Shenzhen Comen Medical Instruments Co., Ltd
Zitong Wang
Regulatory Engineer
Floor 10, Floor 11 and Section C of Floor 12 of Building 1A
& Floor 1 to Floor 5 of Building 2, FIYTA Timepiece Building
Shenzhen, Guangdong 518106
China

Re: K250190
Trade/Device Name: Sequential Compression System (SCD600)
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: November 7, 2025
Received: November 7, 2025

Dear Zitong 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 (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,

Meaghan Erlewein -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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K250190

Device Name
SCD600 Sequential Compression System

Indications for Use *(Describe)*
The SCD600 Sequential Compression System (hereby referenced as "SCD600") is designed to increase the flow rate of the patient's venous blood in order to prevent deep vein thrombosis and pulmonary embolism and treat limb edema via intermittent pneumatic compression. The SCD600 is intended for use only in professional healthcare facilities by medical staff 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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1. Contact Details

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Contact Telephone:	+86 13760125690
Applicant Contant:	Ms. Wang Zitong
Contant Email:	wangzitong@szcomen.com
Date Prepared:	November 07, 2025

2. Device Details

Device Trade Name:	Sequential Compression System (SCD600)
Common Name:	Compressible Limb Sleeve
Classification Name:	Sleeve, Limb, Compressible
510(K) Number:	K250190, Traditional
Regulation Number:	870.5800
Product Code(s):	JOW
Predicate #:	K120944
Predicate Trade Name:	Kendall SCD 700 Sequential Compression Controller
Predicate Product Code:	JOW

3. Device Description

The subject device Sequential Compression System includes 1 model: SCD600.
SCD600 Sequential Compression System is designed to apply intermittent pneumatic compression to increase the flow rate of the patient's venous blood, thereby helping prevent the occurrence of deep vein thrombosis, pulmonary embolism and treat limb edema in professional healthcare facility.
The system consists of the main unit, connecting tubes, battery, AC power cord and accessory compression cuffs. The compression cuffs can increase the venous blood flow by compressing the limbs. When one compression is completed, the system will start the next compression after waiting the predetermined venous fill time.

4. Indications for use

The Comen SCD600 Sequential Compression System (hereby referenced as "SCD600") is designed to increase the flow rate of the patient's venous blood in order to prevent deep vein thrombosis and pulmonary embolism and treat limb edema via intermittent pneumatic compression. The SCD600 is intended for use only in professional healthcare facilities by medical staff as part of a prescribed plan of care.

5. Intended Use

The system consists of the main unit, connecting tubes, battery, AC power cord, and single-patient use cuffs. Both leg cuffs and foot cuffs compress the limbs to enhance venous blood flow. When one round of compression treatment is completed, the system will start the next compression after the preset venous fill time.

6. Technological Comparison

The predicate device for SCD600 Sequential Compression System is Kendall SCD 700 Sequential Compression Controller (K120944). Both devices are sequential compression system for preventing deep vein thrombosis and pulmonary embolism. The predicate (Kendall SCD700) is able to measure the time it takes for the limbs to refill with blood after the first compression and can wait that period of time before initiating the next compression. However, the venous refill time of subject device, SCD600 can only be set by medical staff before initiating compression treatment.

7. Sterilization and shelf life

Sterilization is not applicable. The SCD600 Sequential Compression System are non-sterile when used. No components or accessories are sterile when used.The shelf life of subject device is 10 years.

8. Biocompatibility

All the patient contacting components have less than 24-hour contact time with intact skin and all of the utilized materials of contacting components have been cleared by FDA.
Our evaluation of the patient contacting materials for the subject devices was in accordance with the FDA guidance ***Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"*** (Issued: September 8, 2023). The patient contacting components cleared by FDA used in the same intended patient with the same intended use and contact duration as the subject device.

9. Performance Data

To establish the substantial equivalence of SCD600 Sequential Compression System, we conducted functional and system level testing on the subject device. The functional and system level testing showed that the device continues to meet specifications, and the performance of the device is equivalent to the predicate.
We have conducted testing to ensure the subject device meets relevant consensus standards.

Performance testing – Bench

The subject device has been tested in compliance with the following safety, performance and electromagnetic compatibility standards:

- ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021] Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD) [Including Amendment 2 (2021)]
- IEC 60601-1-2 Edition 4: 2014-02 Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests
- IEC 60601-1-6 Edition 3.2 2020-07 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- IEC 62366-1 Edition 1.1 2020-06 Medical devices - Part 1: Application of usability engineering to medical devices
- IEC 62304 Edition 1.1 2015-06 Medical device software - Software life cycle processes
- ISO 14971 Third Edition 2019-12 Application of Risk Management to Medical Devices

Additionally, to validate the safety and effectiveness of SCD600, transportation testing was performed.

Performance Testing – Animal

Not applicable. Animal testing is not required to support the substantial equivalence of the device.

Performance Testing – Clinical

Not applicable. Clinical data is not required to establish substantial equivalence to the predicate device.

10. Conclusion

The SCD600 Sequential Compression System has similar indications for use and technological characteristics as the predicate. Performance testing and compliance with FDA-recognized consensus standards demonstrate that the subject device is substantially equivalent to the predicate device.