October 8, 2020

Guangzhou Longest Science & Technology Co., LTD.
℅ Jet Li
Regulation Manager
Guangzhou KEDA Biological Tech Co., LTD.
6F, No. 1 TianTai Road, Science City, LuoGang District
Guangzhou, Guangdong
China

Re: K201845
Trade/Device Name: Portable Electro-Stimulation Therapy Device, Model: LGT-232(US)
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: NGX, NUH, NYN
Dated: July 9, 2020
Received: July 13, 2020

Dear Jet 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 (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,

Amber Ballard, PhD
Assistant Director
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201845

Device Name
Portable Electro-Stimulation Therapy Device, Model: LGT-232(US)

Indications for Use *(Describe)*

The Portable Electro-Stimulation Therapy Device, model LGT-232(US) is used to: Stimulate healthy muscles in order to improve or facilitate muscle performance. It is to be used by adults only.

Portable Electro-Stimulation Therapy Device, model LGT-232(US) in TENS mode is used for:

1. Temporary relief of pain associated with sore and aching muscles due to strain from exercise or normal household and work activities;
2. 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.

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510(k) Summary

This summary of 510(K) is being submitted in accordance with the requirement of 21 CFR 807.92.

1. **Date of the summary prepared: 2020-10-05**

2. **Submitter'sInformation**

Company Name: Guangzhou Longest Science & Technology CO., Ltd.

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Application Correspondent:

Company: Guangzhou KEDA Biological Tech Co., Ltd.

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Contact Person: Mr. Jet Li

Title: Regulation Manager

Tel: +86-18588874857

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3. **Subject Device Information**

Type of 510(k) submission: Traditional

Common Name: Powered muscle stimulator

Trade Name: Portable Electro-Stimulation Therapy Device, Model: LGT-232(US)

Classification Name: Stimulator, Muscle, Powered, For Muscle Conditioning

Review Panel: Neurology, Physical Medicine

Product Code: NGX, NUH, NYN

Regulation Number: 890.5850

Regulation Class: 2

4. **Predicate Device Information**

Sponsor	DJO, LLC	Shenzhen As-Tec Technology Co., Ltd.

Device Name	Compex Wireless USA	TENS and Muscle Stimulator (Model AS8012)
510(k) Number	K170903	K200727
Product Code	NGX, NUH, NYN	NUH, NGX
Regulation Number	21 CFR § 890.5850	21 CFR § 890.5850
Regulation Class	2	2

5. **Device Description**

The LGT-232(US) is a lightweight and portable multifunctional electrotherapy device that provides NMES or TENS current. The device consists of the main unit, charging case, charger connector, FDA cleared self-adhesive electrodes (K183154), indicator light, main unit cable, on/off button, decreasing intensity button, and increasing intensity button to complete the function. The device can also be connected to a mobile phone through Bluetooth, and be controlled by the MStim Sport Application on the mobile device to choose the training programs and adjust pulse output intensity. The MStim Sport App can be downloaded from App Store. MStim Sport has up to seven training programs. These include Endurance, Resistance, Strength, Explosive Strength, Potentiation, Training Recovery and Pain Relief programs. The programmed electrical pulses will transfer through electrode plates to the suggested area of the body where the electrodes are placed.

6. **Indications for Use**

The Portable Electro-Stimulation Therapy Device, model LGT-232(US) is used to: Stimulate healthy muscles in order to improve or facilitate muscle performance. It is to be used by adults only.

Portable Electro-Stimulation Therapy Device, model LGT-232(US) in TENS mode is used for:

1) Temporary relief of pain associated with sore and aching muscles due to strain from exercise or normal household and work activities;
2) The symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis.

