April 2, 2021

Jiangsu Synecoun Medical Technology Co., Ltd.
Yue Li
Project Manager
East of 1/F. No. 50, G60, Eastside of Lujia Road, Westside
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Taizhou, Jiangsu 225316
China

Re: K203310
Trade/Device Name: SyneCare 1000 Deep Vein Thrombosis Prevention Therapy System
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: February 11, 2021
Received: March 3, 2021

Dear Yue Li:

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 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)*

K203310

Device Name

Synecare 1000 Deep Vein Thrombosis Prevention Therapy System

Indications for Use *(Describe)*

The Synecare 1000 deep vein thrombosis prevention system is intended to be an easy to use portable system, prescribed by a physician, to help prevent the onset of DVT in patients by stimulating blood flow in the extremities (simulating muscle contractions).

This device can be used in the home or clinical settings to:

- 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
- As a prophylaxis for DVT by persons expecting to be stationary for long periods of time

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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510K Summary

Submitter:

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Taizhou Jiangsu, China
Phone: +86-523-86868618
Contact Person: Lei Zhu
Date Prepare: October 9, 2020

Device:

Common Names: Intermittent Pneumatic Compression Device
Proprietary Name: SyneCare 1000 Deep Vein Thrombosis Prevention Therapy System
Regulatory Class: II
Product Code: JOW

Predicate Devices:

The SyneCare 1000 Deep Vein Thrombosis Prevention Therapy System is equivalent to the following:

Predicate Device	Manufacturer	510(k)#
VenaPro	Innovamed Health, LLC	K133274

Device Description

Premarket notification device:
SyneCare 1000 Deep Vein Thrombosis Prevention Therapy System

The SyneCare 1000 deep vein thrombosis prevention therapy system (referred as SyneCare 1000 below) is an easy to use portable pneumatic compression system that noninvasively helps prevent the onset of DVT in patients by stimulating blood flow in the extremities (simulating muscle contractions). The SyneCare 1000 system consists of a pair of pumps and sleeve assemblies.
The device will alternatively inflate and deflate the garment (sleeve) to stimulate blood flow in the extremities (muscle contraction). The device provides a 50mmHg pressure and followed by a deflation period once it reaches the desired pressure, each cycle time is 60 seconds

Intended Use:

The SyneCare 1000 deep vein thrombosis prevention system is intended to be an easy to use portable system, prescribed by a physician, to help prevent the onset of DVT in

patients by stimulating blood flow in the extremities (simulating muscle contractions).
This device can be used in the home or clinical settings to:

- 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
- As a prophylaxis for DVT by persons expecting to be stationary for long periods of time.

Technological Characteristics:

Below is a table of comparison for the technological characteristics against the predicate device:

Feature	SyneCare 1000	VenaPro	S/D
Manufacturer	Jiangsu Synecoun Medical Technology Co.,Ltd.	Innovamed Health, LLC	S
FDA 510(k)	This submission	K133274	S
Indications for Use	The SyneCare 1000 deep vein thrombosis prevention system is intended to be an easy to use portable system, prescribed by a physician, to help prevent the onset of DVT in patients by stimulating blood flow in the extremities (simulating muscle contractions). This device can be used in the home or clinical setting to: * 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; * As a prophylaxis for DVT by persons expecting to be stationary for long periods of time	The VenaPro Vascular Therapy System model VP-31 ill is intended to be an easy to use portable system, prescribed by a physician, to help prevent the onset of DVT in patients by simulating blood flow in the extremities (simulating muscle contractions). This device can be used in the home or clinical settings to: •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 •As a prophylaxis for DVT by persons expecting to be stationary for long periods of time	S

Prescription Use	Yes	Yes	S
Contraindications	The SyneCare 1000 series system should NOT be used in the following conditions: • Severe arteriosclerosis or other ischemic vascular diseases • Acute or active deep vein thrombosis • Existing pulmonary edema, pulmonary embolisms, and/or congestive cardiac failure • On patients with neuropathy, active infections, and/or thrombophlebitis • On extremities that are extremely deformed, insensitive to pain, or where increased venous or lymphatic return is undesirable • Any local skin or tissue condition in which the garments would interfere including but not limited to: o Vein ligation o Gangrene o Open wounds o Recent skin graft o Dermatitis o Massive edema	The VenaPro Vascular Therapy System model VP-3 111I ***must not*** be used to treat the following conditions: * Persons with suspected, active or untreated: deep vein thrombosis, ischemnic vascular disease, severe arteriosclerosis, pulmonary edema, congestive heart failure, thrombophlebitis or an active infection * On a leg where cuffs would interfere with the following conditions: vein ligation, gangrene, dermatitis, open wounds, a recent skin graft, massive edema or extreme deformity of the leg * On patients with neuropathy * On extremities that are insensitive to pain * Where increased venous or lymphatic return is undesirable	S
Use settings	Home and clinical	Home and clinical	S
Application	Non-invasive / external	Non-invasive / external	S
Portability	Portable, ambulant	Portable, ambulant	S
Basis of operation	Aids venous return by using cyclic, intermittent, pneumatic pressure application (inflation followed by deflation) to compress the lower Hmb(s).	Aids venous return by using cyclic, intermittent, pneumatic pressure application (inflation followed by deflation) to compress the lower Hmb(s).	S
Location of treatment application	Lower limb(s) (Calf)	Lower limb(s) (Calf)	S
System management	Electronic，microprocessor controlled	Electronic, microprocessor controlled	S
Treatment delivery	Uses electronic microprocessor and pneumatics to inflate and deflate bladder cuffs to achieve compression therapy	Uses electronic microprocessor and pneumatics to inflate and deflate bladder cuffs to achieve compression therapy	S

