K021654

FEB 0 5 2003

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter:

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

Contact:

Lorri Chavez
Regulatory Affairs Manager
(480) 763-5300 (o)
(480) 763-5310 (f)

Date of preparation: May 16, 2002

Name of device:

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

Predicate device(s):

K Number	Device Description
K992454	VenaFlow® System, Model 30A
K964238	Aircast® Sterile VenaFlow® Disposable Cuff
K961676	Aircast® VenaFlow® System (Modification)
K932900	Aircast® VenaFlow® System
K011192	Alliance Medical Corporation Reprocessed Compression Sleeves

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.

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:	Reprocessed Compression Sleeves are indicated for use in providing external compression therapy to reduce the incidence of deep vein thrombosis and resulting pulmonary embolism in patients at risk for thrombosis formation.
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 and labeling operations.
Performance data:	Bench and laboratory testing was conducted to demonstrate performance (safety and effectiveness) of Reprocessed Compression Sleeves. Performance testing demonstrates that Reprocessed Compression Sleeves perform as originally intended.
Conclusion:	In accordance with the Federal Food, Drug and Cosmetic Act 21 CFR Part 807 and based on the information provided in this premarket notification, 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 0 5 2003

Alliance Medical Corporation
c/o Mr. Don Selvey
Vice President, Regulatory Affairs and Quality Assurance
10232 South 51st Street
Phoenix, AZ 85044

Re: K021654
Trade Name: Reprocessed Compression Sleeves
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II (two)
Product Code: JOW
Dated: November 6, 2002
Received: November 7, 2002

Dear Mr. Selvey:

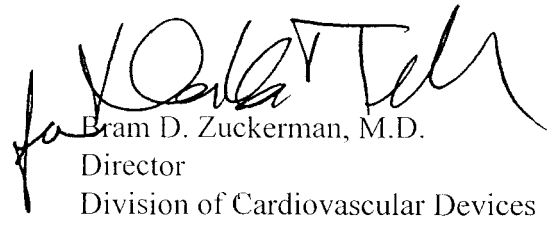
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May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

II. Indications for Use Statement

510(k) Number (if known):

Device Name: Alliance Medical Corporation Reprocessed Compression Sleeves

Indications for Use: Reprocessed Compression Sleeves are indicated for use in providing external compression therapy to reduce the incidence of deep vein thrombosis and resulting pulmonary embolism in patients at risk for thrombosis formation.

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K021654

Prescription Use X
(per 21 CFR 801.109)

or

Over-the-Counter Use ____