7. **Test Summary**

The Device has been evaluated for safety and performance by lab bench testing according to the following standards:

1) IEC 60601-1-2: 2014: Medical Electrical Equipment - Part 1-2: General requirements for basic safety and essential performance. Collateral Standard: Electromagnetic Compatibility
2) IEC 60601-1:2005: Medical Electrical Equipment - Part 1: General requirements for basic safety and essential performance
3) 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

4) IEC 60601-2-10: 2012: Medical Electrical Equipment - Part 2: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators.
5) ANSI IEEE C63.27-2017: American National Standard for Evaluation of Wireless Coexistence
6) IEC 62133-2: 2017: Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems
7) Biological evaluation of medical device Part 10: Tests for irritation and skin sensitization (ISO 10993- 10: 2010)
8) Biological evaluation of medical device Part 5: Cytotoxicity test- In vitro method (ISO 10993-5: 2009)

8. Comparison to predicate device and conclusion

The technological characteristics, features, specifications, materials, mode of operation, and intended use of the Portable Electro-Stimulation Therapy Device, Model: LGT-232(US) are substantially equivalent to the predicate devices quoted above.

The differences between the subject device and predicate device do not raise new issues of safety or effectiveness.

Characteristic	New Device	Predicate Device I	Predicate Device II	Comparison
510 (K) Number	(To Be Assigned)	K170903	K200727	N/A
Device Name and Model	Portable Electro-Stimulation Therapy Device, Model: LGT-232(US)	Compex Wireless USA	TENS and Muscle Stimulator (Model AS8012)	N/A
Manufacturer	Guangzhou Longest Science & Technology CO., Ltd.	DJO, LLC	Shenzhen As-Tec Technology Co., Ltd.	N/A
Prescription/OTC	OTC	OTC	OTC	Same
Indications for use	The Portable Electro-Stimulation Therapy Device, model LGT-232(US) is used to: Stimulate healthy muscles in order to improve or facilitate muscle performance. It is to be used by adults only. Portable Electro-Stimulation Therapy Device, model LGT-232(US) in TENS mode is used for: 1. Temporary relief of pain associated with sore and aching muscles due to strain from	The Compex Wireless USA is an Over-The-Counter device intended to stimulate healthy muscles in order to improve or facilitate muscle performance. It is to be used by adults only. The Compex Wireless USA is not intended for adjunctive therapy in the treatment of medical diseases and conditions of any kind. None of the Compex Wireless USA stimulation programs are designed for injured or disease afflicted muscles. Its use on such muscles is contraindicated. The work imposed on the muscles by the Compex	TENS(Transcutaneous Electric Nerve Stimulation): To be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, upper extremities (arm), and lower extremities (leg) due to strain from exercise or normal household work activities. PMS(Powered Muscle Stimulation): It is intended to be used to stimulate healthy muscles in	Different, but does not raise different questions of safety and effectiveness.

Characteristic	New Device	Predicate Device I	Predicate Device II	Comparison
	exercise or normal household and work activities; 2. The symptomatic relief and management of chronic, intractable pain and reliefof pain associated with arthritis.	Wireless USA programs is definitely not suitable for rehabilitation and physiotherapy. The Compex Wireless USA electrical impulses allow the triggering of action potentials on motoneurones of motor nerves (excitations). These excitations of motoneurones are transmitted to the muscle fibers via the motor endplate where they generate mechanical muscle fiber responses that correspond to muscle work. Depending on the parameters of the electrical impulses (pulse frequency, duration of contraction, duration of rest, total session duration), different types of muscle work can be imposed on the stimulated muscles. The Compex Wireless USA may therefore be considered a technique of muscle training. The Compex Wireless USA TENS is used for: • temporary relief of pain associated with sore and aching muscles due to	order to improve and facilitate muscle performance.	

Characteristic	New Device	Predicate Device I	Predicate Device II	Comparison
		strain from exercise or normal household and work activities. • the symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis.		
Product Code	NGX, NUH, NYN	NGX, NUH, NYN	NUH, NGX	Same
Regulation Number	890.5850	890.5850	890.5850	Same
Power Sources	Adapter model: HYI11-005 Adapter supply voltage: AC100-240V, 50/60Hz Adapter output: DC 5V, 2A. Battery: 3.7V, 500mAh, lithium battery.	Remote: Lithium Polymer (LiPo) rechargeable 3.7[V] / ⩾1500[mAh Stimulation Modules: Lithium Polymer (LiPo) rechargeable 3.7[V] / ⩾450[mAh]	DC 3.7V lithium battery	Different, but does not raise different questions of safety and effectiveness. See Note 1
Method of Line Current Isolation	N/A (battery operated device)	N/A (battery operated device)	Type BF	Different, but does not raise different questions of safety and effectiveness. See Note 1

