September 17, 2020

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: K182020
Trade/Device Name: Portable Electro-Stimulation Therapy Device
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: NGX, NUH, NYN
Dated: July 27, 2020
Received: July 27, 2020

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/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,

Vivek Pinto, PhD
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)*
K182020

Device Name
Portable Electro-Stimulation Therapy Device, model LGT-231

Indications for Use *(Describe)*
Portable Electro-Stimulation Therapy Device, model LGT-231 is to be used by adults only and has two modes NMES, TENS.

NMES is used to: stimulate healthy muscles in order to improve or facilitate muscle performance.

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

1. Submitter's Information

Establishment Registration Information
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TEL: (+86) 020-8224 5821
FAX: (+86) 020-8224 5821
Email: Jet.you@qimmiq-med.com
Date to prepare: 7/5/2018

2. Device Information

Type of 510(K) submission: Traditional
Trade Name: Portable Electro-Stimulation Therapy Device
Model: LGT-231
Regulation name: Powered muscle stimulator.
Transcutaneous electrical nerve stimulator for pain relief.
Review panel: Physical Medicine, Neurology
Product code: NGX, NUH, NYN
Regulation Class: II
Regulation Number: 21 CFR 890.5850, 21 CFR 882.5890

3. Predicate Device Information

510(k) submitter/holder: DJO, LLC
510(K) Number: K170918
Device: Compex Sport Elite
Trade name: Compex Sport Elite
Regulation name: Powered muscle stimulator.
Transcutaneous electrical nerve stimulator for pain relief.
Review panel: Physical Medicine, Neurology
Product code: NGX, NUH, NYN
Regulation Class: II
Regulation Number: 21 CFR 890.5850, 21 CFR 882.5890

4. Device description

The Portable Electro-Stimulation Therapy Device, model LGT-231 is a dual channel stimulator which sends gentle electrical current to underlying nerves and muscle group via electrodes applied on the skin with two operational modes and powered by rechargeable lithium battery; the device system is made up of mobile app MStim Reha, main unit and electrodes.

The Mobile App MStim Reha provides access to treatment controls for Portable Electro-Stimulation Therapy Device from a compatible mobile device for selecting a pre-programmed output mode, adjusting frequency, pulse width and treatment time. Software operating environment of Mobile App MStim Reha are Android 4.3 or later mobile phone, with 4.0 Bluetooth and iOS 8.0 or later iPhone mobile phone, with 4.0 Bluetooth. Click the MStim Reha Application installation package on the phone to install the application. MStim Reha Application and the device can be connected via Bluetooth.

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-231 employs are neuromuscular electrical stimulation (NMES) and transcutaneous electrical stimulation (TENS). Neuromuscular electrical stimulation (NMES) and transcutaneous electrical stimulation (TENS) target different nerve groups of the body.

TENS is specifically targets the sensory nerves, which are responsible for sending pain signals to the brain. TENS use tiny electrical impulses sent through the skin to nerves to modify the pain perception. TENS does not cure any physiological problem; it only helps control the pain, this activates the underlying sensory nerves. Self-adhesive electrodes are placed on the skin close to the area of pain.

NMES targets the muscle itself, specifically through the motor nerves. This allows the NMES machine to create a muscle contraction to recruit more muscle fibers when training; warming up or recovering. The Portable Electro-Stimulation Therapy Device stimulates nerve fibers by means of electrical impulses transmitted by electrodes. The electrical pulses generated by the Portable Electro-Stimulation Therapy Device stimulate motor nerves to stimulate a muscular response. Depending on the parameters of the electrical impulses (pulse frequency, duration of contraction, duration of rest, and total session duration), different types of muscle work can be imposed on the stimulated muscles. The Portable Electro-Stimulation Therapy Device may

therefore be considered a technique of muscle training.

5. Principle of operation:

The Portable Electro-Stimulation Therapy Device, model LGT-231 sends gentle electrical current to underlying nerves and muscle group via electrodes applied on the skin and powered by rechargeable lithium battery. When used in TENS mode, it is 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 the pain perception and finally helps control the pain. IN NMES mode, Portable Electro-Stimulation Therapy Device stimulates nerve fibers by means of electrical impulses transmitted by electrodes, the electrical pulses generated by the Portable Electro-Stimulation Therapy Device stimulate motor nerves to stimulate a muscular response and to create a muscle contraction to recruit more muscle fibers when training.

6. Indications for Use

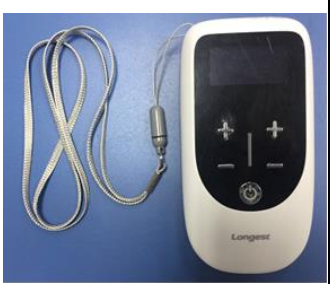
Portable Electro-Stimulation Therapy Device, model LGT-231 is to be used by adults only and has two modes NMES and TENS.

