July 22, 2019

Midway Medical, LLC.
Jim Tobin
Vice President of Business Development
3004 Gill Street
Bloomington, Illinois 61704

Re: K190975
Trade/Device Name: Plexus SCD110 Sequential Compression Device Sleeve
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: April 3, 2019
Received: April 15, 2019

Dear Jim Tobin:

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,

Fernando Aguel
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190975

Device Name
Plexus SCD110 Sequential Compression Device Sleeve

Indications for Use *(Describe)*
The Plexus SCD 110 DVT Sleeve is a prescription device intended to be used preventatively to increase venous blood flow in patients at risk of deep vein thrombosis due to the associated risk factors for thrombus formation during: trauma, critical care, general medicine, general surgery, as well as neurological, orthopedic, urologic, obstetric conditions and treatments.

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.

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MIDWAY MEDICAL

510(k) Summary

Summary Preparation Date:
April 3, 2019

Revision:
July 15, 2019

Submitter / 510(k) Sponsor
Midway Medical, LLC.
3004 Gill Street
Bloomington, IL 61704

Contact Person
Jim Tobin
Vice President of Business Development
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Device Name
Device Name: Disposable Sequential Compression Device (SCD) Sleeve
Proprietary Trade Name: Plexus SCD110 Sequential Compression Device Sleeve
Common Name: Compressible Limb Sleeve

Product Classification
Product Classification: Compressible Limb Sleeve, 21 CFR 870.5800
Product Code: JOW
Device Class: II

Primary Predicate Device:

Product	Manufacturer	510(k) Number
Cirona 6200 DVT Sleeves	Devon Medical Products	K141578

Reference Devices:

Product	Manufacturer	510(k) Number
Excel Flowtron DVT Garments	Arjo Huntleigh	K133119
Aircast VenoFlow Elite Sleeves	DJO, LLC	K122499
Venodyne Advantage Sleeves	Ecolab, Inc. (Microtek Medical)	K110358
VasoPress Compression Sleeve	Compression Therapy Concepts	K101915

SECTION 3

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510(k) Summary

Device Description

The Plexus SCD110 Sequential Compression Device is a non-sterile sequential compression sleeve intended to be used with commercially-available compression pumps*. The device is used to prevent the onset of deep vein thrombosis (DVT) by stimulating blood flow and increasing venous flow velocity. The device consists of a pair of soft pressure garment sleeves with an internal air bladder. Each package of Plexus SCD110 has two compression sleeves – one for the right calf and one for the left calf.

The Plexus SCD110 is a single-bladder sleeve that provides a preset pattern of intermittent pressure to the deep vein in the lower leg. To use the device, the garment sleeve is wrapped around a patient's calf. The compression sleeve is connected to a commercially available DVT compression pump intended to be used with single-chamber air bladder sleeves. The connector of the sleeve is designed such that it will not connect to a pump intended for multi-chamber sleeves. When the compression pump is turned on, air flows from the air pump into the air bladder inside the compression sleeve, providing pneumatic pressure on the calf muscle and veins underneath.

Once the compression pump reaches an air pressure of 40 mmHg (+/- 10 mmHg), a relief valve is triggered within the DVT pump to let air escape from the sleeve and reduces the pressure within the system. With the relief valve opened, the compression sleeve completely deflates and allows blood to re-enter the deep veins of the patient during this cycle. After a pre-set deflation period (~50-second cycle), the relief valve will close and the air pump will start pumping again to 40 mmHg. This cycle of inflation and deflation of the air bladder will continue until the compression pump device is turned off.

The Plexus SCD110 sleeve is made of a soft, lightweight, non-woven foam-felt material with a single-chamber bladder made of polyvinyl chloride (PVC). The Plexus SCD sleeve is intended to be compatible with single-chamber DVT pump systems only and the connectors will not allow the sleeve to be attached to any other compression systems (i.e. multi-chamber DVT systems, lymphedema compression systems)

**All testing was completed using the following DVT compressions pumps: Cirona™ 6200 (Devon Medical), Flowtron® Excel (ArjoHuntleigh), VenaFlow® Elite System (DJO Global/Aircast), VasoPress® Compression Therapy Pumps (Zimmer Biomet / Compression Therapy Concepts), and Venodyne Advantage (EcoLab Inc. / Microtek Medical, Inc.)*

Device Indications for Use:

The Plexus DVT sleeve is a prescription device intended to be used preventatively to increase venous blood flow in patients at risk deep vein thrombosis due to the associated risk factors for thrombus formation during: trauma, critical care, general medicine, general surgery, as well as neurological, orthopedic, urologic, obstetric conditions and treatments

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510(k) Summary

Contraindications:

The Plexus DVT sleeves are contraindicated for use by patients with the following conditions:

- Severe atherosclerosis or other ischemic vascular diseases
- Suspected or known acute deep vein thrombosis
- Severe congestive cardiac failure
- Existing pulmonary edema
- Existing pulmonary embolisms
- Extreme deformity of the limbs
- Any local skin or tissue condition in which the garments would interfere including gangrene, untreated or infected wounds, recent skin graft, and/or dermatitis
- Known presence of malignancy in the legs
- Limb infections, including cellulitis, that have not received antibiotic coverage
- Presence of lymphangiosarcoma
- In situations where increased lymph and blood flow is undesirable

Technical Characteristics

The technological characteristics of the Plexus DVT sleeves are substantially equivalent to the sleeves of the predicate and other single-chamber reference devices. The overall design, materials, mode of operation, and performance characteristics are substantially equivalent to the predicate and reference devices.

Perfomance Data

To validate that the Plexus DVT sleeve meets the intended specifications, a number of non-clinical tests were conducted by a third-party test facility.

Biocompatibility Tests

Standards and Regulations Applied	Results	Equivalence to Predicate Devices*
ISO10993-5:2009 In-Vitro Cytotoxicity	Passed	Equivalent
ISO10993-10:2010 Intracutaneous Reactivity	Passed	Equivalent
ISO10993-10: 2010 Skin Sensitization	Passed	Equivalent

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510(k) Summary

Comparative and Compatibility Performance Tests

Test	Results	Equivalence to Predicate Devices*
Sleeve Burst Test	Passed	Equivalent
Pressure Accuracy Test	Passed	Equivalent
Pull Force Test	Passed	Equivalent

The biocompatibility testing and functional testing confirm that the Plexus DVT sleeves perform as intended and are substantially equivalent to the proposed predicate device. No new or additional risks are presented with the Plexus DVT sleeves.

**All testing was completed using the following DVT compressions pumps: Cirona™ 6200 (Devon Medical), Flowtron® Excel (ArjoHuntleigh), VenaFlow® Elite System (DJO Global/Aircast), VasoPress® Compression Therapy Pumps (Zimmer Biomet / Compression Therapy Concepts), and Venodyne Advantage (EcoLab Inc. / Microtek Medical, Inc.)*

Conclusion

Based on the assessment of the functional testing and biocompatibility testing performed, the Plexus DVT sleeve is substantially equivalent to the predicate device in material content, function and indications for use. As such, these sleeves can be concluded to be as safe and effective as the predicate devices.