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

December 23, 2016

Covidien
Jennifer Sullivan
Regulatory Affairs Manager
15 Hampshire Street
Mansfield, Massachusetts 02048

Re: K163055
Trade/Device Name: Reprocessed Kendall SCD Express Foot Cuff
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: October 31, 2016
Received: November 1, 2016

Dear Jennifer 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 contact the Division of Industry and Consumer Education 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 Industry and Consumer Education 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,

for

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

Enclosure

Device Model	Device Name	Original Manufacturer
5897R	Reprocessed Kendall SCD™ Express Foot Cuff – Regular	Covidien
5898R	Reprocessed Kendall SCD™ Express Foot Cuff – Large	Covidien

Section 4 – Indications for Use Statement

510(k) Number (if known): K163055

Device Name: Reprocessed Kendall SCD™ Express Foot Cuff

Indications for Use:

The Reprocessed Kendall SCD™ Express Foot Cuff is intended to be used with an intermittent pneumatic device and 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)

COVIDIEN

510(k) SUMMARY

1. **510(k) Owner:**

Covidien
15 Hampshire Street
Mansfield, MA 02048

Contact: Jennifer Sullivan
Title: Regulatory Affairs Manager
Telephone: (508) 452-1659
Fax: (508) 452-1659
Email: jennifer.sullivan@medtronic.com
Date Prepared: October 31, 2016

2. **Device:**

Trade Name:	Reprocessed Kendall SCD™ Express Foot Cuff
Classification Name:	Sleeve, Limb, Compressible
Regulation Number:	21 CFR 870.5800
Product Code(s):	JOW
Classification:	Class 2

3. **Predicate Devices:**
Kendall SCD™ Express Foot Cuff, K040511

4. **Device Description:**
The Reprocessed Kendall SCD™ Express Foot Cuff is a single patient use garment that connects to an intermittent pneumatic controller via a tubing set to deliver a set amount of pressure to the foot in order to promote blood flow.

5. **Intended use:** The Reprocessed Kendall SCD™ Express Foot Cuff is intended to be used with an intermittent pneumatic device and 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

6. **Technological Characteristics:**
   The Reprocessed Kendall SCD™ Express Foot Cuffs 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 foot cuffs were tested to demonstrate appropriate functional characteristics through bench top verification. Testing included; hook and loop simulated use, leak testing and system compatibility. Biocompatibility testing was conducted in accordance with ISO 10993-1. The cleaning process was validated in accordance 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 functional testing, Covidien has demonstrated that the Reprocessed Kendall SCD™ Express Foot Cuffs are substantially equivalent to the predicate device as described in this premarket notification.