K031559

Hygia West
Medical Device Reprocessor

510(k) Summary

Summary

Substantial Equivalence Summary for Hygia West Reprocessed Compression Garments.

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

Geoff M. Fatzinger

and

Hygia West, Inc.
9800 Evergreen Way
Everett, Washington 98204

Date: May 13, 2003

1. Contact Person

Geoff M. Fatzinger
Director of Compliance and Regulatory Affairs
Hygia West Corporate Office 425-353-1110

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 Names: Hygia West Reprocessed Novamedix ImPad
Hygia West Reprocessed Huntleigh DVT
Hygia West Reprocessed Huntleigh Foot Wrap
Hygia West Reprocessed Kendall SCD

Proprietary Names (cont): Hygia West Reprocessed NuTech Plexipulse
Hygia West Reprocessed NuTech Combo
Hygia West Reprocessed NuTech Calf Wrap
Hygia West Reprocessed Venodyne

3. Predicate Devices

Classification Name: Compressible Limb Sleeve
Common Name: Intermittent Pneumatic Compressible Limb Sleeve
Classification: Class II
Proprietary Name: Novamedix ImPad® A-V Impulse System Rigid Sole Foot Cover

Classification Name: Compressible Limb Sleeve
Common Name: Intermittent Pneumatic Compressible Limb Sleeve
Classification: Class II
Proprietary Name: Hygia Health Services Reprocessed Novamedix ImPad®
510(k) number: K021509

Classification Name: Compressible Limb Sleeve
Common Name: Intermittent Pneumatic Compressible Limb Sleeve
Classification: Class II
Proprietary Name: Huntleigh DVT Compression Sleeves

Classification Name: Compressible Limb Sleeve
Common Name: Intermittent Pneumatic Compressible Limb Sleeve
Classification: Class II
Proprietary Name: Hygia Health Services Reprocessed Huntleigh DVT
510(k) number: K012654

Classification Name: Compressible Limb Sleeve
Common Name: Intermittent Pneumatic Compressible Limb Sleeve
Classification: Class II
Proprietary Name: Huntleigh Foot Wrap

Classification Name: Compressible Limb Sleeve
Common Name: Intermittent Pneumatic Compressible Limb Sleeve
Classification: Class II
Proprietary Name: Hygia Health Services Reprocessed Huntleigh Foot Wrap
510(k) number: K012651

Hygia West
9800 Evergreen Way • Everett, WA. 98204
VOICE 425-353-1110 • FAX 425-353-9116

Predicate Devices (cont):

Classification Name: Compressible Limb Sleeve
Common Name: Intermittent Pneumatic Compressible Limb Sleeve
Classification: Class II
Proprietary Name: NuTech Calf Wrap

Classification Name: Compressible Limb Sleeve
Common Name: Intermittent Pneumatic Compressible Limb Sleeve
Classification: Class II
Proprietary Name: Hygia Health Services Reprocessed NuTech Calf Wrap
510(k) number: K012657

Classification Name: Compressible Limb Sleeve
Common Name: Intermittent Pneumatic Compressible Limb Sleeve
Classification: Class II
Proprietary Name: NuTech Combo

Classification Name: Compressible Limb Sleeve
Common Name: Intermittent Pneumatic Compressible Limb Sleeve
Classification: Class II
Proprietary Name: Hygia Health Services Reprocessed NuTech Combo
510(k) number: K012956

Classification Name: Compressible Limb Sleeve
Common Name: Intermittent Pneumatic Compressible Limb Sleeve
Classification: Class II
Proprietary Name: NuTech Plexipulse System

Classification Name: Compressible Limb Sleeve
Common Name: Intermittent Pneumatic Compressible Limb Sleeve
Classification: Class II
Proprietary Name: Hygia Health Services Reprocessed NuTech Plexipulse
510(k) number: K012650

Classification Name: Compressible Limb Sleeve
Common Name: Intermittent Pneumatic Compressible Limb Sleeve
Classification: Class II
Proprietary Name: Kendall SCD

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Predicate Devices (cont):

Classification Name: Compressible Limb Sleeve
Common Name: Intermittent Pneumatic Compressible Limb Sleeve
Classification: Class II
Proprietary Name: Hygia Health Services Reprocessed Kendall SCD
510(k) number: K012417

Classification Name: Compressible Limb Sleeve
Common Name: Intermittent Pneumatic Compressible Limb Sleeve
Classification: Class II
Proprietary Name: Microtek Medical Venodyne Sleeve

4. Statement of Substantial Equivalence

The Hygia West Reprocessed Compression Garments employ no new technology other than the method used to reprocess the garment in order to allow the device to be utilized more than once. The Hygia West Reprocessed Compression Garments are substantially equivalent to the listed predicate devices in that the basis of operation of the devices is the intermittent inflation of a bladder or chamber, which is placed around the patient's lower limb. The devices are used on the calf, thigh, whole leg, or foot. The garments are then connected to an approved and device appropriate controller. Inflation of the device is accomplished using ambient air, and a controller cycle that functions to alternately inflate and deflate the device in a predetermined manner and interval.

