November 18, 2021

Jiangsu Synecoun Medical Technology Co., Ltd.
℅ Ivy Wang
Technical Manager
Shanghai SUNGO Management Consulting Company Limited.
14th Floor, 1500# Century Avenue
Shanghai, Shanghai 200122
China

Re: K211937
Trade/Device Name: SyneCare 1100 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: October 11, 2021
Received: October 14, 2021

Dear Ivy Wang:

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,

Nicole Gillette
Acting 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)*
K211937

Device Name
SyneCare 1100 Deep Vein Thrombosis Prevention Therapy System

Indications for Use *(Describe)*
SyneCare 1100 Deep Vein Thrombosis Prevention Therapy System is intended to be an easy to use portable system, prescribed by a physician, for use in the home or clinical setting to help prevent the onset of DVT in patients by stimulating blood flow in the extremities (simulating muscle contractions). This device can be used to:

- Aid in the prevention of DVT;
- Enhance blood circulation;
- Diminish post-operative pain and swelling;
- Reduce wound healing time;
- Aid in the treatment and healing 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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K211937

510(K) Summary

Date of summary prepared: 2021-11-17

A. Applicant:

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B. Device:

Trade Name: SyneCare 1100 Deep Vein Thrombosis Prevention Therapy System
Common Name: Compressible Limb Sleeve Device
Model: SyneCare 1100

Regulatory Information
Classification Name: Compressible limb sleeve
Classification: Class II
Product code: JOW
Regulation Number: 870.5800
Review Panel: Cardiovascular

C. Predicate device:

510(k) #	Device name	Manufacturer
K203310	SyneCare 1000 Deep Vein Thrombosis Prevention Therapy System	Jiangsu Synecoun Medical Technology Co., Ltd.
K203016	DVT-2600	Daesung Maref Co., LTD

D. Indications for use of the device:

SyneCare 1100 Deep Vein Thrombosis Prevention Therapy System is intended to be an easy to use portable system, prescribed by a physician, for use in the home or clinical setting to help prevent the onset of DVT in

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

- Aid in the prevention of DVT;
- Enhance blood circulation;
- Diminish post-operative pain and swelling;
- Reduce wound healing time;
- Aid in the treatment and healing 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.

E. Contraindications:

SyneCare 1100 Deep Vein Thrombosis Prevention Therapy System should NOT be used to treat 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

F. Device Description:

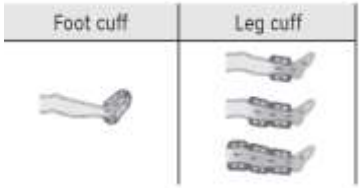
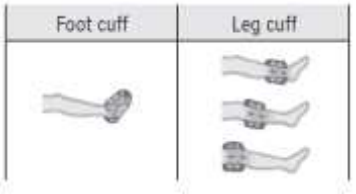
SyneCare 1100 Deep Vein Thrombosis Prevention Therapy System (hereinafter as SyneCare 1100) is an ambulatory, portable, light weight, prescriptive device intermittent pneumatic compression system intended to provide sequential compression therapy to a patient's lower limbs. The SyneCare 1000 system consists of a pair of pumps and sleeve assemblies, in which each sleeve has 2 compression chambers.

The device will alternatively inflate and deflate the sleeve to stimulate blood flow in the extremities (muscle contraction). The compression massage direction is from limb end to body center by inflating the air chambers sequentially and then deflating as one cycle. There are three default modalities. Mode 1 is inflating chamber 1 up to the preset pressure and then deflating, and then inflating chamber 2 up to the preset pressure and then deflating, and repeat the above process with an interval of 40 seconds. Mode 2 is inflating chamber 1 up to the preset pressure and then inflating chamber 2 up to the preset pressure, then deflating at the same time. The above process is repeated with an interval of 40 seconds. The third mode is inflating chamber 1& 2 simultaneously to the preset pressure (50mmHg) and hold for 9 seconds, then deflating to the preset pressure (40mmHg) at the same time and hold for 10 seconds, and then deflating. The above process is repeated with an interval of 30 seconds.

G. Comparison with predicate device

Device	Proposed Device	Predicate Device	Reference Device	Result
510K #	K211937	K203310	K203016	-
Manufacturer	Jiangsu Synecoun Medical Technology Co., Ltd.	Jiangsu Synecoun Medical Technology Co., Ltd.	Daesung Maref Co., LTD	-
Classification	Class II Device, JOW (21 CFR870.5800)	Class II Device, JOW (21 CFR870.5800)	Class II Device, JOW (21 CFR870.5800)	Same
Indications for use	SyneCare 1100 Deep Vein Thrombosis Prevention Therapy System is intended to be an easy to use portable system, prescribed by a physician, for use in the home or clinical setting to help prevent the onset of DVT in patients by stimulating blood flow in the extremities (simulating muscle contractions). This device can be used to: • Aid in the prevention of DVT; • Enhance blood circulation; • Diminish post-operative pain and swelling; • Reduce wound healing time; • Aid in the treatment and healing 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.	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.	A device intended to prevent Deep Vein Thrombosis/Pulmonary Embolism (DVT/PE) by increasing venous blood flow to a patient who has a risk of DVT/PE.	Same
Prescription Use	Yes	Yes	Yes	Same
Contraindications	SyneCare 1100 should NOT be used to treat the following conditions: ● Severe arteriosclerosis or other	SyneCare 1000 series system should NOT be used to treat the following conditions: ● Severe arteriosclerosis or other	The DVT-2600 system is not recommended for use with the following conditions: -pre-existing deep vein	Same

