December 9, 2025

Guangzhou Longest Medical Technology Co., Ltd.
% Jett Li
Manager
Guangdong Jianda Medical Technology Co Ltd
906 Room, Longxiang Garden, Tianhe District
Guangzhou,
China

Re: K252154
Trade/Device Name: Portable Electro Stimulation Therapy Device (LGT-2320BE, LGT-2320ME, and LGT-2320SP)
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: NGX, NYN
Dated: November 7, 2025
Received: November 7, 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,

Tushar Bansal -S

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.

510(k) Number *(if known)*
K252154

Device Name
Portable Electro Stimulation Therapy Device (LGT-2320BE, LGT-2320ME, and LGT-2320SP)

Indications for Use *(Describe)*
The NMES is used for:
The device is intended to stimulate healthy muscles in order to improve or facilitate muscle performance. The work imposed on the muscles by the NMES programs is not suitable for rehabilitation and physiotherapy.

The TENS is intended for:
a) Temporary relief of pain associated with sore and aching muscles due to strain from exercise or normal household and work activities;
b) The symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements according to 21CFR 890.5850 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

Trade Name of Device: Portable Electro Stimulation Therapy Device
Model: LGT-2320ME, LGT-2320BE, LGT-2320SP
Regulation Number: 21 CFR 890.5850
Regulation Name: Stimulator, Muscle, Powered, For Muscle Conditioning. .
Regulatory Class: II
Classification Product code: NGX
Subsequent Product code: NYN
Review Panel: Physical Medicine

3. Predicate Device Information

Trade name: Compex Sport Elite 3.0
Regulation number: 21CFR 890.5850
Regulatory Class: Class II
Product Code: Powered Muscle Stimulator, For Muscle Conditioning – 21 CFR 890.5850; Product Code NGX; Review Panel: Physical Medicine
(primary product code)
Stimulator, Nerve, Transcutaneous, Over-The-Counter- 21 CFR 882.5890; Product Code NUH; Review Panel: Neurology
Stimulator, Electrical, Transcutaneous, For Arthritis 21 CFR 882.5890; Product Code NYN (subsequent code); Review Panel: Neurology
Premarket Notification: K201653
Manufacturer: DJO, LLC

4. Device Description

The Portable Electro Stimulation Therapy Device (***Model: LGT-2320ME, LGT-2320BE, and LGT-2320SP***) is an electrotherapy device, mainly consists of the main unit, hand switch and electrodes, providing three channel groups (CH1-CH6, CH7-CH12 and CV

Output channel) of TENS or NMES current.
The device is designed to deliver modulation waveform microcurrent to patient body via electrode pads which are connected to the output channel with lead wire, and the device is supplied by AC mains 100-240 Vac. The control circuit is enclosed in the enclosure of the main unit of the device, with hand switch and power supply driving circuit.

5. Intended use/ Indication for use
The NMES is used for:
The device is intended to stimulate healthy muscles in order to improve or facilitate muscle performance. The work imposed on the muscles by the NMES programs is not suitable for rehabilitation and physiotherapy.

The TENS is intended for:
a) Temporary relief of pain associated with sore and aching muscles due to strain from exercise or normal household and work activities;
b) The symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis.

6. Test Summary
6.1 Performance test
6.1.1 Main unit lifespan verification
Portable Electro Stimulation Therapy Device (*Model: LGT-2320ME, LGT-2320BE, and LGT-2320SP*) has undergone performance and safety tests before undergoing accelerated aging testing, and has passed the tests; After the experiment, the product underwent performance and safety testing again, and the test passed. The test results met the requirements. By comparing the test results before and after the accelerated life verification, it can be concluded that the performance and safety of the product can still meet the claimed requirements. Therefore, it is appropriate for Portable Electro Stimulation Therapy Device to have a service life of 10 years.
6.1.2 LGT-2320 waveform test
According to the "Guidance Document for Powered Muscle Stimulator 510(k)s" and "IEC 60601-2-10, General requirements for basic safety and essential performance–Collateral Standard: Requirements for the development of physiologic closed-loop controllers", the test recorded graphical waveform, output levels, and static charge/effective value/power calculations for 500Ω, 2kΩ, and 10kΩ. Portable Electro Stimulation Therapy Device (*Model: LGT-2320ME, LGT-2320BE, and LGT-2320SP*) products meet the performance requirements of electrical stimulation waveform parameters

6.2 Electrical safety and electromagnetic compatibility (EMC)
The device complied with the Electrical safety and electromagnetic compatibility (EMC) testing according to the following standards:

- IEC 60601-1:2020, Medical Electrical Equipment - Part 1: General Requirements for

Basic Safety and Essential Performance

- IEC 60601-1-2:2020, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility.
- IEC 60601-2-10: 2016, Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators.
- IEC 60601-1-6: 2020, 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. The client information can be exported by entered Password with USB flash drive. Testing related to Cybersecurity was performed.

6.4 Biocompatibility Testing:

The device complies with the following standard requirement:

- ISO 10993-10:2010, 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 Cytotoxicity.

6.5 Animal Study

Animal testing was not required for this submission.

