SECTION 5: 510(k) SUMMARY

Submitter:
Ascent Healthcare Solutions
10232 South 51st Street
Phoenix, Arizona 85044

JUL 23 2010

Contact:
Ramona Kulik
Regulatory Affairs Engineer
480.763.5300 (o)
480.763.2952 (f)
rkulik@ascenths.com

Date of preparation: March 31, 2010

Name of device:
Trade/Proprietary Name: Reprocessed Compression Sleeves
Common or Usual Name: Compression Sleeve
Classification Name: Compressible Limb Sleeve

Predicate Devices	510(k) Title	Reprocessor
K060049	Reprocessed Compression Sleeves	Alliance Medical Corporation
K060091	Reprocessed Compression Sleeves	Alliance Medical Corporation
K053316	Vanguard Reprocessed Compression Garments	Vanguard Medical Concepts
K051438	Vanguard Reprocessed Compression Garments (Hill-Rom)	Vanguard Medical Concepts
K012403	Vanguard Reprocessed Compression Garments	Vanguard Medical Concepts
K024087	Reprocessed Compression Sleeves	Alliance Medical Corporation
K024074	Reprocessed Compression Sleeves	Alliance Medical Corporation
K021654	Reprocessed Compression Sleeves	Alliance Medical Corporation
K011192	Reprocessed Compression Sleeves	Alliance Medical Corporation

Indications for Use: When coupled with an appropriate inflation system, compression devices are intended for use in preventing deep vein thrombosis (DVT), diminishing post-operative pain and swelling, enhancing blood circulation, and reducing wound healing time.

Device Description: Compression sleeves are part of an external compression system, in which intermittent or sequential compression is provided using a pump/controller and limb garment. The system consists of the following three main components: a control unit, inflatable limb sleeves and conduit tubing with connectors for pump attachment. Only the compression sleeves are reprocessed.

Technological characteristics: The design, materials, and intended use of Reprocessed Compression Sleeves are identical to the predicate devices. The mechanism of action of Reprocessed Compression Sleeves is identical to the predicate devices in that the same standard mechanical design, size, and materials are utilized. There are no changes to the claims, intended use, clinical applications, patient population, performance specifications, or method of operation. In addition, Ascent Healthcare Solutions' reprocessing of Compression Sleeves includes removal of adherent visible soil and decontamination. Each individual compression sleeve is tested for appropriate function of its components prior to packaging and labeling operations.

Performance data: Bench and laboratory testing was conducted to demonstrate performance (safety and effectiveness) of Reprocessed Compression Sleeves. This included the following tests:

- Biocompatibility
- Validation of reprocessing
- Function test(s)

Performance testing demonstrates that Reprocessed Compression Sleeves perform as originally intended.

Conclusion: Ascent Healthcare Solutions concludes that the modified devices (Reprocessed Compression Sleeves) are safe, effective, and substantially equivalent to the predicate devices as described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUL 2 3 2010

Ms. Ramona Kulik
Regulatory Affairs Engineer
10232 South 51st Street
Phoenix, AZ 85044

Re: K100909
Ascent Healthcare Solutions (AHS) Reprocessed Restep Compression Sleeves
Regulation Number: 21 CFR §870.5800
Regulation Name: Sleeve, Limb, Compressible
Regulatory Class: Class II
Product Code: JOW
Dated: July 9, 2010
Received: July 10, 2010

Dear Ms. Kulik:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K100909

Applicant: Ascent Healthcare Solutions
10232 S 51st Street
Phoenix, AZ 85044
Contact Individual: Ramona Kulik, Regulatory Affairs Engineer
Ph: (888)888-3433 Fax: (480)763-2952
Email: rkulik@ascenths.com

JUL 2 3 2010

Classification: Class II, 870.5800
Product Code: JOW
Common Name: Compressible Limb Sleeve

Device Name: Ascent Healthcare Solutions (AHS) Reprocessed Restep Compression Sleeves

Manufacturer	Foot	Calf	Thigh
Kendall	5065, 5075, 5107, 5897, 5898, 5046, 5048, 5057, 5059	5329, 5329-M, 5489, 5489-M, 9529, 9789,	5330, 5330-M, 5345, 5345-M, 5480, 5480-M, 9530, 9545, 9780
Healthcare Services and Supply	PVA-1, PVA-2	ALP-1, ALP-2, ALP-2XL	ALP-3, ALP-3(S), ALP-4
Hill-Rom	P3808	P3801, P3801-L, P3802, P3802-L, P3803, P3803-L, P3804, P3804-L, P3841, P3842, P3843	P3805, P3805-L, P3806, P3806-L, P3807, P3807-L,
Huntleigh Healthcare	FG-100, FG-100(2), FG-100R, FG-100R(2), FG-200, FG-200(2), FG-200R, FG-200R(2)	DVT-10, DVT-10(S), DVT-20, DVT-60, L501-M	DVT-30, DVT-30(S), DVT-40,
Compression Therapy Concepts	VP520, VP520L,	VP501L, VP501M, VP501P,	VP530B, VP530L, VP530M
Kinetic Concepts Inc	235340	112453	112452
Microtek	V3012, V3014, V3022, V3026, V3030		
Aircast Inc.	3016, 3016-5, 3016-PL	3010, 3010-5, 3010-PL, 3012, 3012-5, 3012-PL,	3015, 3015-5, 3015-PL

Indications for Use (IFU)
When coupled with an appropriate inflation system, compression devices are intended for use in preventing deep vein thrombosis (DVT), diminishing post-operative pain and swelling, enhancing blood circulation, and reducing wound healing time.

K100909

SECTION 4: INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K100909

Device Name: Reprocessed Compression Sleeves

Indications For Use:
When coupled with an appropriate inflation system, compression devices are intended for use in preventing deep vein thrombosis (DVT), diminishing post-operative pain and swelling, enhancing blood circulation, and reducing wound healing time.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K100909