Pressure Source	Micropump controlled by electronic processor	Micropump controlled by electronic processor	S
Physical components	Pump and sleeve come assembled	Pump and sleeve come assembled	S
Operating Modes	One	One	S
Cycle time (One inflation and deflation per limb)	Preset at 60 seconds	Preset at 60 seconds	S
Pressure	50mmHg	50mmHg	S
GUI	No	No	S
User interface	One-button operation	One-button operation	S
System diagnostics	Audible and visual alarms prompt recognition of system faults	Audible and visual alarms prompt recognition of system faults	S
Leg cuffs (garments) material	PVC bladder covered with brushed Nylon	PVC bladder covered with brushed Nylon	S
Leg cuff Sterile /Not Sterile	Clean / non sterile	Clean / non sterile	S
Leg cuff usage	Single patient use	Single patient use	S
Battery	3.7 V Li-ion Battery	7.4 V Li-ion Battery	D
Power Requirement	Rechargeable battery and/or AC	Rechargeable batteiy and/or AC	S

*D – Different *S – Same

The SyneCare 1000 and VenaPro are very similar in construction and operation principle. Both devices work in a preset 50mmHg with one button to control the start/stop of the therapy.

SyneCare1000 and VenaPro use different batteries. Though SyneCare 1000 has a lower voltage battery, battery tests and functional tests were conducted to ensure the difference in battery does not affect the effectiveness of the device.

In summary, the SyneCare 1000 is substantially equivalent in device construction, indications for use and contraindications for use to the predicate VenaPro (K133274). Any noted differences between the devices do no raise new issues of the safety and effectiveness. All the results demonstrate that the SyneCare 1000 DVT performs equivalently to the predicate devices .

Performance Tests

To verify that the device design met its function and performance requirements, samples of the device underwent function and mechanical testing. The following tests were conducted:

Function Performance Tests	
RDTR-IP-001.01	Pressure Accuracy Test Report
RDTR-IP-002.01	Cycle Time Test Report
RDTR-IP-003.01	Alarm Function Test Report
RDTR-IP-004.01	Battery Life Test Report
RDTR-IP-005.01	Air Tightness Test Report

The conclusions drawn from the performance tests demonstrate that the device is performing as intended and is substantially equivalent to the predicate.

Biocompatibility

For the sleeve, the SyneCare 1000 uses the same direct body contact method.Biocompatibility testing was done at CCIC Huatongwei International Inspection (Suzhou) Co.,Ltd. The following tests were done:

- Cytotoxicity
- Sensitization
- Irritation

Sterilization and Shelf Life

Sterilization is not applicable to SyneCare 1000.

The shelf life of the product is 3 years. The shelf life was verified.

The following tests were done：

- SyneCare 1000 Accelerated Aging Test Report

Electrical Safety and Electromagnetic Compatibility (EMC)

EMC tests were conducted according to the following standards:

- IEC 60601-1: 2005 Medical electrical equipment Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2: 2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 60601-1-6:2010 Medical electrical equipment Part 1-6: General requirements for safety - Collateral Standard: Usability including IEC 62366: Application of usability engineering to medical devices

- IEC 60601-1-11: 2015 Medical electrical equipment Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

Software Verification and Validation

Software verification and validation was conducted and documentation is provided. The software was considered as a “moderate” level of concern“, since a failure or latent flaw in the software could directly result in serious injury to the patient or operator.

Animal Study and Clinical Study

No animal study or clinical study was conducted.

Statement of Substantial Equivalence

The SyneCare 1000 Deep Vein Thrombosis Prevention Therapy System is substantially equivalent in technology, function, operating parameters, and intended use to predicate devices that are currently commercially available and in distribution, and does not raise any new questions of safety or effectiveness.