The Hygia West Reprocessed Compression Garments are substantially equivalent in function, operating parameters, and intended use to the listed predicate devices that are currently commercially available and in distribution. The predicate devices are marked for "single-patient use only" as are the Hygia West devices. Hygia West does not change the devices in any way except to render the device "reusable" by placing it through a scientifically verified chemical free high-level disinfection process. The Hygia West high-level disinfection protocol does not alter the device's efficacy, safety, composition, or intended use. Hygia West employs very strict device protocols, unique and stringent testing procedures, innovative, and demanding quality measures that in many cases exceed those of the predicate device companies. Although our processes are very different, the core concept regarding the high-level disinfection process is identical to the method used by Hygia Health Services, Inc in their approved reprocessed devices.

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5. Description of the Devices

The Hygia West Reprocessed Compression Garments are intermittent compressible limb devices that are placed around either the patient's foot (with the compression chamber placed under the plantar arch), calf (gastrocnemius muscle), thigh, or a combination there of. The garments are constructed from materials that are common to the medical device industry. Depending on the type of device, the method of fastening to the patient may vary from a hook and loop closure system to a uni-body style that is slipped over the limb. In foot compression devices, as the garment compresses the plantar plexus, the veins collapse longitudinally; this action causes an increase in the venous pressure thus ejecting the blood upward. After compression, the devices deflate allowing the veins to refill bringing oxygenated blood to the lower limbs. In devices used on the calf or thigh the compression to the area causes the blood to be ejected upwards to the heart, as the compression relaxes the valves in the veins close allowing them to refill. This cyclical method removes deoxygenated or stale blood from the region allowing fresh blood to be received. On all devices the controller predetermines the inflation and deflation sequence. The operational characteristics such as the pressure of compression, hold time, and inflation/deflation time are determined by the controller. It is the responsibility of the end user to ensure that the device is connected to an approved controller and to ensure that the controller settings are accurate. *Hygia West does not repair, refurbish, or reprocess the controlling unit. Hygia West guarantees 100% of our devices ONLY if it has been connected to an approved, functional, and correctly adjusted controller.*

Hygia West has included a device specific summary including relevant comparisons in each individual device section. (Please see tab marked "Summary" in each chapter)

6. Intended Use of Device

The Hygia West Reprocessed Compression Garments operate in the identical manner as the predicate devices. They are designed for the prevention of deep vein thrombosis (DVT) as well as the treatment of edema secondary to venous insufficiency. The devices are used in both the home and institutional settings.

7. Technological Characteristics

The technological characteristics of the Hygia West Reprocessed Compression Garments are identical to the predicate devices in overall design, materials, energy source, mode of operation, and performance characteristics.

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8. Performance Data

Non-clinical Tests- Comparative bench testing was utilized to assess and prove similarity of function between the Hygia West Reprocessed Compression Garments and the predicate devices. All tests found that functional and operational performance characteristics including compression, pressure capabilities, safety, and operational parameters were substantially equivalent.

9. Biocompatibility

In order to ensure that the high-level disinfection program does not adversely affect the biocompatibility of the device, a NIH level combination irritation/sensitization human skin patch test was conducted. The detailed protocols of the study are included for each device in that specific device section. No signs of irritation or sensitization were found.

10. Process Validation

Process validation information has been provided as part of this submission to demonstrate the effectiveness of this type of technology.

11. Conclusions

Test Conclusions- Non-clinical and biocompatibility test results indicated substantial equivalence in all aspects to the predicate devices.

Hygia West
9800 Evergreen Way • Everett, WA. 98204
VOICE 425-353-1110 • FAX 425-353-9116

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 12 2003

ReNu Medical
c/o Mr. Geoff M. Fatzinger
Director of Compliance and Regulatory Affairs
9800 Evergreen Way
Everett, WA 98204

Re: K031559
Trade Name: ReNu Medical Reprocessed Compressible Limb Sleeves
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II (two)
Product Code: JOW
Dated: May 13, 2003
Received: May 29, 2003

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.

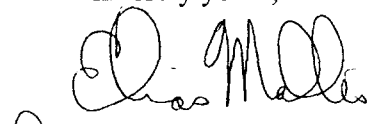
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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), please contact the Office of Compliance at (301) 594-4646. 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/dsma/dsmamain.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

Applicant: Hygia West, Inc.

510(k) Number: K031559

Device Name: Hygia West Reprocessed Huntleigh DVT Sleeve

Indications For Use:

The Hygia West Reprocessed Huntleigh DVT Sleeve is to be used by patients in both the home and institutional settings used as a non-invasive therapeutic method to:

- Prevent deep vein thrombosis and resulting pulmonary embolism
- Intra-operative compression therapy

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.
2. Congestive heart failure.
3. Severe arteriosclerosis or other ischemic vascular disease
4. Pulmonary edema
5. Known or suspected deep vein thrombosis or phlebitis

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Indications for Use

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.

3. If numbness, tingling, or leg pain is experienced by the patient, the sleeve should be removed.

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