August 27, 2019

Alleva Medical (D.G.) Ltd
Max Choi
CEO
Suite M-Q, 12th Floor, Kings Wing Plaza 2, 1 On Kwan Street
Hong Kong, Hk

Re: K191107
Trade/Device Name: Plexus RP100 Disposable Portable Deep Vein Thrombosis Prevention Device
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: July 29, 2019
Received: July 31, 2019

Dear Max Choi:

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)*
K191107

Device Name
Plexus RP100 Disposable Portable Deep Vein Thrombosis Prevention Device

Indications for Use *(Describe)*
The Plexus RP00 Disposable Portable Deep Vein Thrombosis (DVT) Prevention Device is intended to be used in either home or clinical settings for:

- Aiding the prevention of DVT onset
- Enhancing blood circulation in the lower extremities
- Diminishing post-operative pain and swelling
- Reducing wound healing time, and
- Serving as a prophylaxis for DVT for stationary or bedridden individuals
- Aid in the treatment of: stasis dermatitis, venous stasis ulcers, arterial and diabetic leg ulcers, chronic venous insufficiency and reduction of edema in the lower limbs

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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510(k) Summary

Summary Preparation Date:

April 10, 2019

Submitter

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Contact Person

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Device Name

Device Name: Portable Deep Vein Thrombosis Prevention Device
Proprietary Trade Name: Plexus RP100
Common Name: Compressible Limb Sleeve Device

Product Classification

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

Predicate Device:

Cirona 6300 DVT Prevention Device, Devon Medical Products, K151189

Device Description

The Plexus RP100 Portable Deep Vein Thrombosis ("DVT") Prevention Device is an electronic device that helps to prevent the onset of deep vein thrombosis by stimulating blood flow and increasing venous flow velocity. Each RP100 DVT Prevention Device consists of a pump body and a pressure sleeve with internal air bladder. When turned on, the air bladder inside the sleeve will be automatically inflated to a pre-set level, thereby providing intermittent pressure to the calf.

The commercial saleable package will consist of two pump units with their sleeves, one for each leg.

The unit operates by inflating the air bladder until the pressure reaches 50mmHg. After reaching this pressure level, the unit will automatically deflate for 50 seconds to complete one cycle. Therapy could persist as long as the patient needs or is instructed by their physician. When the therapy ends, the patient simply would turn off the device by the press of a power button.

Indications for Use

The Plexus RP100 Portable DVT Prevention Device is intended to be used by patients 21 years of age or older, in either home or clinical settings for:

- Aiding the prevention of DVT onset
- Enhancing blood circulation in the lower extremities
- Diminishing post-operative pain and swelling
- Reducing wound healing time
- Serving as a prophylaxis for DVT for stationary or bedridden individuals
- Aiding in the treatment of: stasis dermatitis, venous stasis ulcers, arterial and diabetic leg ulcers, chronic venous insufficiency and reduction of edema in the lower limbs

Summary of Technological Characteristics

Both the Plexus RP100 and predicate device, Cirona 6300 (*K151189*), share the same operating principles whereby each unit provides intermittent compression and inflation is supplied by a miniature air pump and deflation is managed by the pressure relief valve. Both devices utilize a microprocessor to deliver 50mmHg of pressurized air to the bladders in the sleeve garment for a predefined period of time. Further, both devices have similar usability, in that they both utilize a single button to initiate device use and utilize Velcro in securing the device to the lower limb. Both pump casings are constructed of hard ABS plastic to provide structural protection to the internal components and the sleeves are made of soft, non-woven materials with the bladders made of Polyurethane films. Both devices are also powered by an internal rechargeable battery.

Summary of Non-Clinical Testing

The following non-clinical testing has been completed to demonstrate that the Plexus RP100 device is performing as intended and has performance characteristics that are substantially equivalent to the listed predicate device.

Biocompatibility Testing

Standards and Regulations Applied	Results
ISO10993-5:2009 In-Vitro Cytotoxicity	Passed
ISO10993-10:2010 Intracutaneous Reactivity	Passed

ISO10993-10: 2010 Skin Sensitization	Passed

Electromagnetic Compatibility and Electrical Safety Testing

Standards and Regulations Applied	Results
IEC 60601-1:2005 (Third Edition) + A1:2012(or IEC 60601-1: 2012 reprint)	Passed
IEC 60601-1-2:2014	Passed

Functional Performance Testing

Test Items	Results
Battery charging time test	Design requirements met
Sleeve leakage test	Design requirements met
Pressure accuracy test	Design requirements met
Inflation time test	Design requirements met
Deflation time test	Design requirements met
Battery operating life test	Design requirements met
Sleeve integrity test	Design requirements met
Total worklife test	Design requirements met

Software Verification and Validation

Software verification and validation activities were completed and there were no unresolved anomalies. The software was considered a “moderate” level of concern, since a failure or latent flaw in the software could directly result in minor injury to the user.