Characteristic	New Device	Predicate Device I	Predicate Device II	Comparison
Number of Modes for Micro current stimulation	Two (NMES/TENS)	Two (NMES/TENS)	Two (TENS/PMS)	Only mode designation difference between PMS and NMES, but the function and design for PMS is same with the mode of NMES. It does not raise different questions of safety and effectiveness.
Number of Channels for Micro current stimulation	1	4	2	Different, but does not raise different questions of safety and effectiveness. See Note 1
Synchronous or Alternating	Synchronous	Synchronous, but never 2 channels activated at the same time	Alternating	Different, but does not raise different questions of safety and effectiveness. See Note 1
Regulated Current or Regulated Voltage	Regulated Current	Regulated Current	Voltage control	Different, but does not raise different questions of safety and effectiveness. See Note 1
Software/Firmware /Microprocessor control	Yes	Yes	Yes	Same
Automatic Overload Trip	Yes	Yes	No	Different, but does not raise different questions of safety and effectiveness. See Note 2
Automatic No-load Trip	Yes.	Yes	Yes	Same

Characteristic		New Device	Predicate Device I	Predicate Device II	Comparison
Automatic Shut Off		Yes.	"On/Off" switch	Yes	Different, but does not raise different questions ofsafety and effectiveness. See Note 2.
Patient Override Control		Yes	Yes, push on On/Off button directly pause the program	Yes	Different, but does not raise different questions ofsafety and effectiveness. See Note 2.
Indicator Display	On/Off Status	Yes	Yes	Yes	Same
	Low Battery	Yes	Yes	Yes	Same
	Voltage/Current Level	Yes	Yes	Yes	Same
Timer Range		a) Treatment time: 9min-49min, b) Timer tolerance: ±2%; c) When finish, the device can stop output and prompt	Not publicly available	10 ~ 60 minutes, 10 min/step	Different, but does not raise different questions of safety and effectiveness. See Note 3.

Characteristic	New Device	Predicate Device I	Predicate Device II	Comparison
Console weight	Main unit 60g; Charging case:150g	· Remote: 110 [g] · Stimulation Module:2x60 [g] · Docking Station 800[g]	72g	Different, but does not raise different questions of safety and effectiveness. See Note 8.
Housing Materials and Construction	ABS	not publicly available	ABS+Stainless iron	Different, but does not raise different questions of safety and effectiveness. See Note 8.
Waveform	P1- P7: Symmetrical biphasic pulse	-Endurance: Symmetrical Biphasic -Resistance: Symmetrical Biphasic -Strength: Symmetrical Biphasic -Explosive Strength: Symmetrical Biphasic -Potentiation: Symmetrical Biphasic -Training Recovery (same	Pulsed, symmetric, biphasic	Different, but does not raise different questions of safety and effectiveness. See Note 4.

Characteristic	New Device	Predicate Device I	Predicate Device II	Comparison
		as Active Recovery): Symmetrical Biphasic -Competition Recovery (same as Recovery Plus): Symmetrical Biphasic -Pre-Warmup Program: Symmetrical Biphasic -Muscle Relaxation (same as Massage): Symmetrical Biphasic -Pain relief TENS (same as FM): Balanced, asymmetrical Biphasic		
Shape	Rectangular, with interphase interval	-Endurance: Rectangular -Resistance: Rectangular	Rectangular, with interphase interval	Same

Characteristic	New Device	Predicate Device I	Predicate Device II	Comparison
		-Strength: Rectangular -Explosive Strength: Rectangular -Potentiation: Rectangular -Training Recovery: Rectangular -Competition Recovery: Rectangular -Pre-Warm up: Rectangular -Muscle Relaxation: Rectangular -Pain relief TENS (same as FM):		

