FEB 1 3 2004

# 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: K033615

**Device Name:**

Proprietary Name: WFSI'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 WFSI Reprocessed CSD is substantially equivalent to the legally marketed Huntleigh K881632 Compression Sleeve Predicate Devices.

**Device Description:**

Huntleigh's compression sleeve device (CSD) is an SUD component of Huntleigh's CSD System. The compression sleeve is an inflatable device generally made of PVC or Polyolefin with a bladder that is attached to a pneumatic compression device called a controller and it 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 (see diagrams in appendix 6). The sleeves are constructed with cells running the length of the patient's thigh or calf that are sequentially inflated and deflated 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 Huntleigh 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.

The description of WFSI's Reprocessed Compression Sleeves is substantially equivalent to the above described Huntleigh CSD. The primary descriptive difference between the two products is that WFSI's Reprocessed Compression Sleeves have been reprocessed as

several times and are labeled pasteurized and Huntleigh's CSD 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 WFSI's Reprocessed Compression Sleeves are substantially equivalent in physical, performance and safety characteristics to Huntleigh's CSDs.

WFSIs reprocessing methods does not change the intended use of the compression sleeve devices (CSDs) from the intended use of, Huntleigh's K881632 model AC500/550 predicate devices. Both WFSI's reprocessed device and Huntleigh'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.
The technical characteristics of WFSI's reprocessed device and the Huntleigh predicate Device are substantially equivalent. WFSI's reprocessed devices' seal strength after several reprocessing cycles was reduced from the predicate device. Also the elongation of WFSI'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, WFSI'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.
The performance data and the safety data indicated that WFSI's Reprocessed CSDs were technically substantially equivalent to the Huntleigh CSD. The only difference is that the reprocessed CSDs were a slightly different color and the reprocessed CSDs were intermediate disinfected and the predicate devices were non sterile.

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 pressure deflation, bladder leakage or burst strength 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.

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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 13 2004

Wheaton Franciscan Services, Inc.
c/o Mr. Jack Speer
Jack Speer & Associates, Inc.
1800 East 900 South
Salt Lake City, UT 84108

Re: K033615
WFSI'S Reprocessed Compression Sleeve Devices
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II (two)
Product Code: JOW
Dated: October 17, 2003
Received: November 17, 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.

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.

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): K033615
Device Name: Reprocessed Compression Sleeve Devices

Indications For Use:

The Wheaton Franciscan Huntleigh Reprocessed Compression Sleeve is recommended for use in patients for whom external compression therapy using the Huntleigh Flowtron® System is indicated for the prevention of deep vein thrombosis and resulting pulmonary embolism due to the presence of risk factors for thrombus formation. Intra-operative compression therapy is frequently indicated, sometimes adjunctively with medical measures, during orthopedic, trauma, urologic and general surgery, particularly in patients over the age of 40.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Kochmer
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K033615