HYGIA
HEALTH SERVICES

DEC 2 4 2002

K021509

510(k) Summary

Summary

Substantial Equivalence Summary for the Hygia Health Services Reprocessed Novamedix ImPad®.

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: April 30, 2002

1. Contact Person

Geoff M. Fatzinger BS, MS
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 Novamedix ImPad®.

3. Predicate Device

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

4. Statement of Substantial Equivalence

The Hygia Health Services Reprocessed Novamedix ImPad® employs 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 Health Services Reprocessed Novamedix ImPad® is substantially equivalent to the Novamedix ImPad® 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 plantar arch. The garments are then connected to a 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 Health Services Reprocessed Novamedix ImPad® is substantially equivalent in function, operating parameters, and intended use to the Novamedix ImPad® that is currently commercially available and in distribution. The predicate device, the Novamedix ImPad®, is marked for "single-patient use only". Hygia Health Services does not change the device in any way except to render the device "reusable" by placing it through a scientifically validated chemical free high-level disinfection process. The Hygia Health Services high-level disinfection protocol does not alter the device's efficacy, safety, composition, or intended use. Hygia Health Services also includes the statement "single-patient use only" on the labeling.

5. Description of the Device

The Hygia Health Services Reprocessed Novamedix ImPad® Garment is an intermittent compressible limb device that is placed around the patient's foot with the compression chamber placed under the plantar arch. The garment is constructed out of brushed nylon over a thin layer of closed cell foam. The device is secured using hook and loop fasteners made of polyethylene. As the garment compresses the plantar plexus, the veins collapse longitudinally, which increases the venous pressure thus ejecting the blood upward. After compression, the devices 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, hold time , and inflation/deflation time is 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.

6. Intended Use of Device

The Hygia Health Services Reprocessed Novamedix ImPad® operates in the identical manner as the predicate device, the Novamedix ImPad®. It is designed to apply compression to a patient's plantar plexus 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 on patient populations for which a leg or calf compression device would not be applicable. It can be used under a cast or splint.

7. Technological Characteristics

The technological characteristics of the Hygia Health Services Reprocessed Novamedix ImPad® are identical to the predicate device 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 Novamedix ImPad® and the predicate device. All tests found that functional and operational performance characteristics including compression, pressure capabilities, and both safety and operational parameters were substantially equivalent.

9. Biocompatibility

In order to ensure that the Hygia Health Service high-level disinfection program did 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 in the premarket submission. No signs of irritation or sensitization were found.

Test Conclusions- Nonclinical test results of the Hygia Health Services Reprocessed Novamedix ImPad® indicated substantial equivalence in all aspects to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K021509
Trade Name: Hygia Health Services Reprocessed Novamedix ImPad®
Regulation Number: 21 CFR. 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II (two)
Product Code: JOW
Dated: October 10, 2002
Received: October 11, 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), please contact the Office of Compliance at (301) 594-4646. 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,

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 Health Services, Inc.

510(k) Number: K021509

Device Name: Hygia Health Services Reprocessed Novamedix ImPad®

Indications For Use:

The Hygia Health Services Reprocessed Novamedix ImPad® is designed to enhance circulation of blood. It is to be used by patients in both the home and institutional settings as a non-invasive therapeutic method to:

- DVT prophylaxis
- Acute and chronic edema
- Extreme pain after trauma or surgery
- Treat leg ulcers and venous stasis/insufficiency

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K021509

DJF 12/23

PRECAUTIONS AND CONTRAINDICATIONS

Contraindications:

DANGER: DO NOT USE IN THE PRESENCE OF FLAMMABLE ANESTHETICS. AVOID FREEZING AND EXCESSIVE HEAT.

Wraps may not be recommended for patients with the following:

1. Congestive heart failure or where an increase of fluid to the heart might be detrimental

2. Known or suspected deep vein thrombosis, pre-existing deep vein thrombosis, thrombophlebitis, or pulmonary embolism.

3. Severe arteriosclerosis or other ischemic vascular disease

4. Any local leg condition in which the wrap would interfere such as dermatitis, gangrene, recent skin graft, or untreated infected wounds

Precautions:

1. One must ensure that the wrap is applied properly.

2. One must ensure that the wrap is correctly connected to the pump and that the connection is secure.

3. If the patient experiences numbness, tingling, or leg pain, the wrap should be removed.