Characteristic	New Device	Predicate Device I	Predicate Device II	Comparison
Maximum Output Voltage	<u>For P1:</u> 46.23V ±10% @ 500Ω ; 102.9V ±10% @2KΩ; 108.75V±10% @ 10KΩ <u>For P2:</u> 45.98V±10% @ 5 0 0 Ω 104.45V ±10% @ 2KΩ; 108.75V±10% @ 10KΩ <u>For P3:</u> 45.76 V ±10% @ 500Ω; 103V ±10% @ 2KΩ; 108.7V±10% @ 10KΩ <u>For P4:</u> 45.86V ±10% @ 500Ω;	<u>Endurance:</u> 60 V ±10% @ 500Ω 165 V±10% @ 2 kΩ 165 V±10% @ 10 kΩ <u>Resistance:</u> 60 V±10% @ 500Ω 165 V ±10% @ 2 kΩ 165 V ±10% @ 10 kΩ <u>Strength:</u> 60 V±10% @ 500Ω 165 V±10% @ 2 kΩ 165 V ±10% @ 10 kΩ <u>Explosive Strength</u>: 60 V±10% @ 500Ω	For TENS mode and PMS mode: 49.6V±20% @500Ω; 90V±20% @2kΩ; 120V±20% @10kΩ	Different, but does not raise different questions of safety and effectiveness. See Note 5. Remarks: <u>Compared with predicate device I:</u> P1 is compared to Endurance; P2 is compared to Resistance mode; P3 is compared to Strength mode; P4 is compared to Explosive Strength mode; P5 is compared to Potentiation mode; P6 is compared to Training Recovery; P7 is compared to Pain Relief TENS mode

Characteristic	New Device	Predicate Device I	Predicate Device II	Comparison
	103V ±10% @ 2KΩ; 109.05V±10% @ 10KΩ <u>For P5:</u> 45.74V±10% @ 500Ω; 103.15V ±10% @ 2KΩ; 108.6V±10% @ 10KΩ <u>For P6</u>: 45.73V±10% @ 500Ω; 103.05V±10% @ 2KΩ; 108.5V±10% @ 10KΩ	165 V ±10% @ 2 kΩ 165 V ±10% @ 10 kΩ <u>Potentiation:</u> 60 V ±10% @ 500Ω 152 V ±10% @ 2 kΩ 136 V ±10% @ 10 kΩ <u>Training Recovery:</u> 60 V±10% @ 500Ω 165 V±10% @ 2 kΩ 165 V±10% @ 10 kΩ <u>Competition Recovery:</u> 60 V±10% @ 500Ω 165 V±10% @ 2 kΩ 165 V±10% @ 10 kΩ <u>Pre Warmup</u>		<u>Compared with predicate device II:</u> P1 to P6 is compared to PMS mode; P7 is compared to TENS mode;

Characteristic	New Device	Predicate Device I	Predicate Device II	Comparison
		60 V ±10% @ 500Ω 165 V±10% @ 2 kΩ 165 V ±10% @ 10 kΩ <u>Muscle Relaxation:</u> 60 V ±10% @ 500Ω 165 V ±10% @ 2 kΩ 165 V ±10% @ 10 kΩ <u>Pain Relief TENS:</u> 180[V] peak ±10% on 10[kΩ]; 170[V] peak±10% on 2[kΩ] 58[V] peak ±10% on 500[Ω]		
	<u>For P7:</u> 47.40V ±10% @ 500Ω; 104.45V ±10% @ 2KΩ; 109.3V±10% @ 10KΩ			
Maximum Output Current	<u>For P1:</u> 92mA±10% @500Ω; 51mA±10% @ 2KΩ; 11mA±10% @ 10KΩ	<u>Endurance:</u> 116 mA ±10% @ 500Ω 80 mA±10% @ 2 kΩ 15 mA±10% @ 10 kΩ	For TENS mode and PMS mode: 99.2mA±20% @500Ω; 45mA±20% @2kΩ; 12mA±20% @10kΩ	Different, but does not raise different questions of safety and effectiveness. See Note 5.

