April 24, 2026

Guangzhou Longest Medical Technology Co., Ltd.
% Jett Lee
Regulation Manager
Guangzhou Keada Biological Tech Co., Ltd.
6f, #1 Tiantai Rd., Science City, Luogang District
Guangzhou, 510020
China

Re: K250242
Trade/Device Name: Compression Therapy Device (LGT-2202DVT)
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: April 3, 2026
Received: April 3, 2026

Dear Jett Lee:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K250242

Device Name
Compression Therapy Device (LGT-2202DVT)

Indications for Use *(Describe)*

1. Leg Compression with sleeve is indicated for:
- Deep Vein Thrombosis and pulmonary embolism prophylaxis
2. Foot Compression with sleeve is indicated for:
- Circulation enhancement
- Deep Vein Thrombosis prophylaxis
- Edema - Acute
- Edema - Chronic
- Extremity pain incident to trauma or surgery
- Leg Ulcers
- Venous stasis / venous insufficiency

The Compression Therapy Device is designed to be used in patients over 22 years old.

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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510 (K) Summary

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirements according to 21CFR 870.5800 and there were no prior submissions for the subject device.

1. Submitter Information

Sponsor: Guangzhou Longest Medical Technology Co., Ltd.
Address: 301 of Building 1, No.96, Chuangqiang Road, Ningxi Street, Zengcheng District, Guangzhou, Guangdong Province, 511399, P.R. China.
Contact person: Xiaobing Luo
Title: Deputy general manager
Phone: +86) 20 6635 3999
Email: gzlongest@longest.cn

2. Subject Device Information

Type of 510(k) submission: Traditional
Classification: Compressible Limb Sleeve,
Trade Name: Compression Therapy Device
Model: LGT-2202DVT
Review Panel: Cardiovascular
Product Code: JOW
Regulation Number: 21 CFR 870.5800
Regulation Class: Class II

3. Predicate Device Information

Trade name: Kendall SCD 700 Sequential Compression Controller
Regulation number: 21 CFR 870.5800
Regulatory Class: Class II
Product Code: JOW
Premarket Notification: K120944
Manufacturer: COVIDIEN LLC

4. Device Description

The **LGT-2202DVT** is a compression therapy device comprised of an intermittent pneumatic controller, sleeves and connectable hoses. The working principle is the air inflating and deflating the sleeve sequentially to develop the circulating pressure on the human body, squeezing the proximal and distal of the limbs to promote blood circulation lymphatic system and improve body microcirculation. Besides, it can prevent thrombus and reduce limb drops, and this kind of disease is related to blood and lymph circulation directly or indirectly.

Clinic purpose: Therapeutic and Rehabilitation

Use environments: Clinic and hospital

5. Intended use/ Indication for use

Compression Therapy Device **LGT-2202DVT** is intended for is as follows:

5.1 Leg Compression with sleeve is indicated for:

-Deep vein thrombosis and pulmonary embolism prophylaxis.

5.2 Foot Compression with sleeve is indicated for:

- Circulation enhancement
- Deep vein thrombosis prophylaxis
- Edema - Acute
- Edema - Chronic
- Extremity pain incident to trauma or surgery
- Leg Ulcers
- Venous stasis / venous insufficiency

The compression Therapy Device is designed to be used in patients over 22 years old.

6. Test Summary

6.1 Performance test

6.1.1 Service life evaluation report

Considering the life of the product host and the service life of the main components, accessories, after the evaluation and validation of the life of the main components, it can be concluded that the service life of the intermittent pneumatic pressure system host up to 10 years, single patient use sleeve for 5000 times, connection hose for 1 year, the life of the main components up to 5 years

6.1.2 Performance test after reliability test was executed.

6.2 Electrical safety and electromagnetic compatibility (EMC)

- IEC 60601-1:2012, 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 compatibility
- IEC 60601-1-6: 2010, Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability.

6.3 Software Verification and Validation Testing

There is no wireless connection, Bluetooth, internet connection in the device, and Power socket is only for battery charging connection.

6.4 Animal Study

Animal testing was not required for this submission.

6.5 Clinical Testing

Clinical testing was not required to demonstrate substantial equivalence to the predicate device.

6.6 Biocompatibility Testing:

- ISO 10993-10:2021, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.
- ISO 10993-5: 2009, Biological evaluation of medical device - Part 5: Test for in vitro Cytotoxiciy.
- ISO 10993-23:2021, Biological evaluation of medical device- Part 23: Tests for irritation.

7. Comparison to Predicate Device

The technological characteristics, features, specifications, materials, and intended use of compression therapy device are substantially equivalent to the predicate devices quoted above. The differences between the subject device and predicate devices do not raise new issues of safety or effectiveness.

