SECTION 5: 510(k) SUMMARY

JUL 16 2010

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

Contact:
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Date of preparation: April 15, 2010

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

Predicate Devices	**510(k) Title**	**Manufacturer**
K090308	Restep DVT System	Stortford Medical LLC

Device description:
The Restep Deep Vein Thrombosis (DVT) System, consists of the Restep pump and compatible leg and foot compression garments. The system is a lightweight, portable, prescriptive pneumatic compression device that helps to stimulate blood flow in the deep veins of the legs through the use of pneumatically controlled single chamber pressure cuffs, actuated by an electronically controlled pump unit and solenoid valves.

Note: Only the compression sleeves (garments) are the subject of this submission, the pump is not included in the scope of this submission.

Indications for Use:
Intermittent Pneumatic Compression (IPC) is indicated for use for the prevention of deep vein thrombosis due to the presence of risk factors for thrombus formation during orthopedic, trauma, urologic, neurology, critical care, general medicine, obstetrics, and general surgery.

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 Restep 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 16 2010

Ms. Amanda Babcock
Senior Regulatory Affairs Specialist
10232 South 51st Street
Phoenix, AZ 85044

Re: K101087
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: April 15, 2010
Received: April 19, 2010

Dear Ms. Babcock:

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

K101087

SECTION 4: INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K101087

Device Name: Reprocessed Restep Compression Sleeves

Indications For Use:
Intermittent Pneumatic Compression (IPC) is indicated for use for the prevention of deep vein thrombosis due to the presence of risk factors for thrombus formation during orthopedic, trauma, urologic, neurology, critical care, general medicine, obstetrics, and general surgery.

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 K101087

K101087

Applicant: Ascent Healthcare Solutions
10232 S 51st Street
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Contact Individual: Amanda Babcock, Senior Regulatory Affairs Specialist
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Classification: Class II, 870.5800
Product Code: JOW
Common Name: Compressible Limb Sleeve

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

Manufacturer	Models
Restep	RCG-10 Calf Garment (up to 22") RCG-30 Thigh Garment (up to 32") RCG-60 Bariatric Garment (up to 27") RCG-210 Foot Garment (universal size)

Indications for Use (IFU)
Intermittent Pneumatic Compression (IPC) is indicated for use for the prevention of deep vein thrombosis due to the presence of risk factors for thrombus formation during orthopedic, trauma, urologic, neurology, critical care, general medicine, obstetrics, and general surgery.