Characteristic	New Device	Predicate Device I	Predicate Device II	Comparison
	For P2: 92mA±10% @ 500Ω; 52mA ±10% @ 2KΩ; 11mA±10% @ 10KΩ For P3: 92mA±10% @ 500Ω; 52mA ±10% @ 2KΩ; 11mA±10% @ 10KΩ For P4: 92mA±10% @ 500Ω; 52mA ±10% @ 2KΩ; 11mA±10% @ 10KΩ	Resistance: 116 mA±10% @ 500Ω 80 mA ±10% @ 2 kΩ 17 mA ±10% @ 10 kΩ Strength: 113 mA ±10% @ 500Ω 80 mA ±10% @ 2 kΩ 15 mA ±10% @ 10 kΩ Explosive Strength: 81 mA±10% @ 500Ω 81 mA±10% @ 2 kΩ 15 mA ±10% @ 10 kΩ		Remarks: Compared with predicate device I: P1 is compared to Endurance; P2 is compared to Resistance mode; P3 is compared to Strength mode; P4 is compared to Explosive Strength mode; P5 is compared to Potentiation mode; P6 is compared to Training Recovery; P7 is compared to Pain Relief TENS mode

Characteristic	New Device	Predicate Device I	Predicate Device II	Comparison
	For P5: 92mA±10% @ 500Ω; 52mA ±10% @ 2KΩ; 11mA±10% @ 10KΩ For P6: 92mA±10% @ 500Ω; 52mA±10% @ 2KΩ; 11mA±10% @ 10KΩ	Potentiation: 117 mA ±10% @ 500Ω 80 mA±10% @ 2 kΩ 16 mA±10% @ 10 kΩ Training Recovery: 116 mA±10% @ 500Ω 81mA±10% @ 2 kΩ 16 mA±10% @ 10 kΩ Competition Recovery: 116 mA ±10% @ 500Ω 81 mA±10% @ 2 kΩ 16 mA ±10% @ 10 kΩ		Compared with predicate device II: P1 to P6 is compared to PMS mode; P7 is compared to TENS mode;

Characteristic	New Device	Predicate Device I	Predicate Device II	Comparison
		Pre Warmup 116 mA±10% @ 500Ω 81 mA ±10% @ 2 kΩ 15 mA ±10% @ 10 kΩ Muscle Relaxation: 116 mA ±10% @ 500Ω 81 mA±10% @ 2 kΩ 16 mA ±10% @ 10 kΩ Pain Relief TENS: 18[mA] peak±10% @10[kΩ] 86[mA] peak±10% @2[kΩ] 116[mA] peak±10% @500[Ω]		
	For P7: 95mA±10% @ 500Ω; 52mA ±10% @ 2KΩ; 11mA±10% @ 10KΩ			
Frequency range	1~120Hz	Endurance: 10 [Hz]	For TENS mode and PMS mode: 1 to 100 ±10% [Hz]	Different, but does not raise different questions of safety and effectiveness.

Characteristic	New Device	Predicate Device I	Predicate Device II	Comparison
		Resistance: 50 [Hz] Strength: 75 [Hz] Explosive Strength: 100 [Hz] Potentiation: From 1 to 75 [Hz] Training Recovery: 10 [Hz] Competition Recovery: 0.5 [Hz] Pre-Warmup 4 [Hz] Muscle Relaxation: 1 [Hz] Pain Relief TENS:		See Note 6

Characteristic	New Device	Predicate Device I	Predicate Device II	Comparison
		5 to 122[Hz]		
Pulse width range	P1-P6: Treatment 200~400μs; P7: 70 μs	Endurance: 200 to 400 [μs] Resistance: 200 to 400 [μs] Strength: 200 to 400 [μs] Explosive Strength: 200 to 400 [μs] Potentiation: 200 to 400 [μs] Training Recovery: 200 to 400 [μs] Competition Recovery: 200 to 400 [μs] Pre Warmup	Positive phase: 80μs±10% Negative phase: 80μs±10%	Different, but does not raise different questions of safety and effectiveness. See Note 6 Remarks: <u>Compared with predicate device I:</u> P1 is compared to Endurance; P2 is compared to Resistance mode; P3 is compared to Strength mode; P4 is compared to Explosive Strength mode; P5 is compared to Potentiation mode;

