K052691

MAY 17 2006

SureTek Medical 510(k) Summary

Submitter	SureTek Medical 25-B Maple Creek Circle Greenville, SC 29607
Contact	Mike Sammon, Ph.D. 864-299-9743
Date	9/25/05
Product	SureTek Reprocessed Compression Sleeve
Classification	Code:JOW Regulation: 21 CFR 870.5800 Name: Compressible Limb Sleeve

Predicate Devices

Manufacturer/Reprocessor	Tradename(s)	510(k)'s
Huntleigh Healthcare	Flowtron*	K022786, K010744
Kendall (Tyco Healthcare)	SCD*, Impad*	K992079, K964425
Kinetic Concepts	Plexipulse*	K981311
Compression Therapy	VasoPress*	K003828
Currie Medical	Alternating Leg Pressure, ALP*	K000303
Aircast	Venaflow*	K992454, K023800
Alba Health	pulStar*	K961405
SterilMed	Reprocessed Compression Sleeves	K012597
Vanguard Medical Concepts	Reprocessed Compression Garment	K012403

Device Design and Description

Compression Sleeves are inflatable cuffs designed to apply intermittent pressure to the foot, calf or thigh in order to increase venous return and prevent pooling of blood associated with the formation of Deep Vein Thrombosis (DVT). The devices consist of inflatable vinyl bladder(s) lined with an outer non-woven fabric; the bladder is connected to pneumatic tubing for connection with a compatible pump system that controls the sleeve's pressure cycle. Hook-and-loop fasteners sewn into the fabric are used to secure the sleeve to the foot or leg. Models are available in a range of dimensions in order to fit varying foot, calf and thigh circumferences. Reprocessed sleeves have identical technological characteristics as the predicate devices, i.e. device materials, dimensions, operating principle and system compatibility are unchanged during reprocessing. SureTek sleeves are provided as sterile, while the manufacturer product is provided non-sterile.

Intended Use

SureTek Compression Sleeves are intended for use with a compatible pump controller for intermittent compression of the lower extremities so as to increase venous return as a prophylaxis to Deep Vein Thrombosis.

Testing and Standards

- Bench testing of devices following the maximum number of use and reprocessing cycles found their performance to be substantially equivalent to new, unused devices.
- SureTek cleaning process is validated to be effective for decontamination of grossly contaminated instruments under worst case operational conditions.
- Product packaging conforms to all relevant requirements of ISO 11607 *Packaging for terminally sterilized medical devices*, with performance qualifications tested according to EN868-1 and ASTM F88-00, F2906-04, D4169-04a and F1980-02.
- Product sterility and process validation conform to the relevant requirements of ISO 11135 *Medical Devices – Validation and routine control of ethylene oxide sterilization.*
- Products conform to the relevant requirements of ISO 10993 *Biological Evaluation of Medical Devices* for ethylene oxide residuals and biocompatibility of device materials..

Substantial Equivalence

Product testing and comparisons of specifications determines that SureTek Reprocessed Compression Sleeves are substantially equivalent to their predicate devices with respect to device intended use and performance, as well as product packaging, labeling and safety.

* The listed product tradenames are registered trademarks of their respective manufacturers.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 17 2006

SureTek Medical
c/o Mike Sammon, Ph.D.
CEO President
44 Bellwood Farms
Greenville, SC 29607

Re: K052691
SureTek Reprocessed Compression Sleeve
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: April 1, 2006
Received: April 5, 2006

Dear Dr. Sammon:

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 (240) 276-0120. 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/industry/support/index.html.

Sincerely yours,

Bram R. Zuckerman

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): K052691

Device Name: SureTek Reprocessed Compression Sleeve

Manufacturer	Model Number	Manufacturer	Model Number
Huntleigh	DVT10	Compression Therapy	VP 501M
Huntleigh	DVT20	Compression Therapy	VP 501L
Huntleigh	DVT60	Compression Therapy	VP 501B
Huntleigh	DVT30	Compression Therapy	VP 530M
Huntleigh	DVT40	Compression Therapy	VP 530L
Huntleigh	FG100	Compression Therapy	VP 520
Huntleigh	FG200	Currie Medical	ALP 1
Kendall	5329	Currie Medical	ALP 2
Kendall	5489	Currie Medical	ALP 5
Kendall	5345	Currie Medical	ALP 3
Kendall	5330	Currie Medical	ALP 4
Kendall	5480	Currie Medical	PVA 1
Kendall	5065	Currie Medical	PVA 2
Kendall	5075	Aircast	3010
Kinetic Concepts	28900000	Aircast	3012
Kinetic Concepts	28900001	Aircast	3014
Alba Healthcare	51558-01	Aircast	3015
Alba Healthcare	51558-02	Aircast	3016

Indications for Use: SureTek Compression Sleeves are intended for use with a compatible pump controller for intermittent compression of the lower extremities so as to increase venous return as a prophylaxis to Deep Vein Thrombosis.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R Vochanel

(Division Sign-Off)
Division of Cardiovascular Devices

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