FEB 1 1 2002

K012597

SECTION 2. SUMMARY AND CERTIFICATION

A. 510(K) SUMMARY

Submitter: SterilMed, Inc.

Contact Person: Patrick Fleischhacker
11400 73rd Avenue North
Minneapolis, MN 55369
Phone: 888-856-4870
Fax: 763-488-3350

Date Prepared: August 8, 2001

Trade Name: SterilMed Reprocessed Compression Sleeves

Classification Name: and Number: Class II, 21 CFR 870.5800

Product Code: JOW

Predicate Device(s): SterilMed's reprocessed compression sleeves are substantially equivalent to the Kendall Company models 5329, 5330 (K781357) 5065, 5066, and 5075 (K953648 and K951683), and the Huntleigh Technology Inc. models GS337M and GS334 (K910188), and to the original manufacturers' devices.

Device Description: Reprocessed Compression Sleeves are inflatable devices that are fitted to a patient's foot and/or leg. They are connected to a separate pneumatic compressor, which provides intermittent, graduated pressure. When the sleeve compresses, the veins collapse, forcing blood to flow. When pressure is reduced, the sleeve deflates, allowing the veins to fill with blood. The cycle is then repeated.

It should be noted that this submission applies to the compression sleeve only. It does not include any other components in a compression system such as the pneumatic compressor.

Intended Use: Compression sleeves are designed to provide external intermittent or sequential limb compression to artificially imitate the pumping action of the lower limbs to prevent

deep vein thrombosis, enhance venous and arterial circulation, and reduce lower limb pain and swelling.

Functional and Safety Testing:

Representative samples of reprocessed compression sleeves underwent bench testing to demonstrate appropriate functional characteristics. Process validation testing was done to validate the cleaning procedures as well as the device's packaging. In addition, the manufacturing process includes visual inspection and functional testing of all products produced.

Conclusion:

The compression sleeves reprocessed by SterilMed are substantially equivalent to the Kendall Company models 5329, 5330 (K781357) 5065,5066, and 5075 (K953648 and K951683), and the Huntleigh Technology Inc. models GS337M and GS334 (K910188), and their counterparts from the original manufacturers. This conclusion is based upon the fact that these devices' are essentially identical to the predicate devices in terms of functional design, materials, indications for use, construction, and principles of operation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 1 2002

Mr. Patrick Fleischhacker
Vice President Regulatory and Quality Control
SterilMed, Inc
11400 73rd Avenue North
Minneapolis, MN 55369

Re: K012597
Trade Name: Reprocessed Compression Limb Sleeves
Regulation Number: 21 CFR 870.5800
Regulation Name: Compression Limb Sleeve
Regulatory Class: Class II (two)
Product Code: JOW
Dated: December 6, 2001
Received: December 7, 2001

Dear Mr. Fleischhacker:

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 (if known): K012597

Device Name: Reprocessed Pneumatic Compression Sleeves

Indications For Use:

These devices are reprocessed compression sleeves from various original equipment manufacturers (OEM.) Compression sleeves are designed to provide external intermittent or sequential limb compression to artificially imitate the pumping action of the lower limbs to: prevent deep vein thrombosis, enhance venous and arterial circulation, and reduce lower limb pain and swelling.

(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 K012597

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)