoperative).
2. Congestive heart failure.
3. Severe arteriosclerosis or other ischemic vascular disease
4. Pulmonary edema
5. Known or suspected deep vein thrombosis or phlebitis
6. Deformity of the leg

Precautions:

1. One must ensure that the sleeve is applied properly.
2. One must ensure that the sleeve is correctly connected to the pump and that the connection is secure.

