K053316

FEB 13 2006

SECTION B: 510(k) SUMMARY

Submitter:
Alliance Medical Corporation
10232 South 51st Street
Phoenix, Arizona 85044

Contact:
Moira Barton
Regulatory Affairs Manager
(480) 763-5350 (o)
(480) 763-5310 (f)
mbarton@alliance-medical.com

Date of preparation: July 25, 2005

Name of device:
Trade/Proprietary Name: Reprocessed Compression Sleeves
Common or Usual Name: Compression Sleeve
Classification Name: Compressible Limb Sleeve

Predicate device:

K Number	**Device Description**
K012994	WizAir DVT™ Compressible Limb Sleeve

Device description: Compression sleeves are part of an external compression system, in which intermittent or sequential compression is provided using a pump/controller and limb garment. The system consists of the following three main components: a control unit, inflatable limb sleeves and conduit tubing with detachable connections. Only the compression sleeves are reprocessed.

Intended use: Reprocessed Compression Sleeves are intended to help prevent deep vein thrombosis and pulmonary embolism by supplying a measured, intermittent pressure into the compression sleeves worn on the lower extremities of a recumbent patient, resulting in a gradient, sequential, repetitive squeezing and relaxing action, simulating normal muscle contractions.

Indications statement: When coupled with an appropriate inflation system, compression devices are intended for use in preventing deep vein thrombosis (DVT), diminishing post-operative pain and swelling, enhancing blood circulation, and reducing wound healing time.

Technological characteristics: The design, materials, and intended use of Reprocessed Compression Sleeves are identical to the predicate devices. The mechanism of action of Reprocessed Compression Sleeves is identical to the predicate devices in that the same standard

mechanical design, materials and sizes are utilized. There are no changes to the claims, intended use, clinical applications, patient population, performance specifications, or method of operation.

Alliance Medical Corporation's reprocessing of compression sleeves includes removal of adherent visible soil and decontamination. Each individual compression sleeve is tested for appropriate function of its components prior to packaging, labeling, and EO exposure operations.

Performance data: Bench and laboratory testing was conducted to demonstrate performance (safety and effectiveness) of Reprocessed Compression Sleeves.

- Biocompatibility
- Function Test(s)
- Validation of Processing

Performance testing demonstrates that Reprocessed Compression Sleeves perform as originally intended.

Conclusion: Alliance Medical Corporation concludes that the modified devices (Reprocessed Compression Sleeves) are safe, effective and substantially equivalent to the predicate devices as described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 13 2006

Allance Medical Corporation
c/o Ms. Moira Barton
Regulatory Affairs
10232 South 51st Street
Phoenix, AZ 85044

Re: K053316
Reprocessed Compression Sleeves
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II (Two)
Product Code: JOW
Dated: November 15, 2005
Received: November 29, 2005

Dear Ms. Barton:

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,

Donna R Bachman

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

Enclosure

1. Indications For Use Statement

510(k) Number (if known): K053316

Device Name: Alliance Medical Corporation Reprocessed Compression Sleeves

Indications For Use: When coupled with an appropriate inflation system, compression devices are intended for use in preventing deep vein thrombosis (DVT), diminishing post-operative pain and swelling, enhancing blood circulation, and reducing wound healing time.

Prescription Use __X__ (per 21 CFR 801 Subpart D)	AND/OR	Over-the-Counter Use ____ (21 CFR 801 Subpart C)

(PLEASE DO NONT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vo Ames

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K053316