NMES is used to: stimulate healthy muscles in order to improve or facilitate muscle performance.

TENS is used to:
1. Temporary relief of pain associated with sore and aching muscles due to strain from exercise or normal household and work activities.
2. Symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis.

7. Summary of technological characteristics of device compared to the predicate devices (K170918)

Basic Device Characteristics – Comparison with Predicate Device

Characteristic	**Subject device Present application (Portable Electro-Stimulation Therapy Device, model LGT-231)**	**Predicate device (K170918, Compex Sport Elite)**	**Discussion of difference**
Manufacturer	Guangzhou Longest Science & Technology Co., Ltd	DJO, LLC	/
Picture			***/***

Classification		21 CFR 890.5850, 21 CFR 882.5890	21 CFR 890.5850, 21 CFR 882.5890	**Same**
Prescription/OTC		OTC	OTC	**Same**
Product Code		NGX, NUH, NYN	NGX, NUH, NYN	**Same**
FDA Class		II	II	**Same**
Intended Use		Portable Electro-Stimulation Therapy Device, model LGT-231 is to be used by adults only and has two modes NMES and TENS. NMES is used to: stimulate healthy muscles in order to improve or facilitate muscle performance. TENS is used to: 1. Temporary relief of pain associated with sore and aching muscles due to strain from exercise or normal household and work activities. 2. Symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis.	NMES: 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 not suitable for rehabilitation or physiotherapy. TENS: The Compex Sport Elite TENS is intended for: • Temporary relief of pain associated with sore and aching muscles due to strain from exercise or normal household and work activities • They 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.	**Same**
target population		adults	adults	**Same**
Power Source		Rechargeable lithium battery 3.7V	Rechargeable Ni-Mh Battery 4.8V	**Similar** The proposed device was demonstrated electromagnetic compatility and electrical safety by the testing. The difference does not raise the issue of product's safety and effectiveness.
Method of line current isolation		N/A (battery operated device)	N/A (battery operated device)	**Same**
Patient Leakage Current	Normal condition	N/A (battery operated device)	N/A (battery operated device)	**Similar** The proposed device was demonstrated electrical safety by passing ANSI AAMI ES60601-1 and IEC 60601-2-10 tests. The difference does not raise the issue of product's safety and effectiveness.
	Single fault condition	N/A (battery operated device)	N/A (battery operated device)	**Same**

Number of Output Channels	Number	Two	Four	**Different** More channels means it can be applied on more different body sides at the same time, and all output channel works independently from each other, the proposed device has less channels than equivalent device, this can be addressed by applied two proposed device, therefore, the different channel number will not affect the safety and effectiveness of the proposed device.
	Synchronous or Alternating?	Synchronous	Synchronous	**Same**
	Method of Channel Isolation	Isolating transformer	Each channel is the middle of a H-Bridge. Except when it is activated, each channel is always in high impedance state.	**Similar** The proposed device was demonstrated electrical safety by passing ANSI AAMI ES60601-1 and IEC 60601-2-10 tests. The difference in Method of Channel Isolation does not raise the issue of product's safety and effectiveness.
Number of Output Modes		Two (TENS and NMES)	two (TENS and NMES)	**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" switch	**Same**
User Override Control?		Yes	Yes	**Same**
Indicator Display	On/Off Status?	Yes	Yes	**Same**
	Low Battery?	Yes	Yes	**Same**
	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)		Maximum = 60 minute	Maximum = 55 minute	**Different** The treatment time is adjusted by the user or depend on selected programs, so the difference doesn't affect the safety and effectiveness of the proposed device.
Compliance with 21 CFR 898?		Yes	Yes	**Same**
ANSI AAMI ES60601-1		Yes	Yes	**Same**
ANSI AAMI ES60601-1-2		Yes	Yes	**Same**

IEC 60601-2-10	Yes	Yes	**Same**
Weight	120g (only main unit)	300 g	**Different** The Weight will not affect the safety and effectiveness of the proposed device
Dimensions (mm) (W x H x D)	62 (W) × 122 (L) × 27 (H) (mm)	99 x 142 x 36 (mm) 3.9 x 5.6 x 1.4 (in)	**Different** The dimensions will not affect the safety and effectiveness of the proposed device
Housing Materials and Construction	Casing: Plastic (PC+ABS, with PMMA on the button panel) Buttons: ABS Light pipe: PC	Casing: Plastic (ABS, with PMMA on the windows) Buttons: Silicon, rubber Battery Pack: Rigid, ABS housing around the battery cells Battery contacts: SK5 steel	**Similar** The Housing Materials and Construction form the basic construction and ensure the basic safety of device, since the proposed device was demonstrated electrical safety by passing ANSI AAMI ES60601-1 and IEC 60601-2-10 tests, the existed difference will not affect the safety of the proposed device.
Programs	**NMES:** **TENS:** - Normal - Sweep - Random - Alternation represents different frequency modulation methods)	**NMES:** - Endurance - Resistance - Strength - Explosive Strength - Potentiation - Training Recovery (same as Active Recovery) - Competition Recovery (same as Recovery Plus) - Pre-Warmup Program - Muscle Relaxation (same as Massage) **TENS:** -Pain relief TENS (same as FM)	**Similar** The two devices have two same main Output Modes: NMES and TENS, both modes NMES and TENS of these two devices also have same indications respectively, although both modes have different output programs, these two modes have almost the same parameter range, and the NMES of the proposed device can be adjusted arbitrarily within the parameter range, the TENS output programs: Normal, Sweep, Random, Alternation represents different frequency adjustment methods, same as Frequency Modulation which is same with the equivalent device. Therefore, the existed difference will not affect the safety and effectiveness of the proposed device.

