K120944

510(k) Summary of Safety and Effectiveness

MAY 3 1 2012

SUBMITTER:	Covidien 15 Hampshire St Mansfield, MA 02048 Tel. No.: (508) 452-1659
CONTACT PERSON:	Jennifer Sullivan Sr. Regulatory Affairs Specialist
DATE PREPARED:	March 28, 2012

TRADE/PROPRIETARY NAME: Kendall SCD™ 700 Sequential Compression Controller

COMMON/USUAL NAME:	Compressible Limb Sleeve Device
CLASSIFICATION NAME:	Sleeve, Limb, Compressible
PREDICATE DEVICE(S):	Kendall SCD™ 700 Sequential Compression Controller (K102737)
DEVICE DESCRIPTION:	The Kendall SCD™ 700 Sequential Compression controller is an intermittent pneumatic compression device for applying sequential, gradient pressure to a patient's limbs for the prevention of DVT and PE. The controller delivers air though the tubing sets to the pair of disposable garments (one for each limb).
INTENDED USE:	The Kendall SCD™ 700 Sequential Compression System (hereby referenced as "Kendall SCD™ 700 Series") is designed to apply intermittent pneumatic compression to increase venous blood flow in at-risk patients in order to help prevent deep vein thrombosis and pulmonary embolism. The Kendall SCD™ 700 Series is a prescription device for use in a clinical setting or in the home.
TECHNOLOGICAL CHARACTERISTICS:	The modified device has the same technological characteristics as compared to the predicate device.
PERFORMANCE DATA:	A Use Failure Modes and Effects Analysis (UFMEA) was created to adequately assess the risks related to the home user. Known and potential hazards for operation of the Kendall SCD™ 700 Series system were evaluated for risk and the severity of the failure effects to the patient and servicing personnel and probability of occurrence were categorized. The output of the UFMEA identified the need to conduct validation testing. A Human Factors and Usability Study was conducted to validate usability of the Kendall SCD™ 700 Series system in the home environment. The result of the Human Factors and Usability Study substantiates the acceptability of the risks identified during the risk assessment activities. In addition, Electrical Safety testing according to IEC 60601-1 and UL60601-1 and Electromagnetic Compatibility according to IEC 60601-1-2 were conducted.

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

MAY 3 1 2012

Covidien
c/o Ms. Jennifer Sullivan
Senior Regulatory Affairs Specialist
15 Hampshire Street
Mansfiled, MA 02048

Re: K120944
Trade/Device Name: Kendall SCD™ 700 Sequential Compression Controller
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeves
Regulatory Class: Class II
Product Code: JOW
Dated: March 28, 2012
Received: March 29, 2012

Dear Ms. Sullivan:

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,

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

510(k) Number (if known): K120944

Device Name: **Kendall SCD™ 700 Sequential Compression Controller**

Indications For Use:

The Kendall SCD™ 700 Sequential Compression System (hereby referenced as "Kendall SCD™ 700 Series") is designed to apply intermittent pneumatic compression to increase venous blood flow in at-risk patients in order to help prevent deep vein thrombosis and pulmonary embolism. The Kendall SCD™ 700 Series is a prescription device for use in a clinical setting or in the home.

The System consists of the controller, the tubing sets (provided with the controller) and single-patient use garments (purchased separately from this controller). The garments, both leg sleeves and foot cuffs, compress the limbs to enhance venous blood movement. After the compression cycle has reached set pressure, the Controller measures the time it takes for the limbs to refill with blood and waits that period of time before the next compression is initiated.

The use of the Kendall SCD™ 700 Series Compression System with Leg Sleeves is indicated for:

- Deep vein thrombosis and pulmonary embolism prophylaxis.

The use of the Kendall SCD™ 700 Series Compression System with Foot Cuffs is indicated for:

- Circulation enhancement.
- Deep vein thrombosis prophylaxis.
- Edema - Acute.
- Edema - Chronic.
- Extremity pain incident to trauma or surgery.
- Leg Ulcers.
- Venous stasis / venous insufficiency.

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 K120944

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