

OCT 16 2003

510(K) SUMMARY

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(K) number is: _____.

Device Name:

Proprietary Name: UUHC'S Reprocessed Compression Sleeve Devices

Common/Usual Name: Compressible Limb Sleeve Device

Classification:

Class II per 21 CFR 870.5800

Panel Number: Panel 70

Product Code: JOW

Predicate Device:

The UUHC'S Reprocessed CSD is substantially equivalent to the legally marketed Kendall K94664 and K890938 Compression Sleeve Predicate Devices.

Device Description:

The description of UUHC'S Reprocessed Compression Sleeves is substantially equivalent to the above described Kendall CSD. The primary descriptive difference between the two products is that UUHC'S Reprocessed Compression Sleeves have been reprocessed as many as eleven (11) times and are labeled pasteurized and Kendall product is a non-sterile product that has not been reprocessed. The studies summarized in section 9.0 Safety and Efficacy and the comparison tables in section 5 demonstrate that UUHC'S Reprocessed Compression Sleeves are substantially equivalent in physical, performance and safety characteristics to Kendall's CSDs.

Kendall's compression sleeve device (CSD) is an SUD and it is a component of Kendall's CSD System. The compression sleeve is an inflatable device generally made of PVC or Polyolefin attached to a pneumatic compression device called a controller that is capable of performing multiple low pressure inflation cycles. It is offered in four different sizes that are configured to fit on the patient's thigh or calf. The sleeves are constructed with a series of cells running the length of the patient's thigh or calf that are sequentially inflated to impart intermittent compression to the respective section of the limb. This "milking" action forces the blood flow in the direction of the heart and prevents back

flow of blood. The sleeves are wrapped around the patient's limb and secured with valcor tabs.

Because the Kendall CSD is placed on the patient's intact skin, it falls under the Spaulding Non-Critical device classification. The CSD procedure is considered a safe, non invasive, less expensive and simple alternative to anti-coagulant drug therapy and it is one of the least expensive, yet most effective non invasive systems available for the prevention of venous thrombosis.

Intended Use:

UUHC's reprocessing methods do not change the intended use of the CSDs from the intended use of, Kendall's K890938 model 5325 and K94664 model 6325 predicate devices. Both UUHC's reprocessed device and Kendall's predicate CSDs are intended to be placed on the intact skin of the patient's limb and to be periodically inflated for preventing pooling of blood in the patient's limb.

controllers - not sleeves

Technical Characteristics:

The technical characteristics of UUHC's reprocessed device and the Kendall predicate Device are substantially equivalent. UUHC's reprocessed devices' seal strength after several reprocessing cycles was reduced from the predicate device. Also the elongation of UUHC's reprocessed device was slightly greater than the predicate device. This is to be understood since the materials would naturally loose a little strength due to the reprocessing procedures.

Also, UUHC's Reprocessed CSDs are pasteurized and passed an intermediate level of disinfection testing whereas the predicate device is non-sterile; which may be considered a technological advantage of the reprocessed device over the predicate device.

Substantial Equivalency:

The performance data and the safety data indicated that UUHC's Reprocessed CSDs were technically substantially equivalent. The only difference between the predicate device and the reprocessed device was that the seal strengths were slightly less in the reprocessed device. This did not affect the safety and efficacy of the reprocessed device compared to the predicate device. In addition the reprocessed device is pasteurized and the predicate device is sold non-sterile. This difference did not affect the safety and efficacy of the reprocessed device.

The reprocessed device was tested for biocompatibility and performance and they were substantially equivalent in all required categories to the predicate device.

Conclusion:

The following conclusions can be drawn from reviewing the safety and efficacy data of the 510(K):

Functional Testing:

The results of this test indicated that the CSDs can be reprocessed several times through the reprocessing steps with no functional characteristic changes that would pose any substantial equivalency differences from the predicate devices.

Intermediate Disinfection:

Based on test results the pasteurization procedure used for reprocessing CSDs is deemed fully capable of and qualified for intermediate disinfection of the CSDs.

Seal Strength:

The seal strength of the samples reprocessed were reduced slightly due to reprocessing. The reduction of strength did not affect the function of the product in a simulated functional use test.

Biocompatibility/Toxicological Characteristics:

Based on test results, we conclude that the CSDs can be reprocessed and may then be used on the patient without posing any new biocompatibility or toxicological hazard to the patient.

Cleaning Efficacy:

Based on test results, we conclude that the cleaning efficacy of the washer was capable or meeting the required cleaning efficacy end-point and that the cleaned reprocessed CSDs pose no new safety or efficacy issues to the patient over the predicate device.



OCT 16 2003

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

University of Utah Hospital and Clinics
c/o Mr. Jack Speer
Jack Speer and Associates, Inc.
1800 East, 900 South
Salt Lake City, UT 84108

Re: K031189
Reprocessed Compression Sleeve Devices
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeves
Regulatory Class: Class II (two)
Product Code: JOW
Dated: July 17, 2003
Received: July 18, 2003

Dear Mr. Speer:

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.

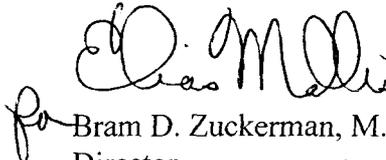
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Page 2 – Mr. Jack Speer

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) you may obtain. 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,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman". The signature is written in a cursive style with a large initial "B".

Bram D. Zuckerman, M.D.
Director

Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

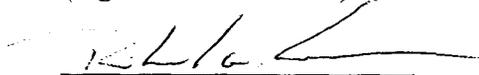
INDICATIONS FOR USE STATEMENT

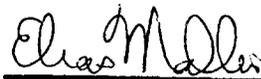
510(k) Number Unknown

Device Name: Reprocessed Compression Sleeve Devices

Indications for Use: University of Utah Hospital and Clinics (UUHC) reprocessing methods do not change the intended use of the compression sleeve devices (CSDs) from the intended use of, Kendall's K890938 model 5325 and K94664 model 6325 predicate devices. Both UUHC's reprocessed device and Kendall's predicate CSDs are intended to be placed on the intact skin of the patient's limb and to be periodically inflated for preventing pooling of blood in the patient's limb.


(Signature of Verifier)


Richard Lee



(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K031189