APR 6 2006

K051227

510 (k) Summary

Submitters Name and Address: ReNu Medical
9800 Evergreen Way
Everett, WA 98024
Phone: 425-353-1110
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FDA Registration Number: 3034520

Contact Person: L. Bruce Pierson
Chief Operating Officer

Date Summary Prepared: 3-12-05

Trade or Proprietary Name(s): ReNu Medical Reprocessed ALP®1 Calf Garment (up to 18" calf circumference)

Common Name:

Sleeve, Limb, Compression

Product Code:

JOW

Panel

Cardiovascular 870.5800

Classification:

Class II

Equivalent Device(s)

Re Nu Medical Reprocessed Kendall Impad – 510(k) # K031559
Re Nu Medical Reprocessed Huntleigh Flowtron – 510(k) # 031559

Device Description:

The ReNu Medical Reprocessed (up to 18" calf circumference)

Intended Use

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

Technological Characteristics of the ReNu Medical Reprocessed Healthcare Service and Supply ALP™ 1 Calf Garment.

The predicate devices and the ReNu Medical Medical ALP®1 Sequential Compression Sleeve are identical in overall design, materials, energy source, mode of operation, performance techniques, and reprocessing methodology.

Summary of Comparison Tests

Bench testing was conducted to ensure that reprocessing did not compromise the performance of the device.

Biocompatability

Reprocessing does not affect the biocompatibility of the device.

Process Validation:

Validation information has been provided as part of this submission to demonstrate that the device safety and. performance is not impacted by subsequent reprocessing

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 6 2006

ReNú Medical
c/o Mr. L. Bruce Pierson
Chief Operating Officer
9800 Evergreen Way
Everett, WA 98204-2780

Re: K051227
ReNu Reprocessed ALP®1 Calf Garment (up to 18" calf circumference)
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II (two)
Product Code: JOW
Dated: December 23, 2005
Received: January 11, 2006

Dear Mr. Pierson:

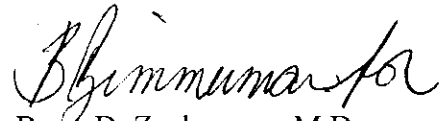
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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):

Device Name: ReNu Reprocessed ALP®1 Calf Garment (up to 18" calf circumference)

Indications for Use:

The ReNu Medical Reprocessed ALP®1 is to be used by patients in both the home and institutional settings as a non-invasive therapeutic method to:

- Prevent deep vein thrombosis and resulting pulmonary embolism.

Precautions and Contraindications:

Sleeves may not be recommended for patients with the following:

- Any local leg condition in which sleeves would interfere: dermatitis, gangrene, recent skin graft, untreated infected wounds.
- Congestive heart failure.
- Severe arteriosclerosis or other ischemic vascular disease.
- Pulmonary edema.
- Known or suspected deep vein thrombosis or phlebitis.

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 In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K051027