K101702
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510(k) Summary

AUG 27 2010

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

Midwest Reprocessing Center, LLC.
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Date Prepared: June 16, 2010

1. Contact Person

Jerome James
Consultant
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2. Name of Device

Classification Name: Sleeve, Limb, Compressible
Classification Product Code: JOW
Common Name: Compressible Limb Sleeve Device
Trade or Proprietary Name: Midwestern Reprocessing Center Reprocessed Sleeves/Foot Cuffs

3. Predicate Devices

Corresponding Compression Sleeves/Foot Cuffs legally marketed under various 510(k) premarket notifications:

510(k)	Product	Manufacturer
K090074, K012956, K012657, K012654, K012651, K012650	Reprocessed Compression Sleeves and Foot Cuffs	Hygia Health Services, Inc.
K061967, K061814, K000147	VasoPress Compression Sleeve	Compression Therapy Concepts
K011318, K001802, K930526	Venodyne Sleeves and Foot Cuffs	Microtek Medical, Inc.
K881632	Flowtron Garments	Huntleigh Healthcare
K981311,K944567	Nutech Combo, Calf Wrap, and Foot Wrap	Kinetic Concepts, Inc.

4. Device Description

The Midwestern Reprocessing Center 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 Midwestern Reprocessing Center 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 Midwestern Reprocessing Center 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, Midwestern Reprocessing Center concludes that the Midwestern Reprocessing Center reprocessed sleeves/foot cuffs are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Midwest Reprocessing Center
c/o Mr. Jerome James
Regulatory Consultant
3995 Fashion Square Blvd., Suite 11
Saginaw, MI 48603

AUG 27 2010

Re: K101702
Midwest Reprocessing Center Reprocessed Venodyne Sleeves
Midwest Reprocessing Center Reprocessed Venodyne Foot Cuffs
Midwest Reprocessing Center Reprocessed CTC VasoPress Compression Sleeves
Midwest Reprocessing Center Reprocessed Nutech® Combo
Midwest Reprocessing Center Reprocessed Nutech® Calf Wrap
Midwest Reprocessing Center Reprocessed Nutech® Foot Wrap
Midwest Reprocessing Center Reprocessed Huntleigh Flowtron® Single Pulse DVT Sleeves
Midwest Reprocessing Center Reprocessed Huntleigh Foot Wrap
Regulation Number: 21 CFR §870.5800
Regulation Name: Sleeve, Limb, Compressible
Regulatory Class: Class II (two)
Product Code: JOW
Dated: June 16, 2010
Received: June 17, 2010

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

Enclosure

K101702

Indications for Use

510(k) Number (if known): _____

Device Name: Midwest Reprocessing Center Reprocessed Venodyne Sleeves

Indications For Use:

The Midwest Reprocessing Center Reprocessed Venodyne Sleeves are used in the treatment of venous leg ulcers and edema which are disorders associated with venous insufficiency.

The Midwest Reprocessing Center 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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Concurrence of CDRH, Office of Device Evaluation (ODE)

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of Cardiovascular Devices
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Indications for Use

510(k) Number (if known): _____

Device Name: Midwest Reprocessing Center Reprocessed Venodyne Foot Cuffs

Indications For Use:

The Midwest Reprocessing Center Reprocessed Venodyne Foot Cuffs are used in the treatment of venous leg / foot ulcers and edema which are disorders associated with venous insufficiency.

The Midwest Reprocessing Center 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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Indications for Use

510(k) Number (if known): _____

Device Name: Midwest Reprocessing Center Reprocessed CTC VasoPress Compression Sleeves

Indications For Use:

The Midwest Reprocessing Center 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)

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Indications for Use

510(k) Number (if known): _____

Device Name: Midwest Reprocessing Center Reprocessed Nutech® Combo

Indications For Use:

The Midwest Reprocessing Center Reprocessed NuTech® Combo is used as a non-invasive therapeutic method by patients in the home or institutional setting in order to:

- Prevent deep vein thrombosis
- Reduce wound healing time
- Treat and assist healing of venous leg ulcers
- Reduce edema caused by venous insufficiency in the lower extremities

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

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Indications for Use

510(k) Number (if known): _____

Device Name: Midwest Reprocessing Center Reprocessed Nutech® Calf Wrap

Indications For Use:

The Midwest Reprocessing Center Reprocessed NuTech® Calf Wrap is used as a non-invasive therapeutic method to be used by patients in the home or institutional setting in order to:

- Prevent deep vein thrombosis
- Reduce wound healing time
- Treat and assist healing of venous leg ulcers
- Reduce edema caused by venous insufficiency in the lower extremities

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

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Indications for Use

510(k) Number (if known): _____

Device Name: Midwest Reprocessing Center Reprocessed Nutech® Foot Wrap

Indications For Use:

The Midwest Reprocessing Center Reprocessed NuTech® Foot Wrap is designed to enhance circulation of blood in the venules and arterioles. It to be used by patient's in both the home and institutional settings as a non-invasive therapeutic method to prevent:

- Deep vein thrombosis
- Reduce wound healing time
- Treat and assist healing of venous leg ulcers
- Reduce edema caused by venous insufficiency in the lower extremities
- Decrease compartmental pressures

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

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Indications for Use

510(k) Number (if known): _____

Device Name: Midwest Reprocessing Center Reprocessed Huntleigh Flowtron® Single Pulse DVT Sleeve

Indications For Use:

The Midwest Reprocessing Center 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.

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

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K101702

Indications for Use

510(k) Number (if known): _____

Device Name: Midwest Reprocessing Center Reprocessed Huntleigh Foot Wrap

Indications For Use:

The Midwest Reprocessing Center Reprocessed Huntleigh Foot Wrap is designed to enhance circulation of blood in the venules and arterioles. It is to be used by patient's in both the home and institutional settings as a non-invasive therapeutic method to prevent:

- Deep vein thrombosis
- Reduce wound healing time
- Treat and assist healing of venous leg ulcers
- Reduce edema caused by venous insufficiency in the lower extremities
- Decrease compartmental pressures

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

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