Characteristic	New Device	Predicate Device I	Predicate Device II	Comparison
		200 to 400 [μs] Muscle Relaxation: 200 to 400 [μs] Pain Relief TENS: 70 to 300[μs] (measured at 50% of positive pulse)		P6 is compared to Training Recovery; P7 is compared to Pain Relief TENS mode <u>Compared with predicate device II:</u> P1 to P6 is compared to PMS mode; P7 is compared to TENS mode
Pulse duration	0.5s-2s	Not publicly available	10 ms-1000ms	Different, but does not raise different questions of safety and effectiveness. See Note 6
Net Charge	0uC @ 500Ω	Endurance: 0 [μC] @ 500Ω Excitation pulse fully compensated	0uC @ 500Ω	Different, but does not raise different questions of safety and effectiveness. See Note 7

Characteristic	New Device	Predicate Device I	Predicate Device II	Comparison
		Resistance: 0 [µC] @ 500Ω Excitation pulse fully compensated Strength: 0 [µC] @ 500Ω Excitation pulse fully compensated Explosive Strength: 0 [µC] @ 500Ω Excitation pulse fully compensated Potentiation: 0 [µC] @ 500Ω Excitation pulse fully compensated Training Recovery:		

Characteristic	New Device	Predicate Device I	Predicate Device II	Comparison
		0 [µC] @ 500Ω Excitation pulse fully compensated Competition Recovery: 0 [µC] @ 500Ω Excitation pulse fully compensated Pre Warm up 0 [µC] @ 500Ω Excitation pulse fully compensated Muscle Relaxation: 0 [µC] @ 500Ω Excitation pulse fully Compensated Pain Relief TENS: 0 [µC] @ 500Ω		

Characteristic	New Device	Predicate Device I	Predicate Device II	Comparison
		Excitation pulse fully compensated		
Maximum Current Density	P1: 0.082mA/c m² @ 500Ω, P2: 0.011mA /cm²@500Ω, P3: 0.079mA/c m²@500Ω, P4: 0.110mA/cm²@500Ω, P5: 0.055mA/cm²@500Ω, P6: 0.007mA/cm²@500Ω, P7: 0.031mA/cm²@500Ω	4.8 [mA/cm2] @ 500Ω	0.06mA@500Ω	Different, but does not raise different questions of safety and effectiveness. See Note 7
Maximum Power Density	P1: 85.202mW/cm² @500Ω, P2: 1.480mW/cm² @500Ω, P3: 78.96mW/cm²@500Ω, P4: 150.262mW/cm²@500Ω, P5: 37.647mW/cm²@500Ω, P6: 0.551mW/cm² @500Ω, P7: 12.32mW/cm²@500Ω	27.6 [mW/cm2] @ 500Ω	1.57 mW/cm² @500Ω,	Different, but does not raise different questions of safety and effectiveness. See Note 7

Characteristic	New Device	Predicate Device I	Predicate Device II	Comparison
Electrical Safety, EMC	Compliant with requirements of IEC 60601-1, IEC60601-2-10, IEC 60601-1-2, 1. IEC 60601-1-11, IEC 62133-2 safety standards	IEC 60601-1, IEC 60601-1-2, IEC 60601-2-10, FCC part 15 subpart C and B1	AAMI/ANSI ES 60601-1, IEC 60601-1-2, IEC 60601-2-10, IEC 62133, IEC 60601-1-11	Same

Comparison in Detail(s):

Note 1 (Power Source(s), Method of Line Current Isolation, Number of Channels for Micro current stimulation, Synchronous or Alternating, Regulated Current or Regulated Voltage):

For Power Sources: The power source is the only energy source for the operation of the device, it does not affect the output of the micro current. And the device complies with IEC 60601-1 requirements for evaluation of safety. So, such a minor difference does not raise different question of safety and effectiveness.

For Method of Line Current Isolation: The subject device complies with electric shock isolation protection for operator and patient according to IEC60601-1 standard requirement. So, such a minor difference does not raise different question of safety and effectiveness.

For Number of Channels for Micro current stimulation: The number of channels of output current do not affect the treatment, and the design of subject device comply with IEC60601-2-10 for performance requirement. So, such a minor difference does not raise different question of safety and effectiveness.

