JUL 15 2014

K140813

COVIDIEN

TRADITIONAL 510(K) SUMMARY

1. 510(k) Owner:

Applicant:	Covidien 15 Hampshire Street Mansfield, MA 02048
Telephone:	(508) 452 – 4135
Fax:	(508) 452 – 1640
Contact:	Daniel Campion
Title:	Director Regulatory Affairs
Date Prepared:	3/28/2014

2. Device:

Trade Name:	Covidien Reprocessed Compression Garments
Classification Name:	Sleeve, Limb Compressible
Regulation Number:	21 CFR 870.5800
Product Code(s):	JOW
Classification:	Class II

3. Predicate Device:

The Reprocessed Compression Garments are substantially equivalent in intended use and operation to the predicate Compression Garments (K051805 and K781357).

4. Device Description:

The Reprocessed Compression Garments are the compressible limb sleeve component of a pneumatic compression system intended to apply pressure to a patient's leg to aid in the prevention of deep vein thrombosis (DVT) and pulmonary embolism (PE).

The Reprocessed Compression Garments are compatible with the OEM pneumatic compression controller. The controller provides air to the sleeves through tubing connected to each bladder of the sleeve for the purposes of delivering pneumatic pressure to the limb. The controller software monitors the pressure in the bladders and releases the pressure by venting the air from the sleeve bladders through a valve system.

The proposed reprocessed device is for single-patient-use and will be available in knee and thigh configurations.

5. Intended Use:

Intended use for following codes: 9529(R), 9530(R), 9545(R),
The Reprocessed Compression Garments are intended to be used with an intermittent pneumatic device to increase venous blood flow in at risk patients in order to help prevent deep vein thrombosis and pulmonary embolism.

Intended use for following codes: 9780(R), 9789(R), 9790(R),
The Reprocessed Compression Garments are intended to be used with an intermittent pneumatic device to increase venous blood flow in at risk patients, including bariatric and morbidly obese patients, in order to help prevent deep vein thrombosis and pulmonary embolism.

6. Technological Characteristics:

The Reprocessed Compression Garments are identical to the predicate device in design, materials of construction, and intended use. There are no changes to the clinical applications, patient population, performance specifications, or method of operation.

7. Performance Data:

Representative samples of the Reprocessed Compression Garments were tested to demonstrate appropriate functional characteristics through bench top verification and process validation. Visual inspection, leak testing, reliability testing and biocompatibility performance data were used to demonstrate the device function. Testing was performed to validate the cleaning process in line with AAMI TIR 30:2011 requirements. The manufacturing process includes visual and functional testing of all reprocessed products prior to release.

8. Conclusion:

Based on the performance and cleaning results Covidien concludes that the Reprocessed Compression Garments are safe, effective, and substantially equivalent to the predicate device as described in this premarket notification submission

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

July 15, 2014

Covidien
Mr. Daniel Campion
Director Regulatory Affairs
15 Hampshire Street
Mansfield, MA 02048 US

Re: K140813
Trade/Device Name: Reprocessed Kendall SCD Express Compression Sleeves
Regulation Number: 21 CFR 870.5800
Regulation Name: Sleeve, Limb, Compressible
Regulatory Class: Class II
Product Code: JOW
Dated: June 18, 2014
Received: June 20, 2014

Dear Mr. Campion:

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 contact 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

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

Enclosure

Indications for Use Statement

510(k) Number (if known): K140813

Device Name: Covidien Reprocessed Compression Garments

Indications for Use:

Intended use for following codes: 9529(R), 9530(R), 9545(R),
The Reprocessed Compression Garments are intended to be used with an intermittent pneumatic device to increase venous blood flow in at risk patients in order to help prevent deep vein thrombosis and pulmonary embolism.

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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)

M A Hillebrenner