

# 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  
Fax: (205) 314-3959

APR 22 2009

Date Prepared: November 26, 2008

1. Contact Person

Jerome James  
Director, R&D  
Phone: (205) 314-3920  
Fax: (205) 314-3959  
Email: [jerry.james@hygia.net](mailto:jerry.james@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 CTC and Venodyne Compression Sleeves/Foot Cuffs legally marketed under various 510(k) premarket notifications:

K061967	Compression Therapy Concepts
K061814	Compression Therapy Concepts
K000147	Compression Therapy Concepts
K022786	Huntleigh Healthcare
K010744	Huntleigh Healthcare
K974318	Healthcare Services and Supply
K011318	Microtek Medical, Inc.
K001802	Microtek Medical, Inc.
K930526	Microtek Medical, Inc.

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

HHS Reprocessed Sleeves/Foot Cuffs	K053575
HHS Reprocessed Kendall SCD™ Sleeves	K012417
HHS Reprocessed Huntleigh Flowtron®	K012654
HHS Reprocessed Huntleigh Foot Cuff	K012651

#### 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 product's 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.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

APR 22 2009

Hygia Health Services, Inc.  
c/o Mr. Jerome James  
Director of R&D  
434 Industrial Lane  
Birmingham, AL 35211

Re: K090074

Hygia Health Services Reprocessed Venodyne Sleeves & Foot Cuffs and CTC VasoPress  
Compression Sleeves  
Regulation Number: 21 CFR §870.5800  
Regulation Name: Sleeve, Limb, Compressible  
Regulatory Class: Class II  
Product Code: JOW  
Dated: December 31, 2008  
Received: January 12, 2009

Dear Mr. James:

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.

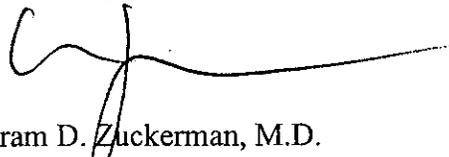
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to <http://www.fda.gov/cdrh/mdr/>.

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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



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

Enclosure

## K090074

Applicant: Hygia Health Services, Inc.  
434 Industrial Lane  
Birmingham, AL 35211

Classification: Class II, 870.5800  
Product Code: JOW  
Common Name: Compressible Limb Sleeve

Device Name: Hygia Health Services (HHS) Reprocessed Venodyne Sleeves  
Hygia Health Services (HHS) Reprocessed Venodyne Foot Cuffs  
Hygia Health Services (HHS) Reprocessed CTC VasoPress Compression Sleeves

OEM Catalog #	Hygia Catalog #	Product Description	Max. # Reprocessing Cycles
V3012	HHS-V3012	Venodyne Sleeve Size 12"-16"	10
V3014	HHS-V3014	Venodyne Sleeve Size 14"-18"	10
V3022	HHS-V3022	Venodyne Sleeve Size 14"-20.5"	10
V3026	HHS-V3026	Venodyne Sleeve Size 14"-24"	10
V6010	HHS-V6010	Venodyne Foot Cuff	10
VP501M	HHS-VP501M	VasoPress Calf Garment, Med.	5
VP501L	HHS-VP501L	VasoPress Calf Garment, Lg	5
VP530M	HHS-VP530M	VasoPress Thigh Garment, Med.	5
VP530L	HHS-VP530L	VasoPress Thigh Garment, Lg	5

1K090074

### Indications for Use

510(k) Number (if known): 1K090074

Device Name: Hygia Health Services Reprocessed Venodyne Sleeves

#### Indications For Use:

The Hygia Health Services Reprocessed Venodyne Sleeves are used in the treatment of venous leg ulcers and edema which are disorders associated with venous insufficiency.

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

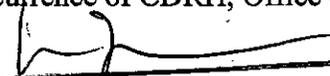
Prescription Use   x    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

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NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Cardiovascular Devices  
510(k) Number 1K090074

K090074

### Indications for Use

510(k) Number (if known): K090074

Device Name: Hygia Health Services Reprocessed CTC VasoPress Compression Sleeves

**Indications For Use:**

The Hygia Health Services Reprocessed CTC VasoPress Compression Sleeves are used as a non-invasive therapeutic method to prevent deep vein thrombosis, and treat venous leg ulcers and edema that result from venous insufficiency.

Prescription Use   x    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF  
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Concurrence of CDRH, Office of Device Evaluation (ODE)



\_\_\_\_\_  
(Division Sign-Off)  
Division of Cardiovascular Devices  
510(k) Number K090074

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K090074

## Indications for Use

510(k) Number (if known): K090074

Device Name: Hygia Health Services Reprocessed Venodyne Foot Cuffs

### Indications For Use:

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

Prescription Use   x    
(Part 21 CFR 801 Subpart D)

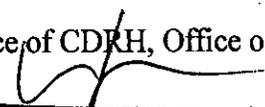
AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

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NEEDED)

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Concurrence of CDH, Office of Device Evaluation (ODE)

  
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(Division Sign-Off)

Division of Cardiovascular Devices

510(k) Number K090074

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