April 26, 2018

Guangzhou Longest Science & Technology Co., Ltd.
% You Yijie
Manager
Qimmiq Medical Consulting Service Co., Ltd
RM.1711, Building K, NO.101 Science Ave International
Creative Valley
Guangzhou, 510663 Cn

Re: K182108
Trade/Device Name: Portable Electro-Stimulation Therapy Device
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: GZJ
Dated: March 29, 2019
Received: March 29, 2019

Dear You Yijie:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Pamela D. Scott -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
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)*
K182108

Device Name
Portable Electro-Stimulation Therapy Device

Indications for Use *(Describe)*

Portable Electro-Stimulation Therapy Device, model LGT-235 is indicated for the Symptomatic relief of chronic intractable pain, Post-traumatic pain and Post-surgical pain of the arms and legs.

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

Date: April 24, 2019

1. Submitter's Information

Establishment Registration Information
Name: Guangzhou Longest Science & Technology Co., Ltd.
Address: 5&6f, Building B4, No.11, Kaiyuan Avenue Science City, Hi-Tech Industrial Zone Guangzhou, Guangdong CHINA

Contact Person of applicant
Name: Xiaobing Luo
Address: 5&6f, Building B4, No.11, Kaiyuan Avenue Science City, Hi-Tech Industrial Zone Guangzhou, Guangdong CHINA
TEL: +86 020-66353999
FAX: +86 020-66353999
Email: gzlongest@126.com

Contact Person of the Submission:
Name: You Yijie
Address: RM.1711, Building K, NO.101 Science Ave International Creative Valley Development Zone, Guangzhou China
TEL: +86 020-8224 5821
FAX: +86 020-8224 5821
Email: Jet.you@qimmiq-med.com

2. Device Information

Type of 510(K) submission: Traditional
Trade Name: Portable Electro-Stimulation Therapy Device
Model: LGT-235
Regulation name: Transcutaneous electrical nerve stimulator for pain relief.
Review panel: Neurology
Product code: GZJ
Regulation Class: II
Regulation Number: 21 CFR 882.5890

3. Predicate Device Information

510(k) submitter/holder:	Mettler Electronics Corp.
510(K) Number:	K111482
Regulation Class:	2
Device:	Sonicator Plus 920
Trade name:	Sonicator Plus 920, Model ME 920

4. Device description

The Portable Electro-Stimulation Therapy Device, model LGT-235 is a stimulator which sends gentle electrical current to underlying nerves via electrodes (Knee brace or self-adhesive electrode) applied on the skin with two operational modes and powered by rechargeable lithium battery; the device system is made up of mobile app MStim Arth, main unit and electrodes (Knee brace and self-adhesive electrode).

The Mobile App MStim Arth provides access to treatment controls for Portable Electro-Stimulation Therapy Device from a compatible mobile device for selecting a pre-programmed output mode and treatment time.

The main unit provides access to adjust the intensity up or down, put ON/OFF the main unit.

The two modes that Portable Electro-Stimulation Therapy Device, model LGT-235 employs are transcutaneous electrical stimulation (TENS) and Microcurrent (MCR).

TENS and MCR are both specifically targets the sensory nerves, which are responsible for sending pain signals to the brain. TENS and MCR use tiny electrical impulses sent through the skin to nerves to modify the pain perception. TENS and MCR do not cure any physiological problem; it only helps control the pain, this activates the underlying sensory nerves. Knee brace is placed on the leg or arm close to the area of pain.

5. Principle of operation:

The Portable Electro-Stimulation Therapy Device, model LGT-235 sends gentle electrical current to underlying nerves and muscle group via electrodes (Knee brace or self-adhesive electrode) applied on the skin and powered by rechargeable lithium battery. When used in TENS or MCR mode, it specifically targets the sensory nerves, which are responsible for sending pain signals to the brain; and it uses tiny electrical impulses sent through the skin to nerves to modify pain perception and finally helps control the pain.

