October 28, 2025

Wellell Inc.
Chieh Yang
Quality Engineering Manager
No. 9, Min Sheng St., Tu-Cheng Dist.
New Taipei City, 236044
Taiwan

Re: K251466

Trade/Device Name: VenAir, Sequential Compression System (9P-089000); VenAir, Sequential Compression System (PM01D01 / Calf garment (S)); VenAir, Sequential Compression System (PM01E01 / Calf garment (M)); VenAir, Sequential Compression System (PM01F01 / Calf garment (L)); VenAir, Sequential Compression System (PM01G01 / Thigh garment (S)); VenAir, Sequential Compression System (PM01H01 / Thigh garment (M)); VenAir, Sequential Compression System (PM01I01 / Thigh garment (L)); VenAir, Sequential Compression System (PM01J01 / Foot garment (Uni-size)); VenAir, Sequential Compression System (PM00B05 / Tubing)

Regulation Number: 21 CFR 870.5800

Regulation Name: Compressible limb sleeve

Regulatory Class: Class II

Product Code: JOW

Dated: October 3, 2025

Received: October 3, 2025

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Kathleen M. Grunder -S

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K251466

Please provide the device trade name(s).

VenAir, Sequential Compression System (9P-089000);
VenAir, Sequential Compression System (PM01D01 / Calf garment (S));
VenAir, Sequential Compression System (PM01E01 / Calf garment (M));
VenAir, Sequential Compression System (PM01F01 / Calf garment (L));
VenAir, Sequential Compression System (PM01G01 / Thigh garment (S));
VenAir, Sequential Compression System (PM01H01 / Thigh garment (M));
VenAir, Sequential Compression System (PM01I01 / Thigh garment (L));
VenAir, Sequential Compression System (PM01J01 / Foot garment (Uni-size));
VenAir, Sequential Compression System (PM00B05 / Tubing)

Please provide your Indications for Use below.

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.

Please select the types of uses (select one or both, as applicable).

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

1. **Type of Submission:** Special

2. **Date of Summary:** October 23, 2025

3. **Submitter information**

Name:	Wellell Inc.
Address:	No. 9, Min Sheng St., Tu-Cheng, New Taipei City, 236044, Taiwan (R.O.C.)
Phone:	+886-2-2268-5568
Correspondent:	Chieh Yang (meow.yang@wellell.com)

4. **Identification of the subject device (510(k) Number:K251466)**

Trade Name:	VenAir, Sequential Compression System
Review Panel:	Cardiovascular
Regulation Number:	870.5800
Regulation Description:	Compressible limb sleeve
Product Code:	JOW
Device Class:	Class II

5. **Identification of the predicate device**

510(k) Number:	K213577
Predicate Trade Name:	VenAir, Sequential Compression System
Applicant:	Apex Medical Corp.
Regulation Number:	870.5800
Regulation Description:	Compressible limb sleeve
Product Code:	JOW
Device Class:	Class II

Note: Due to company's global brand strategy, we formally updated the company name in the FDA system from "Apex Medical Corp." to "Wellell Inc." on March 21, 2024.

6. **Intended 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.

7. Device description

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

8. Contraindications

Leg / Foot Compression.

(1) Severe arteriosclerosis or other ischemic vascular disease.
(2) Suspected pre-existing deep venous thrombosis, pulmonary embolism, or phlebitis.
(3) Congestive heart failure, or any condition where the increased fluid to heart may be harmful.
(4) The biocompatibility of the VenAir garments have only been evaluated for contact with intact skin and should not be used with an open wound or broken skin. Wound should be appropriately covered with an FDA-cleared dressing before the garment is applied for therapy in order to avoid any garment contact with the wound.
(5) Massive edema of legs (or pulmonary edema).

9. Non-clinical testing

A series of tests were performed to assess the safety and effectiveness of subject device. 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
- Software Validation
- Function test
- Usability evaluation

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.

