FEB 15 2006

K053575

510(k) Summary

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

Hygia Health Services, Inc.
434 Industrial Lane
Birmingham, Alabama 35211
Phone: (205) 314-3920
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Date Prepared: December 19, 2005

1. Contact Person

Mr. Kyle Ferguson
R&D Director
Phone: (205) 314-3920
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Email: kyle.ferguson@hygia.net

2. Name of Device

Classification Name:	Sleeve, Limb, Compressible
Common Name:	Compressible Limb Sleeve Device
Trade or Proprietary Name:	Hygia Health Services Reprocessed Sleeves/Foot Cuffs

3. Predicate Device

Corresponding Kendall, Aircast, and Healthcare Service and Supply Sleeves/Foot Cuffs legally marketed under various 510(k) premarket notifications:

Tyco Healthcare/Kendall	K040511
Tyco Healthcare/Kendall	K040649
Healthcare Service and Supply	K974318
Aircast, Inc.	K992454

Previous Hygia Health Services (HHS) devices which are found to be substantially equivalent:

HHS Reprocessed Kendall SCD™ Sleeves K012417

HHS Reprocessed Huntleigh Flowtron®	K012654
HHS Reprocessed Novamedix Impad®	K021509

4. Device Description

The Hygia Health Services reprocessed sleeves/foot garments are compression devices that, when attached to an approved controller, provide intermittent, sequentially gradient pressure to a patient's leg/foot for the prevention of Deep Vein Thrombosis (DVT). As the sleeves/cuffs compress the legs/feet, veins collapse, forcing the blood to move upward towards the heart. After compression, the sleeves/cuffs deflate which allows the veins to reopen and bring oxygenated blood to the region. The inflation and deflation sequence is predetermined by the products specific controller. The pressure of compression is determined by the controller.

5. Device Intended Use

The Hygia Health Services reprocessed sleeves/foot garments are intended to be used in the same manner as the predicated devices. They are designed to apply intermittent pneumatic compression to the lower limbs to help prevent deep vein thrombosis in patients at risk. The devices are intended to be used in both the home and institutional settings on patient populations for which these devices are applicable.

6. Technological Characteristics

The Hygia Health Services reprocessed sleeves/foot garments are identical to the original OEM devices in reference to the technological characteristics. The overall designs, materials, energy sources, modes of operation, and performance characteristics are no different than the original devices.

7. Performance Data

Functional Testing, cleaning validation, and biocompatibility testing demonstrates that the reprocessed sleeves/foot cuffs perform as intended and are safe and effective.

8. Conclusion

Based on the assessment of functional testing, cleaning validation, and biocompatibility testing performed, Hygia Health Services concludes that the Hygia Health Services reprocessed sleeves/foot cuffs are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 15 2006

Hygia Health Services
c/o Mr. Kyle Ferguson
434 Industrial Lane
Birmingham, Alabama 35211

Re: K053575
Hygia Health Services Reprocessed Sleeves/Foot Cuffs
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II (Two)
Product Code: JOW
Dated: December 19, 2005
Received: December 23, 2005

Dear Mr. Ferguson:

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), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number (if known): K053575

Device Name: Hygia Health Services Reprocessed Aircast Sleeves/Foot Cuffs

Indications For Use:

The Hygia Health Services Reprocessed Aircast Sleeves/Foot Cuffs are used in the treatment of venous leg/foot ulcers and edema which are disorders associated with venous insufficiency.

The Hygia Health Services Reprocessed Aircast Sleeves/Foot Cuffs are also a non-invasive therapeutic method for prevention of deep vein thrombosis.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K053575