6. Indications for Use

Portable Electro-Stimulation Therapy Device, model LGT-235 is indicated for the Symptomatic relief of chronic intractable pain, Post-traumatic pain and Post-surgical pain of the arms and legs..

7. Summary of technological characteristics of device compared to the predicate devices (K111482)

Basic Device Characteristics – Comparison with Predicate Device

Characteristic	Subject device Present application (Portable Electro-Stimulation Therapy Device, model	Predicate device (K111482, Sonicator Plus 920, Model ME 920 (TENS and Microurrent mode))	Discussion of difference

		LGT-235)		
Classification		21 CFR 882.5890	21 CFR 890.5890	**Same**
Product Code		GZJ	GZJ	**Same**
FDA Class		2	2	**Same**
Intended Use		Symptomatic relief of chronic intractable pain 2. Post-traumatic pain 3. Post-surgical pain	Symptomatic relief of chronic intractable pain 2. Post-traumatic pain 3. Post-surgical pain	**Same**
Principle of operation		sends gentle electrical current to muscle group via electrodes applied on the skin	sends gentle electrical current to muscle group via electrodes applied on the skin	**Same**
target population		adults	adults	**Same**
anatomical site		Arm and legs	Arm and legs	**Same**
Material of Patient contact components		**Electrodes:** Knee brace: OK cloth + SBR + dacron Conductive fabric: Silver wire + nylon Self-adhesive electrode: conductive hydrogel	Electrode: conductive hydrogel	**Different** Knee brace was demonstrated biocompability safety by passing ISO 10993-5 and ISO 10993-10 tests. The difference does not raise the issue of product's safety and effectiveness.
where used		home	home	**Same**
Design		Handheld	Desk type	**Different** This difference existed will not affect the safety and effectiveness of the proposed device
Power Source		Rechargeable lithium battery 3.7V	AC line	**Different** The proposed device was demonstrated electrical safety by passing ANSI AAMI ES60601-1. The difference does not raise the issue of product's safety and effectiveness.
Method of line current isolation		N/A (3.7V rechargeable lithium battery operated device)	Double isolation	**Different** This difference existed will not affect the safety and effectiveness of the proposed device.
Patient Leakage	Normal condition	< 1μA	Meet requirement of ANSI/AAMI ES60601-1	**Similar** The proposed device was

Current	Single fault condition	< 1μA	>50μA	demonstrated electrical safety by meet the requirement of chapter 8.7.4.7 of ANSI AAMI ES60601-1. The difference does not raise the issue of product's safety and effectiveness.
Number of Output Channels	Number	One	two	**Different** This will not affect the safety and effectiveness of the proposed device
	Synchronous or Alternating?	Synchronous	Synchronous	**Same**
Number of Output Modes		two (TENS + MCR)	two (TENS + MCR modes)	**Same**
Regulated Current or Regulated Voltage?		Current	Current	**Same**
Software/Firmware/Microprocessor Control?		Yes	Yes	**Same**
Automatic Overload Trip?		Yes	Yes	**Same**
Automatic No-Load Trip?		Yes	Yes	**Same**
Automatic Shut Off?		"On/Off" button	"On/Off" button	**Same**
User Override Control?		No, On/Off	No, On/Off, Hold or Stop	**Same**
Indicator Display	On/Off Status?	Yes	Yes	**Same**
	Low Battery?	Yes	N/A	**Different** This difference existed will not affect the safety and effectiveness of the proposed device
	Voltage/ Current Level?	Yes (on app)	Yes	**Same** System validation testing scenarios covering mitigation of wireless risks in accordance with RED were added to our full system testing protocol to ensure safe and effective use.
Timer Range (minutes)		1~60 minutes	0~60 minutes	**Same**