Summary of Clinical Testings

No clinical testing was performed to support the claim of substantial equivalence to the Cirona 6300 device.

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Summary of Substantial Equivalence

Characteristics	Subject Device	Predicate Device	Comparison
Manufacturer	Alleva Medical (D.G) Ltd	Ascent Healthcare, LLC, DBA Devon Medical Products	-
510(k) Number	N/A	K151189	-
Class	II	II	Equivalent
Product Name	Disposable Deep Vein Thrombosis Prevention Device	Disposable Deep Vein Thrombosis Prevention Device	-
Product Code	JOW	JOW	Equivalent
Regulation Number	21 CFR 870.5800	21 CFR 870.5800	Equivalent
Intended Use	• Aiding the prevention of DVT onset • Enhancing blood circulation in the lower extremities • Diminishing post-operative pain and swelling • Reducing wound healing time • Serving as a prophylaxis for DVT for stationary or bedridden individuals • Aid in the treatment of: stasis dermatitis, venous stasis ulcers, arterial and diabetic leg ulcers, chronic venous insufficiency and reduction of edema in the lower limbs	• Aid in the prevention of DVT • Enhance blood circulation • Diminish post-operative pain and swelling • Reduce wound healing time • Aid in the treatment of: stasis dermatitis, venous stasis ulcers, arterial and diabetic leg ulcers, chronic venous insufficiency and reduction of edema in the lower limbs • Serve as a prophylaxis for DVT by persons expecting to be stationary for long periods of time	Equivalent
Use Settings	Home, hospital, surgery center	Home, hospital, surgery center	Equivalent
Portability	Portable	Portable	Equivalent
Principles of operation	Air pump supplying pressure to the air bladder on the pressure garment. Air pressure is relieved through an open air valve	Air pump supplying pressure to the air bladder on the pressure garment. Air pressure is relieved through an open air valve	Equivalent
Location of treatment	Lower limbs/calves	Lower limb/calves	Equivalent
Pressure source	Miniature air pump	Miniature air pump	Equivalent
Therapy Mode	One	One	Equivalent

Compression pressure level	50mmHg	50mmHg	Equivalent
Cycle pattern	Inflation to target pressure, then 50 seconds rest period	Inflation to target pressure, then 50 seconds rest period	Equivalent
Sterility	Clean/non-sterile	Clean/non-sterile	Equivalent
Source of power	Lithium Battery 3.7V 2600mAh	Lithium Battery 3.7V 1350mAh	RP100/Plexus has a higher battery capacity, otherwise equivalent
Power supply	AC Input: 100~240V, AC50/60Hz, 500mA Max; DC output 5V 2A (2 Plugs)	AC Input: 100~240V, AC50/60Hz, 500mA Max; DC output 5V 2A (2 Plugs)	Equivalent
Sleeve material	Soft non-woven fabric	Soft non-woven fabric	Equivalent
Pump housing material	Hard Plastic (ABS)	Hard Plastic (ABS)	Equivalent
Sleeve orientation	Left and right sleeves are different. Indicated on sleeve.	Left and right sleeves are different. Indicated on sleeve	Equivalent
LED indicator	Yes (Blue & Yellow)	Yes (Yellow)	Equivalent in both having a LED indicator; (Plexus has two colors to provide visual aid on power and alarm status)
Alarm communications	Audible and Visual	Audible and Visual	Equivalent: only different in color and duration of the alarm
Alarm modes	Pressure error, low battery error, charging error	Pressure error, low battery error, charging error	Equivalent
Operating time	16 hours continuous for a single charge	8 hours continuous for a single charge	Equivalent; RP100/Plexus has a longer operating time
Storage Requirements	-25-70°C, <93% relative humidity (RH)	-25-70°C, <93% relative humidity (RH)	Equivalent
Operating requirements	+5°C to 40°C (41°F to 104°F), 15%-93% RH	+5°C to 40°C (41°F to 104°F), 15%-93% RH	Equivalent

Conclusions

The Plexus RP100 device has the same intended use and performance characteristics as the predicate device. The results of non-clinical testing demonstrate that the device met all performance requirements and that the subject device is substantially equivalent to the predicate device.