



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

August 18, 2016

Covidien  
Wing Ng  
Director, Regulatory Affairs  
15 Hampshire Street  
Mansfield, Massachusetts 02048

Re: K161105

Trade/Device Name: Reprocessed Compression Garments  
Regulation Number: 21 CFR 870.5800  
Regulation Name: Compressible Limb Sleeve  
Regulatory Class: Class II  
Product Code: JOW  
Dated: July 11, 2016  
Received: July 14, 2016

Dear Wing Ng:

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 yours,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman". The signature is written in a cursive style and is positioned above the typed name.

for

Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

## Reprocessed Single-Use Device Models Included in Clearance:

<b>Device Model</b>	<b>Device Name</b>	<b>Original Manufacturer</b>
9529R	Reprocessed Express Sleeve –Knee Length Medium	Covidien
9789R	Reprocessed Express Sleeve –Knee Length Large	Covidien
9790R	Reprocessed Express Sleeve –Knee Length X- Large	Covidien
9545R	Reprocessed Express Sleeve –Thigh Length Small	Covidien
9530R	Reprocessed Express Sleeve – Thigh Length Medium	Covidien
9780R	Reprocessed Express Sleeve - Thigh Length Large	Covidien
74021R	Reprocessed Comfort Sleeve – Knee Length Small	Covidien
74022R	Reprocessed Comfort Sleeve – Knee Length Medium	Covidien
74023R	Reprocessed Comfort Sleeve – Knee Length Large	Covidien





## 510(K) SUMMARY

### 1. 510(k) Owner:

Covidien  
15 Hampshire Street  
Mansfield, MA 02048

Contact: Mr. Wing Ng  
Title: Director, Regulatory Affairs  
Telephone: (508) 261 – 6596  
Fax: (508) 261 – 6596  
Date Prepared: April 18, 2016

### 2. Device:

Trade Names: SCD™ Express Compression Sleeve  
SCD™ Comfort Compression Sleeve  
Common Name: Compression Garment  
Classification Name: Sleeve, Limb, Compressible  
Regulation Number: 21 CFR 876.5800  
Product Code: JOW  
Classification: Class II

### 3. Predicate Devices:

Covidien Reprocessed Compression Garments (K140813)

### 4. Device Description:

The Reprocessed Compression Garment is the sleeve component of the pneumatic compression system intended to apply circumferential pressure to a patient's leg. This pressure will aid in the prevention of deep vein thrombosis (DVT) and pulmonary embolism (PE).

The Reprocessed Compression Garment is compatible with the OEM pneumatic compression controller. The controller generates air pressure which is transferred through tubing to individual bladders within the garment. The controller's software delivers and monitors the pressure within the bladders. Once predetermined time and pressure criteria are met, the pressure is released by venting air through a valve system.

The modified reprocessed compressible garment is for single-patient-use and is available in knee length and thigh length configurations.

## **5. Intended Use:**

### Compression Garments (Large and X-Large Sizes)

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.

### Compression Garments (Small and Medium Sizes)

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.

## **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. 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 modified Reprocessed Compression Garment is substantially equivalent to the existing Reprocessed Compression Garment (K140813).