July 25, 2025

Guangzhou Longest Medical Technology Co., Ltd.
% Jett Li
Regulation Manager
Guangzhou KEADA Biological Tech Co., Ltd.
6F, No.1 TianTai road, Science City, LuoGang District
Guangzhou, 510010
China

Re: K250244
Trade/Device Name: Compression Therapy Device (LGT-2210DS)
Regulation Number: 21 CFR 890.5650
Regulation Name: Powered Inflatable Tube Massager
Regulatory Class: Class II
Product Code: IRP
Dated: June 27, 2025
Received: June 27, 2025

Dear Jett 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 (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,

JULIA E. SLOCOMB -S 2025.07.25 10:31:49 -04'00'

for Tushar Bansal, PhD
Acting Assistant Director, Acute Injury Devices Team
DHT5B: Division of Neuromodulation and Physical Medicine Devices
OHT5: Office of Neurological and Physical Medicine 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.

Submission Number *(if known)*

K250244

Device Name

Compression Therapy Device (LGT-2210DS)

Indications for Use *(Describe)*

Compression Therapy Device (Model: LGT-2210DS) is intended for Prophylaxis and treatment of edema (Chronic venous edema, Lymphedema, Post-mastectomy lymphedema).
Compression Therapy Device (Model: LGT-2210DS) is intended exclusively for use by medical specialists and is only allowed to be used by qualified and instructed medical persons in clinical and hospital. The compression Therapy Device (Model: LGT-2210DS) 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.

510(k) Summary

K250244

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirements according to 21CFR 890.5650 and there were no prior submissions for the subject device.

1. Submitter Information

Sponsor: Guangzhou Longest Medical Technology Co., Ltd.
Address: 301&401 of Building 2&Building 3, No.96, Chuangqiang Road, Ningxi Street, Zengcheng District, Guangzhou, Guangdong Province.

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: Powered inflatable tube massager
Trade Name: Compression Therapy Device
Model: LGT-2210DS
Review Panel: Physical Medicine
Product Code: IRP
Regulation Number: 21 CFR 890.5650
Regulation Class: Class II

3. Predicate Device Information

Trade name: Compressible Limb Therapy System MK300L
Regulation number: 21CFR 890.5650
Regulatory Class: Class II
Product Code: IRP
Premarket Notification: K112441
Manufacturer: DAESUNG MAREF CO.,LTD.

4. Device Description

The LGT-2210DS is a compression therapy device comprised of an intermittent pneumatic controller, sleeves with 6-chamber, 4-chamber combined 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.
Clinic purpose: Therapeutic and Rehabilitation
Suitable places: Clinic and hospital

5. Intended use/ Indication for use

Compression Therapy Device LGT-2210DS is intended for is as follows:

Prophylaxis and treatment of edema (Chronic venous edema, Lymphedema, Post-mastectomy lymphedema).

Compression Therapy Device (Model: LGT-2210DS) is intended exclusively for use by medical specialists and is only allowed to be used by qualified and instructed medical persons in clinical and hospital.

The compression Therapy Device (Model: LGT-2210DS) 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 verification of the product host life, life evaluation and verification of the main components, can conclude that the service life of Compression Therapy Device host can reach 10 years, Reusable sleeve for 30000 times, the life of the main components up to 5 years.

6.1.2 Performance test after reliability test was executed.

6.1.3 Reliability bench 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. The client information can be exported by entered Password with USB flash drive. Testing related to Cybersecurity was performed.

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 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 devices — 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 (K112441)**	**Comments**
Trade name	Compression Therapy Device	Compressible Limb Therapy System MK300L	N/A
510 (K) number	K250244	K112441	N/A
Manufacturer	Guangzhou Longest Medical Technology Co., Ltd.	DAESUNG MAREF CO.,LTD.	N/A
Environment of use	Clinic and hospital	Hospital or home use	Identical
Rx or OTC	Rx	Rx	Identical
Product code	IRP	IRP	Identical
Regulation number	21CFR 890.5650	21CFR 890.5650	Identical
Class	Class II	Class II	Identical
Mode of Compression	Sequential/Squeeze/Flush/Flow /Release/Wave	Sequential	Similar
Indications for use	Compression Therapy Device (Model: LGT-2210DS) is intended for use Prophylaxis and treatment of edema (Chronic venous edema, Lymphedema, Post-mastectomy lymphedema). Compression Therapy Device (Model: LGT-2210DS) is intended exclusively for use by medical specialists and is only allowed to be used by qualified and instructed medical persons in clinical and hospital. The compression Therapy Device (Model: LGT-2210DS) is designed to be used in patients over 22 years old.	MK300L is intended for use by medical professionals and patients at home, who are under medical supervision, in treating many conditions, such as Primary lymphedema, Edema following trauma and sport injuries, Postimmobilization edema, Venous insufficiencies, Lymphedlema.	Similar Note 1
Treatment area	Arm/Leg	Arm/Leg/Full Body	Identical
Sleeve Type	6-Chamber Leg/Arm Sleeve; 4-Chamber Leg/Arm Sleeve;	6-Chamber Leg/Arm Sleeve Full body Sleeve (Optional)	Identical
Treatment time	1-120 min	1-90 min	Similar Note 2