6.6 Clinical Testing

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

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.

Table 1 Substantial equivalence discussion

Device Feature	**Subject Device**	**Predicate Device (K201653)**
Trade name, Model	Portable Electro Stimulation Therapy Device; LGT-2320BE (Theme color: Purple), LGT-2320ME (Theme color: Blue), LGT-2320SP (Theme color: Black+Orange)	Compex Sport Elite3.0
510 (K) number	K252154	K201653
Manufacturer	Guangzhou Longest Medical Technology Co., Ltd.	DJO, LLC
Product code	NGX, NYN	NGX, NUH, NYN
Regulation number	21CFR 890.5850, 21CFR 882.5890	21CFR 890.5850, 21CFR 882.5890
Prescription/OTC	Prescription	OTC
Class	Class II	Class II
Indications for use	The NMES is used for: The device is intended to stimulate healthy muscles in order to improve or facilitate muscle performance. The work imposed on the muscles by the NMES programs is not suitable for rehabilitation and physiotherapy. The TENS is intended for: a) Temporary relief of pain associated with sore and aching	The Compex Sport Elite EMS is used for: The Compex Sport Elite is intended to stimulate healthy muscles in order to improve or facilitate muscle performance. The work imposed on the muscles by the Compex Sport Elite programs is definitely not suitable for rehabilitation and physiotherapy. The Compex Sport Elite TENS is intended for: Temporary relief of pain associated with sore and aching muscles due to strain from exercise

	muscles due to strain from exercise or normal household and work activities; b) The symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis.	or normal household and work activities The symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis. The Compex Sport Elite is an Over-the-Counter device to be used by adults only.
Application	Non-invasive, external	Non-invasive, external
Product Dimension (WxLxH)	LGT-2320BE: 450×468×200 mm LGT-2320ME: 450×405×200 mm LGT-2320SP: 450×405×200 mm	Without silicone sleeve: 136mm*76mm*21mm With silicone sleeve: 140mm*80mm*24.6mm
Weight	LGT-2320BE (main unit): 5.2 kg LGT-2320ME (main unit): 5.1 kg LGT-2320SP (main unit): 5.1 kg Trolley: 12.0 kg	Not published
Duration (Treatment Time)	5-95 min in steps of 5 min, tolerance at ±2%	max = 55 min
Electrode	Self-adhesive Electrode	Not Published
Self-adhesive Electrode Material	Non-woven Fabric + Hydrogel	Not Published
Control panel	Yes	Yes
Software/Firmware/Microprocessor Control?	Yes	Yes
Automatic Overload Trip	Yes	Yes

Automatic No-Load Trip	Yes	Yes
User Override Control	Yes	Yes
Automatic Shut Off	“On/Off” switch	“On/Off” switch
Indicator Display - On/Off Status	Yes	Yes
Indicator Display - Low Battery Detection	No	Yes
Indicator Display Voltage/Current Level	Yes	Yes
Power source	AC100-240V, 50/60Hz	Rechargeable Li-ion. battery 3.7V (one cell); not replaceable.
Mode of Operation	Continuous	Continuous
Library Update Port	USB	USB
Output Mode	Normal, Sweep, Random, Alternate	Two (NMES/TENS)
Channel	3 channel groups (CH1-CH6, CH7-CH12, CV Output)	Four
Output Waveform	Symmetrical, Biphasic, Pulsed	Symmetrical Biphasic
Shape	Rectangular	Rectangular
Pulse Duration	80-400 μs, in steps of 10 μs, ±20% tolerance	NMES:200 to 400 [μs](microseconds) TENS:70 to 300[μs] (measured at 50% of positive pulse)
Pulse Frequency	1-120 Hz	1 to 120 Hz

Maximum Output Voltage	54.4 V @ 500 Ω 148 V @ 2 kΩ 156 V @ 10 kΩ	60 V @ 500 Ω, Tolerance at ±10% 165 V @ 2 kΩ, Tolerance at ±10% 165 V @ 10 kΩ, Tolerance at ±10%
Maximum Output Current	108.8 mA @ 500 Ω 74 mA @ 2 kΩ 15.6 mA @ 10 kΩ,	120 mA @ 500 Ω, Tolerance at ±10% 82 mA @ 2 kΩ, Tolerance at ±10% 16 mA @ 10 kΩ, Tolerance at ±10%
Maximum Phase Charge	42.328 μC @ 500 Ω	48 μC @ 500 Ω
Maximum Current Density	1.275 mA/cm²@ 500 Ω	1.49 mA/cm² @ 500Ω
Maximum Power Density	19.51 mW/cm²@ 500 Ω	27.6 mW/cm² @ 500 Ω
Environmental Conditions of Operation	• Temperature: 5 to 40°C • Rel. humidity: ≤80% • Atmosphere Pressure: 70 to 106 kPa	• Temperature: 0 to 45°C • Rel. humidity: 30 to 75% • Atmosphere Pressure: 700 to 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 45°C • Rel. humidity: ≤75% • Atmosphere Pressure: 700 to 1060 hPa

8. Summary Prepared Date

2025-12-09