Apex Medical Corp.
Chieh Yang
Quality Engineering Manager
No. 9, Min Sheng St., Tu-Cheng,
New Taipei City, 23679
Taiwan

Re: K213577
Trade/Device Name: VenAir, Sequential Compression System
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: May 31, 2022
Received: June 2, 2022

Dear Chieh Yang:

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,

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.

510(k) Number *(if known)*
K213577

Device Name
VenAir Sequential Compression System

Indications for Use *(Describe)*
The intended use of the VenAir Sequential Compression System (hereby referenced as "VenAir system") is to help prevent Deep Vein Thrombosis (DVT) and pulmonary embolism. The garments are single patient use - do not reuse. The VenAir system is intended for use only in professional healthcare facility environment by trained medical staff. It is not for use in the home healthcare environment. The VenAir system should be used as part of a prescribed plan of care.

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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510(k) Summary

5.1 Type of submission: Traditional

5.2 Date of summary: May 31, 2022

5.3 Submitter: Apex Medical Corp.

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Contact: Chieh Yang (meow.yang@apexmedicalcorp.com)
Job title: Quality Engineering Manager

5.4 Identification of the device:

Proprietary/Trade name:	VenAir Sequential Compression System
Classification product Code:	JOW
Regulation number:	870.5800
Regulation description:	Compressible limb sleeve
Review panel:	Cardiovascular
Device class:	II

5.5 Identification of the Predicate Device:

Predicate device name:	Kendall SCD 700 Sequential Compression Controller
Manufacturer:	Covidien LLC.
Classification product code:	JOW
Regulation number:	870.5800
Device class:	II
510(k) number:	K120944

5.6 Indication for use

The intended use of the VenAir Sequential Compression System (hereby referenced as "VenAir system") is to help prevent Deep Vein Thrombosis (DVT) and pulmonary embolism. The garments are single patient use - do not reuse. The VenAir system is intended for use only in professional healthcare facility environment by trained medical staff. It is not for use in the home healthcare environment. The VenAir system should be used as part of a prescribed plan of care.

5.7 Device description

The VenAir Sequential Compression System is a sequential pneumatic compression system by applying sequential and gradient pressure to increase venous blood flow and circulation in at-risk patients to help prevent deep vein thrombosis and pulmonary embolism.

The product consists of the machine, tubing sets, and disposable (single patient use) garments (thigh, calf, and foot optional purchase) and focuses on compressing the limbs to enhance better blood circulation.

The system has digital sensors to check the garment connections, pressure output and power supply. On the other hand, operator can follow the user manual to check the error code and action as advised.

5.8 Non-clinical testing

A series of tests were performed to assess the safety and effectiveness of VenAir Sequential Compression System. All the test results demonstrate that subject device meets the requirements of its pre-defined acceptance criteria and intended use.

- Shelf life test
- Biocompatibility test
  - Cytotoxicity test
  - Skin irritation test
  - Skin sensitization test

  Test results performed in biocompatibility test reports demonstrated that subject device complies with ISO 10993-1: 2018, ISO 10993-2: 2006, ISO 10993-5: 2009, ISO 10993-10: 2010, ISO 10993-12:2021, USP <87>: 2020, OECD404: 2015, OECD406: 1992.

- Software Validation
- Electromagnetic compatibility and electrical safety
- Performance test
  - Alarm function test report
  - Battery charging and discharging test report
  - Cycle time test report
  - Pressure resistance test report
  - Pressure accuracy test report
  - Air tightness and pull force test report
  - Venous refill detection function test report
- Usability test

All the test results demonstrate VenAir Sequential Compression System meets the requirements of its pre-defined acceptance criteria and intended use, and is substantially equivalent to the predicate device.

5.9 Clinical testing

No clinical test data was used to support the decision of substantial equivalence.

5.10 Substantial equivalence determination

VenAir Sequential Compression System submitted in this 510(k) file is substantially equivalent to the predicate device. Differences between the devices cited in this section do not raise any new issue of substantial equivalence.

Item	Subject device	Predicate device	Substantial equivalence determination
Proprietary name	VenAir Sequential Compression System	Kendall SCD 700 Sequential Compression Controller	
510(k) No.	K213577	K120944	
Indication for use	The intended use of the VenAir Sequential Compression System (hereby referenced as “VenAir system") is to help prevent Deep Vein Thrombosis (DVT) and pulmonary embolism. The	The Kendall SCD™ 700 Sequential Compression System (hereby referenced as "Kendall SCD™ 700 Series") is designed to apply intermittent pneumatic compression to increase venous blood flow in	Similar. Indication for use of both devices has slight different. However, both devices are designed to help prevent deep vein thrombosis and