ANSI AAMI ES60601-1	Yes	Yes	**Same**
IEC 60601-1-2	Yes	Yes	**Same**
IEC 60601-2-10	Yes	Yes	**Same**
Weight	main unit: 120g Charging case: 150g	11(lbs.)	**Different** The Weight will not affect the safety and effectiveness of the proposed device
Dimensions (W x H x D)	59mm (W) × 59mm (L) × 22mm (H) (mm)	4.9 x 13.6 x10.5(in.)	**Different** The dimensions will not affect the safety and effectiveness of the proposed device
Operating condition	Temperature: 5 to 40°C; Rel. humidity: ≤80%; Atmosphere Pressure: 86.0 to 106.0kPa.	Temperature of use from 10°C to 40°C Max. relative humidity from 30% to 75% Atmospheric pressure from 700 hPa to1060 hPa	**Similar** The operating condition of subject device has passed the safety test, and the Instructions for Use provides the operating condition, so the difference between the operating conditions of subject device and predicate device will not affect the safety and effectiveness of subject device.

Output Specifications – Comparison with Predicate Device

Characteristic	**Subject device** **Present application** **(Portable Electro-Stimulation Therapy Device, model LGT-235)**	**Predicate device** **(K111482, Sonicator Plus 920, Model ME 920 (TENS and Microurrent mode))**	**Discussion of difference**
Waveform	Symmetrical biphasic	Symmetrical Biphasic	**Same**
Maximum Output Voltage (± 20%)	TENS: 50V @ 500 Ω 115 V @ 2 kΩ 125 V @ 10 kΩ MCR: 0.45 V@ 500 Ω 1.8 V@ 2 kΩ 7.4 V @ 10 kΩ	TENS: 50 V @ 500 Ω 115 V @ 2 kΩ 125 V @ 10 kΩ MCR: 0.37 V @ 500 Ω 1.5 V @ 2 kΩ 7.4 V @ 10 kΩ	**Similar** The error existed in MCR mode between proposed device and predicate device are acceptable. The difference does not raise the issue of product's safety and effectiveness.
Maximum Output	TENS:	TENS:	**Similar**

Current (± 20%)	100 mA@ 500 Ω 58 mA@ 2 kΩ 13 mA@ 10 kΩ <u>MCR:</u> 0.92 mA@ 500 Ω 0.90 mA@ 2 kΩ 0.74 mA@ 10 kΩ	100 mA@ 500 Ω 58 mA@ 2 kΩ 13 mA@ 10 kΩ <u>MCR:</u> 0.74 mA@ 500 Ω 0.75 mA@ 2 kΩ 0.74 mA@ 10 kΩ	The error existed in MCR mode between proposed device and predicate device are acceptable. The difference does not raise the issue of product's safety and effectiveness.
Pulse Width	TENS: 50 to 500 μs MCR: 4.16 ms ~ 0.5s	TENS: 100 ~ 600us MCR: 1.25ms ~ 1.67s	**Similar** The predicate device is safe and effective in pulse width range 100 ~ 600us for TENS mode and 1.25ms ~ 1.67s for MCR mode, since the pulse width range of proposed device are in the range of predicate device, the proposed device is also safe and effective with its pulse width, therefore, the difference does not raise the issue of product's safety and effectiveness.
Frequency	TENS: 1 ~ 120 Hz MCR: 1 ~ 120 Hz	TENS: 0.5 ~ 250 Hz MCR: 0.3 ~ 400 Hz	**Similar** The frequency range of predicate device is overriding the range of proposed device, since the predicate device is safe and effective, therefore the proposed device is also safe and effective, the difference does not raise the issue of product's safety and effectiveness.
Maximum intensity	100mA	100 mA	**Same**
For multiphasic / Symmetrical phases?	Yes	Yes	**Same**

