September 3, 2021

Surgical Instrument Service and Savings (dba Medline ReNewal)
Richard Wynkoop
VP Quality Assurance and Regulatory Affairs
2747 SW 6th St.
Redmond, Oregon 97756

Re: K143166
Trade/Device Name: Medline ReNewal Reprocessed Compression Limb Sleeves
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible limb sleeve
Regulatory Class: Class II
Product Code: JOW

Dear Richard Wynkoop:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated January 16, 2015. Specifically, FDA is updating this SE Letter due to the clearance date not appearing on the original letter

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Nicole Gillette, OHT2: Office of Cardiovascular Devices, 240 – 402 – 6630, Nicole.Gillette@fda.hhs.gov.

Sincerely,

Nicole M. Gillette -S

Nicole Gillette
Acting Assistant Director
DHT2B: Division of Circulatory Support,
Structural and Vascular Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

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

Surgical Instrument Service and Savings (dba Medline Renewal)
Richard Wynkoop
VP Quality Assurance and Regulatory Affairs
2747 SW 6th St.
Redmond, Oregon 97756

Re: K143166
Trade/Device Name: Medline Renewal Reprocessed Compression Limb Sleeves
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: December 15, 2014
Received: December 17, 2014

Dear Richard Wynkoop,

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,

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143166

Device Name

Medline ReNewal Reprocessed Compression Limb Sleeves

Indications for Use *(Describe)*

Medline ReNewal Reprocessed Compression Limb Sleeves are designed to be used with a pump system to apply sequential compression to the lower limbs to prevent deep vein thrombosis.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

7.0 510(k) Summary

Submitter/ Owner	Medline ReNewal 2747 SW 6th St. Redmond, OR 97756	
Contact Names	Brandi Panteleon Director, Regulatory Affairs P: 541-923-3310 F: 541-923-3375 E: bpanteleon@medline.com	Richard D. Wynkoop VP, QA/RA P: 541-923-3310 F: 541-923-3375 E: rwynkoop@medline.com
Date Prepared	January 15, 2014	
Device Names	Proprietary Name: Medline ReNewal Reprocessed Compression Limb Sleeves Common Name:, Compression Limb Sleeves	
Classification	Sleeve, limb, compressible § 870.5800 Class II Product Code: JOW	
Predicate Device	K012658 - Surgical Instrument Service and Savings, Inc. Reprocessed Compression Limb Sleeves	
Device Description	Medline ReNewal Reprocessed Compression Limb Sleeves are used with a pump system to apply sequential compression to the lower limbs (leg and foot). They are made of a variety of materials and come in various sizes. They are originally manufactured as single use devices.	
Indications for Use	Medline ReNewal Reprocessed Compression Limb Sleeves are designed to be used with a pump system to apply sequential compression to the lower limbs to prevent deep vein thrombosis.	
Technological Characteristics	The technological characteristics of the devices are identical to the predicate devices. There has been no change to the fundamental scientific technology of the devices.	
Performance Testing	The functional characteristics of the proposed devices have been evaluated and found to be equivalent to the predicate devices after the specified number of reprocessing cycles. Testing included: • bioburden testing; • biocompatibility testing (cytotoxicity, irritation, sensitization); • cleaning process validation; • equipment qualification; and • visual inspection.	

Conclusion	Based on the information provided, the modified Medline ReNewal Reprocessed Compression Limb Sleeves are substantially equivalent to the predicate device.