	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	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	thrombosis, phlebothrombosis or pulmonary embolism -presumptive evidence of congestive heart failure -inflammatory phlebitis process -severe arteriosclerosis or other ischemic vascular disease -decompensated cardiac insufficiency -carcinoma metastasis in the affected extremity -lymphatic return is undesirable -severe arteriosclerosis or active infection	
Use settings	Home and clinical	Home and clinical	Professional healthcare environment	Same
Application	Non-invasive / external	Non-invasive / external	Non-invasive / external	Same
Portability	Portable, ambulant	Portable, ambulant	Portable	Same
Basis of operation	Aids venous return by using cyclic, intermittent, pneumatic pressure application (inflation followed by deflation) to compress the lower Limb(s).	Aids venous return by using cyclic, intermittent, pneumatic pressure application (inflation followed by deflation) to compress the lower Limb(s).	Aids venous return by using cyclic, intermittent, pneumatic pressure application (inflation followed by deflation) to compress the treated area.	Same
Location of treatment application	Lower limb(s) (Calf)	Lower limb(s) (Calf)	Lower limbs (Calf, Thigh, Foot)	Same
System	Electronic，microprocessor controlled	Electronic，microprocessor controlled	Electronic，microprocessor	Same

management			controlled	
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	Uses electronic microprocessor and pneumatics to inflate and deflate bladder cuffs to achieve compression therapy	Same
Pressure Source	Micropump controlled by electronic processor	Micropump controlled by electronic processor	Micropump controlled by electronic processor	Same
Physical components	Pump and sleeve come assembled	Pump and sleeve come assembled	Controller, air connectable hose, AC power cord	Same
Operating Modes	3 different modes  Mode 1  Mode 2  Mode 3 	1 mode	2 different modes DVT operation mode  Lymph operation mode  	Different Although the operating modes are different, the working pressure range is same, no adverse effect would cause by this difference.
Hold time	Mode 1 & 2: 0s Mode 3: 9+10s	0s	0s	Different The hold time is different due to the operating modes, while the working pressure range is same, no adverse effect would cause by this difference. This difference will not affect safety.

Number of chambers	2	1	3	Different Similar and less than the reference device.
Working pressure	50 mmHg, 40 mmHg	50 mmHg	LEG: 20-60mmHg FOOT: 120-140mmHg	Different The working pressure is same or lower than that of the predicate device. This will not affect safety.
System diagnostics	Audible and visual alarms prompt recognition of system faults	Audible and visual alarms prompt recognition of system faults	Not available	Same
Leg cuffs material	PVC bladder covered with brushed Nylon	PVC bladder covered with brushed Nylon	Not available	Same
Leg cuff Sterile /Not Sterile	Clean / non sterile	Clean / non sterile	Clean / non sterile	Same
Leg cuff usage	Single patient use	Single patient use	Single patient use	Same
Battery	3.7 V Li-ion Battery	3.7 V Li-ion Battery	3200mAh, 3350mAh	Same
Power Requirement	Rechargeable battery and/or AC	Rechargeable battery and/or AC	Rechargeable Battery and/or AC	Same

H. Summary of Non-Clinical Test

Non-clinical tests were conducted to verify that the proposed device met all design specifications as same to the predicate device.

Performance tests

The following tests were conducted to verify that the device design meet its function and performance requirements.

- Appearance test
- Button function test
- Alarm function test
- Pressure delivery test
- Time parameter test
- Battery charging test
- Noise test
- Bust and leak test

Biocompatibility

The sleeve parts are directly contact human body. Biocompatibility testing including Cytotoxicity, Sensitization and Irritation were conducted and the test results showed the material is non-toxic, non-sensitizing and non-irritating.

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

The software was considered as a “moderate” level of concern and had been verified and validated by the manufacturer.

I. Summary of Clinical Test

No clinical study is included in this submission.

J. Conclusion

Based on the comparison and analysis above, the proposed device is same or similar in design, intended use, technological characteristics to the predicate device. Differences between the subject device and predicate devices did not raise any new concerns regarding safety and effectiveness.

The conclusions drawn from the nonclinical tests demonstrate that the subject device is as safe, as effective, and performs as well as or better than the legally marketed predicate device.