5.1 Clinical testing

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

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**	**VenAir, Sequential Compression System**	
510(k) No.	**To be assigned**	**K213577**	
Intended 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	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	Same

Item	Subject device	Predicate device	Substantial equivalence determination
Proprietary name	**VenAir, Sequential Compression System**	**VenAir, Sequential Compression System**	
510(k) No.	**To be assigned**	**K213577**	
	part of a prescribed plan of care.	part of a prescribed plan of care.	
Type of use	Prescription Use	Prescription Use	Same
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.	Same
Intended use environment	Healthcare facilities.	Healthcare facilities.	Same
Application	Non-invasive, external	Non-invasive, external	Same
Anatomic location	Calf, thigh, foot	Calf, thigh, foot	Same
Dimension of pump (mm)	195×178×186	195×178×186	Same
Weight	2.765 kg / 2.977 kg (Inc. Battery)	2.765 kg / 2.977 kg (Inc. Battery)	Same
Power supply	100-240 V A.C., 50/60 Hz	100-240 V A.C., 50/60 Hz	Same

Item	Subject device	Predicate device	Substantial equivalence determination
Proprietary name	**VenAir, Sequential Compression System**	**VenAir, Sequential Compression System**	
510(k) No.	**To be assigned**	**K213577**	
Battery	Yes	Yes	Same
Battery type	Lithium Battery	Lithium Battery	Same
Electrical classification	Class I, Type BF	Class I, Type BF	Same
Ingress of water protection	IP23	IP23	Same
Control panel	Yes	Yes	Same
Mode of operation	Continuous	Continuous	Same
Set pressure	Calf, thigh: 45 mmHg Foot: 130 mmHg	Calf, thigh: 45 mmHg Foot: 130 mmHg	Same
Inflation time	Calf, thigh: 11 sec Foot: 3.5 sec	Calf, thigh: 11 sec Foot: 5 sec	Different. We have executed software validation and a series of function test. Test results meet pre-defined criteria, and it does not raise new issues of SE.
Deflation time	Calf, thigh: Based on Venous Reflux Sensing Technology Foot: 60 sec	Calf, thigh: Based on Venous Reflux Sensing Technology Foot: 60 sec	Same
Applied part	Calf garment, Thigh garment,	Calf garment, Thigh garment,	Same

Item	Subject device	Predicate device	Substantial equivalence determination
Proprietary name	**VenAir, Sequential Compression System**	**VenAir, Sequential Compression System**	
510(k) No.	**To be assigned**	**K213577**	
	Foot garment	Foot garment	
Main material of applied part	Nylon & TPU / Polyester & TPU Nylon / TPU, Nylon + Spandex (Lycra) / PU Foam	Polyester & PVC Polyester & Polyamide, PU & Nylon	Different. We have conducted a series of biocompatibility tests. Test results meet pre-defined criteria, and it does not raise new issues of SE.
Applied part chamber	Calf, thigh: 3 Foot: 1	Calf, thigh: 3 Foot: 1	Same
Operating conditions	-	-	Same
Temperature	5° C to 40° C	5° C to 40° C	
Relative humidity	30% to 75% non-condensing	30% to 75% non-condensing	
Pressure Range	1,060 hPa ~752 hPa	1,060 hPa ~752 hPa	

11. Similarity and difference

The subject device, VenAir, Sequential Compression System, has same intended use, principle of operation and similar technological characteristics with the predicate (unmodified) device (K213577).

Although the several specifications are different between two devices, the comparison table is completed to demonstrate that the differences between these parameters would not impact on the safety and effectiveness of the subject device. The subject device has also undergone safety and performance tests, and the results complied with the test requests. Therefore, the differences between the subject device and the predicate device did not raise any problem of substantial equivalence.

12. Conclusion

Based on the pre-clinical testing data, the subject device is considered substantially equivalent to the predicate device in terms of safety and effectiveness.