waveforms only	Phase Duration (include units) (state range, if applicable) (both phases, if asymmetrical)	TENS: 50 to 500 μs MCR: 4.16 ms ~ 0.5s	TENS: 100 ~ 600us MCR: 1.25ms ~ 1.67s	**Similar** The predicate device is safe and effective in pulse width range 100 ~ 600us for TENS mode and 1.25ms ~ 1.67s for MCR mode, since the pulse width range of proposed device are in the range of predicate device, the proposed device is also safe and effective with its pulse width, therefore, difference existed does not raise the issue of product's safety and effectiveness.
Stimulating surface area of electrode (minimum)		2500mm^2 (50mm, square)	2015.80mm^2 (50.8mm diameter, round)	**Similar** The smaller of the surface area the higher risk is, the difference does not raise the issue of product's safety and effectiveness.
Net Charge (μC/pulse)		TENS:0μC @ 500Ω MCR: 0μC@ 500Ω	0 μC @ 500Ω	**Same**.
Maximum Phase Charge (μC)		TENS: 48 (μC) @ 500Ω MCR: 34 (μC) @ 500Ω	TENS: 60 (μC) @ 500Ω MCR: 75 (μC) @ 500Ω	**Similar** The Maximum Phase Charge of predicate device is overriding the proposed device, since the predicate device is safe and effective, therefore the proposed device is also safe and effective, difference existed does not raise the issue of product's safety and effectiveness.
Maximum Current Density, (mA / cm^2, r.m.s.)		TENS: 0.81mA/cm2 @ 500Ω MCR: 0.036mA/cm2@ 500Ω	TENS: 1.97 (mA/cm2) @ 500Ω MCR: 0.026mA/cm2 @ 500Ω	**Similar** For TENS mode, the maximum current density of proposed device is overriding the proposed device which means the proposed device is safe and effective. As for mode MCR, the maximum current density of proposed device is little bigger than predicate device, however the proposed device was demonstrated safety by meet the requirement of

			IEC 60601-2-10. The difference does not raise the issue of product's safety and effectiveness.
Maximum Power Density (W/cm^2)	TENS: 8.26 mW/cm2 @ 500Ω MCR: 0.016 W/cm2 @ 500Ω	TENS: 39 mW/cm2 @ 500Ω MCR: 0.007 mW/cm2 @ 500Ω	**Similar** For TENS mode, the maximum power density of proposed device is overriding the proposed device which means the proposed device is safe and effective. As for mode MCR, the maximum power density of proposed device is bigger than predicate device but far less than 0.25 W/cm^2 required by Guidance Document for Powered Muscle Stimulator (June 9, 1999), the difference does not raise the issue of product's safety and effectiveness.

8. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

Non-clinical verification testing of the Portable Electro-Stimulation Therapy Device, model: LGT-235 included electrical, mechanical, and software tests to show the device meets its design specifications. Validation and performance testing validates that the device meets its user needs. Verification and validation test results established that the device meets its intended use, that it is as safe, as effective, and performs as well as the predicate devices, and that no new issues of safety and effectiveness were raised. The Portable Electro-Stimulation Therapy Device, model: LGT-235 was designed, verified, and validated according to the company's Design Control process and has been subjected to extensive safety and performance testing as shown in the test results provided in this submission. Verification and Validation testing data demonstrate that the device meets all of its specifications including compliance with the following standards:

1. ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicityISO 10993-10:2010 Biological evaluation of medical devices. Tests for irritation and skin sensitization
2. ANSI AAMI ES60601-1:2005/(R) 2012 and A1:2012 Medical electrical equipment. General requirements for basic safety and essential performance
3. IEC 60601-1-2:2014 Medical electrical equipment - part 1-2: general requirements for safety - collateral standard: electromagnetic compatibility - requirements and tests
4. IEC 60601-2-10:2012 Medical Electrical equipment - Part 2-10: Particular requirements for the safety of nerve and muscle stimulators
5. 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.

9. Conclusions

The electrical safety, EMC, biocompatibility, software verification and validation, basic unit characteristics, and output specifications information provided is sufficient to demonstrate substantial equivalence to the predicate device. As the Portable Electro-Stimulation Therapy Device, model: LGT-235 is nearly identical to the predicate device, differences in their characteristics do not raise any raise new questions regarding safety and effectiveness with identical indications for use and essentially identical technological characteristics, the Portable Electro-Stimulation Therapy Device, model: LGT-235 is substantially equivalent to the predicate device Sonicator Plus 920, Model ME 920 (TENS and MCR mode).