April 3, 2023

Cardinal Health200, LLC
Katy Piper
Regulatory Affairs Manager
3651 Birchwood Drive
Waukegan, Illinois 60085

Re: K230028
Trade/Device Name: Kendall SCD SmartFlow Controller, Cardinal Health Element Sleeves, Kendall SCD Express Sleeves, Kendall SCD Express Foot Cuff, Kendall SCD Sequential Compression Comfort Sleeves, Kendall SCD SmartFlow Controller Tubing Assembly
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible limb sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: January 4, 2023
Received: January 4, 2023

Dear Katy Piper:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Eric E. Richardson -S Digitally signed by Eric E. Richardson -S
Date: 2023.04.03 07:55:30 -04'00'

for Nicole Gillette
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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K230028

Device Name

Kendall SCD SmartFlow Controller
Cardinal Health Element Sleeves
Kendall SCD Express Sleeves
Kendall SCD Express Foot Cuff
Kendall SCD Sequential Compression Comfort Sleeves
Kendall SCD SmartFlow Controller Tubing Assembly

Indications for Use *(Describe)*

Intended Use
The Kendall SCD SmartFlow Compression system (hereby referenced as “Kendall SCD SmartFlow”) is designed to apply Intermittent Pneumatic Compression (IPC) to increase venous blood flow in at-risk patients in order to help prevent deep vein thrombosis and pulmonary embolism. The system, additionally, will enhance circulation and treats venous stasis, addressing associated symptoms such as pain and swelling. The system consists of the controller, the tubing assemblies (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, the controller measures the time it takes for the limbs to refill with blood and adjusts the compression frequency to maximize flow rate.

The system may be used for all ages of adults and children when indicated to apply intermittent pneumatic compression. System is also designed 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. The system is intended for use in a clinical setting by health care professionals.

Indications
Leg Compression
The use of the Kendall SCD SmartFlow Compression System with Sequential, Gradient, Circumferential (SGC) compression is indicated for:
• Deep Vein Thrombosis and Pulmonary Embolism Prophylaxis.
• Treatment of pain and swelling related to venous stasis
• Circulation enhancement
The use of the Kendall SCD SmartFlow Compression System with uniform, posterior compression is indicated for:
• Deep Vein Thrombosis Prophylaxis.

Foot Compression
The use of the Kendall SCD SmartFlow Compression System with foot compression is indicated for:
• Circulation Enhancement
• Deep Vein Thrombosis Prophylaxis
• Edema - Acute
• Edema - Chronic
• Extremity Pain Incident to Trauma or Surgery
• Leg Ulcers

• Venous Stasis

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.

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