Item	Subject device	Predicate device	Substantial equivalence determination
Proprietary name	VenAir Sequential Compression System	Kendall SCD 700 Sequential Compression Controller	
510(k) No.	K213577	K120944	
	garments are single patient use - do not reuse. The VenAir system is intended for use only in professional healthcare facility environment by trained medical staff. It is not for use in the home healthcare environment. The VenAir system should be used as part of a prescribed plan of care.	at-risk patients in order to help prevent deep vein thrombosis and pulmonary embolism. The Kendall SCD ™ 700 Series is a prescription device for use in a clinical setting or in the home.	pulmonary embolism. It doesn't raise any new issues of substantial equivalence.
Type of use	Prescription Use	Prescription Use	Equivalence
Mechanism of action	The device is a sequential pneumatic compression system by applying sequential and gradient pressure to increase venous blood flow and circulation in at-risk patients that aids in the prevention of deep vein thrombosis (DVT) a potentially life threatening condition which can lead to pulmonary embolism.	The device is a sequential pneumatic compression system by applying sequential and gradient pressure to increase venous blood flow and circulation in at-risk patients that aids in the prevention of deep vein thrombosis (DVT) a potentially life threatening condition which can lead to pulmonary embolism.	Equivalence
Intended use environment	Healthcare facilities.	Clinical, home use	Similar. It does not raise new issue of substantial equivalence.
Application	Non-invasive, external	Non-invasive, external	Equivalence
Anatomic location	Calf, thigh, foot	Leg (calf and thigh), foot	Equivalence

Item	Subject device	Predicate device	Substantial equivalence determination
Proprietary name	VenAir Sequential Compression System	Kendall SCD 700 Sequential Compression Controller	
510(k) No.	K213577	K120944	
Dimension of pump (mm)	195x178x186	196x173x185 (free standing) 196x173x114 (place on foot board)	Different. It does not raise new issue of substantial equivalence.
Weight	2.765 kg 2.977 kg (Inc. Battery)	2.3 kg	Different. It does not raise new issue of substantial equivalence.
Power supply	100-240 V A.C., 50/60 Hz	100-240 V A.C., 50/60 Hz	Equivalence
Battery	Yes	Yes	Equivalence
Battery type	Lithium Battery	Lithium Battery	Equivalence
Electrical classification	Class I, Type BF	Class I, Type BF	Equivalence
Ingress of water protection	IP23	IP23	Equivalence
Control panel	Yes	Yes	Equivalence
Mode of operation	Continuous	Continuous	Equivalence
Set pressure	Calf, thigh: 45 mmHg Foot: 130 mmHg	Leg (calf and thigh): 45 mmHg Foot: 130 mmHg	Equivalence
Inflation time	Calf / thigh: 11 sec Foot: 5 sec	Leg (calf and thigh): 11 sec Foot: 5 sec	Equivalence
Deflation time	Calf / thigh: Based on Venous Reflux Sensing Technology Foot: 60 sec	Leg (calf and thigh): Based on Vascular refill detection measurement technology Foot: 60 sec	Both devices complied with the IEC 62304. Differences do not raise new issue of substantial equivalence.

Item	Subject device	Predicate device	Substantial equivalence determination
Proprietary name	VenAir Sequential Compression System	Kendall SCD 700 Sequential Compression Controller	
510(k) No.	K213577	K120944	
Applied part	Calf garment, Thigh garment, Foot garment	Leg (calf and thigh) sleeves, Foot cuff	Similar It does not raise new issue of substantial equivalence.
Main material of applied part	Polyester, Polyvinyl Chloride, Polyamide, Nylon, Polyurethane	Meet ISO10993-1 requirement	Similar Both devices complied with the ISO10993. It does not raise new issue of substantial equivalence.
Applied part chamber	Calf, thigh: 3 Foot: 1	Leg (calf and thigh): 3 Foot: 1	Equivalence
Operating conditions	-	-	Different. It does not raise new issue of substantial equivalence.
Temperature	5° C to 40° C	10°C to 40°C	
Relative humidity	30% to 75% non-condensing	85% Maximum, non-condensing	
Atmospheric pressure	752 hPa to 1,060 hPa	700 hPa to 1060 hPa	

5.11 Similarity and difference

The VenAir Sequential Compression System has been compared with Kendall SCD 700 Sequential Compression Controller (K120944). The subject device has the similar indication for use, intended use environment, intended use anatomical location, set pressure and applied part as the predicate devices.

Although the dimension, weight, inflation time and deflation time are different between the subject device and predicate devices, a series testing were demonstrate that the differences do not raise any new issue of substantial equivalence.

In conclusion, the subject device has undergone a series of testing, and the results complied with the test requests; therefore, the difference between the subject device and the predicate device did not raise any problem of safe and effectiveness. The subject device is substantially equivalent to the predicate devices as it claims.

5.12 Conclusion

After analyzing non-clinical laboratory studies and safety testing data, it can be concluded that VenAir Sequential Compression System is substantially equivalent to the predicate device.