For Synchronous or Alternating: There is only one output channel of output current stimulation in subject device. It will not cause safety issue of output current by synchronous or alternating stimulation mode, and the design of the subject device comply with IEC60601-2-10 for performance requirement. So, such a minor difference does not raise different question of safety and effectiveness.

For Regulated Current or Regulated Voltage: There is minor difference output control design theory for output waveform regulation by regulated current or regulated voltage. And the design of subject device complies with IEC60601-2-10 for performance requirement. So, such a minor difference does not raise different question ofsafety and effectiveness.

Note 2 (Automatic Overload Trip, Automatic Shut Off, Patient Override Control):

The design of the Automatic Overload Trip, Shut Off and Patient Override Control are different but subject device has an automatic shutdown function and an overload protection function, which can prevent the patient from unexpected conditions. The patient override control design can make the operator shut down the device output manually at any time. Therefore, the difference would not affect safety and effectiveness of the subject device.

Note 3 (Timer Range):

The design of the timer range is based on the intended use. For the Portable Electro-Stimulation Therapy Device, Model: LGT-232(US), the operating time is adjustable by the operator according to physician's direction. So, the difference in timer setting range would not impact its safety and effectiveness compared to the predicate devices.

Note 4 (Waveform):

Both asymmetrical biphasic wave and symmetrical biphasic wave are common waveforms of low frequency electrical stimulation.

For NMES mode, both the subject device and predicate device are using a symmetrical biphasic wave. For TENS mode, the predicate device is using a balanced, asymmetrical biphasic wave, and the subject device is using a symmetrical biphasic wave. But as long as it has a specific frequency and pulse width, the therapeutic effect can also be achieved. So, the difference would not impact its safety and effectiveness compared to the predicate devices.

Note 5 (Maximum Output Voltage and Maximum Output Current):

The effect of micro current stimulation is determined by micro-current output waveform and output current. There is some difference between the output voltage and current of the subject device compared to the predicate device I. But compared with the predicate device II (K200727) as a complementary predicate device, the max output voltage and current are similar to the subject device. Also, the output voltage and current of the subject device comply with standard requirement of IEC60601-2-10. Therefore, the difference would not affect safety and effectiveness of the subject device.

Note 6 (Frequency, Pulse-width and Pulse duration):

Frequency range: There is a minor difference between the frequency range of the subject device and the predicate device II (K200727). This minor difference does not raise different questions of safety and effectiveness.

Pulse width range: The stimulation time ofmicro current stimulation is determined by pulse width of micro-current output waveform. Frequency and pulse are the time parameter of the waveform. There is only little difference between the pulse width range of the subject device and the predicate device, and the same effect can still be obtained. Also, the subject device complies with IEC 60601-1, and IEC60601-2- 10 for safety evaluation. Therefore, the minor difference in the pulse width range would not affect the safety and effectiveness of subject device.

Pulse duration: There is only little difference between the pulse duration of the subject device and the predicate device (K200727), the pulse duration is the pulse period in a complete cycle of the output waveform; the pulse duration difference only affects the number of pulses per burst in one cycle of the output waveform. However, the operator can adjust the device use time to obtain the treatment time range according to their need. And the subject device complies with IEC 60601-1, and IEC60601-2- 10 for safety evaluation. Therefore, the minor difference in the pulse duration would not affect the safety and effectiveness of subject device.

Note 7 (Maximum current density, Maximum power density and Net Charge):

The effect of the micro-current stimulation is determined by the micro-current output pulse width and output current. The difference between the value of maximum current density and maximum power density of the subject device and the predicate device is due to electrode pad size, but the value of the maximum current density and the maximum power density of subject device are within range and the maximum power density meets with the maximum allowed value 0.25 (W/cm^2) required in FDA guidance. Therefore, the subject device and predicate device are substantially equivalence on these parameters.

Note 8 (Console weight, Housing Materials and Construction):

There are minor differences between the subject device and the predicate devices on device weight and its housing material and construction. But the subject device complies with IEC60601-1, and IEC60601-2-10 Standard requirement. These differences would not impact the safety and effectiveness of the subject device.

Finial Conclusion:

The subject device Portable Electro-Stimulation Therapy Device, Model: LGT-232(US) is substantially equivalent to the predicate devices.