Device Feature	Subject Device	Predicate Device (K120944)	Predicate Device (K141064)	Comments
Trade name	Compression Therapy Device LGT-2202DVT	Kendall SCD 700 Sequential Compression Controller	VESOFLOW R PLUS DVT Compression Device (Model: SQS)	N/A
510 (K) number	K250242	K120944	K141064	N/A
Manufacturer	Guangzhou Longest Medical Technology Co., Ltd.	COVIDIEN LLC	Caremed Supply Inc.	N/A
Environment of use	Clinic and hospital	Hospital or home use	Clinic and hospital	Identical
Rx or OTC	Rx	Rx	Rx	Identical
Product code	JOW	JOW	JOW	Identical
Regulation number	21CFR 870.5800	21CFR 870.5800	21CFR 870.5800	Identical
Class	Class II	Class II	Class II	Identical
Indications for use	1. Leg Compression with sleeve is indicated for: ● Deep vein thrombosis and pulmonary embolism prophylaxis. 2. Foot Compression with sleeve is indicated for: ● Circulation enhancement ● Deep vein thrombosis prophylaxis ● Edema - Acute ● Edema - Chronic ● Extremity pain incident to trauma or surgery ● Leg Ulcers	1. The use of the Kendall SCD 700 Series Compression System with Leg Sleeves is indicated for: ● Deep vein thrombosis and pulmonary embolism prophylaxis. 2. The use of the Kendall SCD 700 Series Compression System with Foot Cuffs is indicated for: ● Circulation enhancement. ● Deep vein thrombosis prophylaxis. ● Edema - Acute. ● Edema - Chronic.	The Caremed Supply Inc. VESOFLOW PLUS SQS and IPCS Deep Vein Thrombosis (DVT) Compression Devices are intended to increase venous blood flow in at risk patients in order to help prevent deep vein thrombosis.	Identical

	• Venous stasis / venous insufficiency	• Extremity pain incident to trauma or surgery. • Leg Ulcers. • Venous stasis / venous insufficiency.		
Application	Non-invasive, external	Non-invasive, external	Non-invasive, external	Identical
Product Dimension (WxLxH)	145x166x188 mm	196x173x185 mm (free standing) 196x173x114 mm (when placed on a foot board)	7.54"x 5.12"x7.95"	Different but does not raise any new issue of substantial equivalence
Weight	1.5 Kg	2.3 Kg	2.8kg	
Control panel	Yes	Yes	Yes	Identical
Set pressure	Calf/Thigh: 45, 40 and 30 mmHg Foot Cuffs: 130 mmHg	Leg Sleeves: 45 mmHg Foot Cuffs: 130 mmHg	Calf/Thigh : 45, 40 and 30mmHg Foot: 130mmHg	Different but same as reference device K141064 Calf/thigh: 45, 40 and 30 mmHg; Foot: 130 mmHg.
Timer	Continuous	Continuous	Not published	Identical
Sleeve Type	DVT sleeves	DVT sleeves	Not published	Identical
Compression Mode	4 modes (M1-M4)	Leg Sleeves: Sequential, Gradient, Circumferential; Foot Cuffs: Uniform	Sequential	Different but does not raise any new issue of substantial equivalence
Power source	AC100-240V, 50/60Hz	AC100-240V, 50/60Hz	AC 100-240V, 50/60Hz	Identical
Battery	Battery: 11.1V, 3500mAh,	Battery : 10.8 V, 2200mAh,	Not published	Different but does not

	lithium battery Battery hours:9 h	Lithium Ion pack Run Time: 6-8 hours Charge Time: 4 hours (charging only)		raise any new issue of substantial equivalence
Mode of Operation	Continuous	Continuous	Not published	Identical
System of Protection	Class I, Type B Applied Part	Class I, Type BF	Not published	Different but does not raise any new issue of substantial equivalence
Ingress of water Protection	IPX0	IP23 (IEC 529)	Not published	Different but does not raise any new issue of substantial equivalence
Anatomic location	Calf, thigh, foot	Leg (calf and thigh), foot	Leg (calf and thigh), foot	Identical
Electrical Safety	Evaluated according to IEC 60601-1	Evaluated according to IEC 60601-1	Evaluated according to IEC 60601-1	Identical
EMC	Evaluated according to IEC 60601-1-2	Evaluated according to IEC 60601-1-2	Evaluated according to IEC 60601-1-2	Identical
Environmental Conditions of Operation	Temperature: 5 to 40 °C Rel. humidity: ≤80% Atmosphere Pressure: 62 to 106 kPa	Temperature: 10 to 40 °C Rel. humidity:85 % Maximum, non-condensing Atmosphere Pressure: 700-1060 hPa	Rel. humidity: 30-75% Temperature:15- 35°C	Different but does not raise any new issue of substantial equivalence
Environmental Conditions of Transport and Storage	Temperature: -20 to 55 °C Rel. humidity: ≤93 % Atmosphere Pressure: 62 to 106 kPa	Temperature: -20 to 55 °C	Not published	Different but does not raise any new issue of substantial equivalence

Conclusion: The Compression Therapy Device has the same intended use, technology, design and performance specifications are either identical or substantially

equivalent to existing legally marketed predicate devices. The differences between the Compression Therapy Device do not alter suitability of the proposed device for its intended use.

8. Summary Prepared Date

30Mar2026