Pressure ranges	7.5-187 mmHg	10-200 mmHg	Similar Note 3
Product Dimension (WxLxH)	385x348x185 mm	415x310x160 mm	Similar Note 4
Weight	10.0 Kg	6.5 Kg	Similar Note 4
Power source	AC 100-120V, 60 Hz	AC 220-230V, 50/60Hz	Similar Note 5
Treatment Modes	4-Chamber mode: There are 10 modes of M1-M10, among in which M1-M4 and M8- M10 have gradient pressure. 6-chambr mode: There are 10 modes of M1-M10, among in which M1-M5 and M9- M10 have gradient pressure.	A mode (Wave mode by 1 chamber): The selected air chamber(s) inflate(s) and deflates by one chamber sequentially up to thigh from foot B mode (Squeezing mode): After all the selected air chamber(s) inflate(s) sequentially up to thigh from foot, the inflated chambers at once. C mode (B mode two times + Reversed A mode 1 time): It repeats that B mode operates two times and A mode operates reversely one time.	Similar Note 6
Software/firmware/ microprocessor control	Microprocessor	Microprocessor	Identical
Electrical Safety	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	Identical
Safety feature	Power button on main unit or hand switch allows user to stop therapy session at any time	There is a safety switch for emergency to make stop working during operation.	Identical
Technology	Compressor and valve system which sequentially inflates inflatable chambers	Compressor and valve system which sequentially inflates inflatable chambers	Identical
Environmental Conditions of Operation	Temperature: 5 to 40 °C Rel. humidity: ≤80% Atmosphere Pressure: 62 to 106	Temperature: 0 to 40 °C Rel. humidity: 10-90 % Atmosphere Pressure: 700-	Similar Note 7

	kPa	1060 hPa	
Environmental Conditions of Transport and Storage	Temperature: -20 to 55 °C Rel. humidity: ≤93 % Atmosphere Pressure: 70 to 106 kPa	Temperature: -20 to 60 °C Rel. humidity: 0-90 % Atmosphere Pressure: 500 to 1060 hPa	Similar Note 7

Note 1: Although there is a little difference about the description of indication for use, the meanings are the same. This difference does not affect the safety and effectiveness.

Note 2: Although the treatment time range of subject device is 1 to 120 min, which seems to be longer than the predicate devices, the default value is 30 min which is suitable for daily use. And the treatment time is optionally set by medical professionals, so the difference of treatment time would not raise adversely impact on safety and effectiveness.

Note 3: Although the pressure range of subject device is different to the predicate devices, the range is smaller and contained by the predicate device, so the difference of pressure range would not raise adversely impact on safety and effectiveness.

Note 4: Although there is a bit difference of the size and weight between the predicate device and subject device, they are all complied with the IEC 60601-1. Thus the differences do not affect the safety and effectiveness.

Note 5: The little difference of the input power and Power consumption does not affect the safety and effectiveness for the predicate device and subject device are complied with the IEC 60601-1.So the differences do not affect the safety and effectiveness.

Note 6: Although the treatment mode of subject device is different to the predicate devices, while the work modes of subject device just have difference about the inflatable order of the different chambers. The treatment pressure ranges are the smaller and contained by the predicate device under different work modes, so the difference of treatment mode would not raise adversely impact on safety and effectiveness.

Note 7: Although the environmental conditions of operation and transport and storage of subject device is different to the predicate devices, the difference of environmental conditions of operation and transport and storage would not raise adversely impact on safety and effectiveness.

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.