FEB 1 2 2002

K012675


# *Adven Medical, Inc.*

*1001 Slaton Hwy.*
*Lubbock, Texas 79404*

*Tel: (806) 745-7718*
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**510(k) SUMMARY**

Reference: Adven Medical, Incorporated
Section 510(k) Notification
Reprocessed Used Disposable Sequential Compression Sleeves / Wraps
Classification name: Pumps and Sleeves, 21 CFR 870.5800, Product Code: JOW
Common/Usual Name: Femoral Compressible Limb Sleeve or Wrap
Proprietary Name: Reprocessed Used Disposable Sequential Compression Sleeves / Wraps
Establishment Registration Number: 1649663
Classification: Class II.

AMI intends to market reprocessed sequential compression sleeves and wraps. Reprocessing sequential compression sleeves and wraps is performed by AMI to AMI protocol Number 40009.

"Reprocessed," means all operations performed to render a contaminated single-use device patient ready (*Enforcement Priorities for Single-Use Devices Reprocessed by Third Party Reprocessors and Hospitals*). AMI is a "third party reprocessor" and reprocesses used single-used medical devices.

AMI believes that sequential compression sleeves and wraps can be considered "reusable" - by AMI, as defined in the Food and Drug Administration Compliance Policy Guide #7124.16: they are able to withstand the necessary cleaning and sterilization process, the physical characteristics or quality of the device will not be adversely effected, and the device remains safe and effective for its intended use.

Sequential compression sleeves and wraps are designed to increase venous blood flow in the non-ambulatory patient in order to help prevent deep vein thrombosis and pulmonary embolism.

AMI intends to reprocess disposable sequential compression sleeves and wraps manufactured by Kendall (sleeves and foot wraps), Huntleigh and Plexipulse.

Adven Medical, Inc., reprocessed sequential compression sleeves and wraps are substantially equivalent to sequential compression sleeves and wraps sold new by Kendall under 510K 942664

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 2 2002

Mr. Mark W. Aldana
President
Adven Medical, Inc.
1001 Slaton Highway
Lubbock, TX 79404

Re: K012675
Trade Name: Reprocessed Used Disposable Sequential Sleeves/Wraps
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II (two)
Product Code: JOW
Dated: January 23, 2002
Received: January 24, 2002

Dear Mr. Aldana:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), 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.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510)k) Number: K012675

Device Name: Reprocessed Sequential Compression Device

Indications For Use:

Sequential compression sleeves are intended to increase venous return from the lower extremities as a prophylaxis for the formation of deep vein thrombosis or pulmonary embolism in non ambulatory patients.

Sequential compression sleeves are single patient use devices only.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K012675

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ___
(Optional Format 1-2-96)