Output Specifications – Comparison with Predicate Device

Characteristic	**Subject device** **Present application (**Portable Electro-Stimulation Therapy Device, model LGT-231**)**	**Predicate device (**K170918, Compex Sport Elite**)**	**Discussion of difference**
Manufacturer	Guangzhou Longest Science & Technology Co., Ltd	DJO, LLC	/

Waveform	**NMES:** Symmetrical biphasic **TENS:** <u>- Normal:</u> Balanced Symmetrical biphasic <u>- Random:</u> Balanced Symmetrical biphasic <u>- Sweep:</u> Balanced Symmetrical biphasic <u>- Alternation</u> Balanced Symmetrical biphasic	**NMES:** -Endurance: Symmetrical Biphasic -Resistance: Symmetrical Biphasic -Strength : Symmetrical Biphasic -Explosive Strength: Symmetrical Biphasic -Potentiation: Symmetrical Biphasic -Training Recovery (same 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 **TENS:** -Pain relief TENS (same as FM): Balanced, asymetrical Biphasic	**Same**
Shape (e.g., rectangular, spike, rectified sinusoidal)	**NMES:** Rectangular **TENS:** <u>- Normal:</u> Rectangular <u>- Random:</u> Rectangular <u>- Sweep:</u> Rectangular <u>- Alternation</u> Rectangular	**NMES:** <u>-Endurance:</u> Rectangular <u>-Resistance:</u> Rectangular <u>-Strength:</u> <u>Rectangular</u> -Explosive Strength: Rectangular <u>-Potentiation:</u> Rectangular <u>-Training Recovery</u> (same as Active Recovery): Rectangular <u>-Competition</u>	**Same**

		Recovery (same as Recovery Plus): Rectangular <u>-Pre-Warmup</u> Program: Rectangular <u>-Muscle Relaxation</u> (same as Massage): Rectangular **TENS:** <u>-Pain relief TENS</u> (same as FM): Rectangular	
Maximum Output Voltage (± 10%)	**NMES:** 50 V @ 500 Ω 115 V @ 2 kΩ 125 V @ 10 kΩ **TENS:** <u>- Normal:</u> 50 V @ 500 Ω 115 V @ 2 kΩ 125 V @ 10 kΩ <u>- Random:</u> 50 V @ 500 Ω 115 V @ 2 kΩ 125 V @ 10 kΩ <u>- Sweep:</u> 50 V @ 500 Ω 115 V @ 2 kΩ 125 V @ 10 kΩ <u>- Alternation</u> 50 V @ 500 Ω 115 V @ 2 kΩ 125 V @ 10 kΩ	**NMES:** <u>- Endurance:</u> 60 V @ 500 Ω 165 V @ 2 kΩ 165 V @ 10 kΩ <u>- Resistance:</u> 60 V @ 500 Ω 165 V @ 2 kΩ 165 V @ 10 kΩ <u>- Strength:</u> 60 V @ 500 Ω 165 V @ 2 kΩ 165 V @ 10 kΩ <u>- Explosive Strength:</u> 60 V @ 500 Ω 165 V @ 2 kΩ 165 V @ 10 kΩ <u>- Potentiation:</u> 60 V @ 500 Ω 152 V @ 2 kΩ 136 V @ 10 kΩ <u>- Training Recovery:</u> 60 V @ 500 Ω 165 V @ 2 kΩ 165 V @ 10 kΩ <u>- Competition Recovery:</u> 60 V @ 500 Ω 165 V @ 2 kΩ 165 V @ 10 kΩ <u>- Pre Warmup:</u> 60 V @ 500 Ω 165 V @ 2 kΩ 165 V @ 10 kΩ <u>- Muscle Relaxation:</u> 60 V @ 500 Ω 165 V @ 2 kΩ	**Similar** The max output voltage of proposed device is smaller than predicate device, the predicate device is safe and effective with its output voltage range which means the proposed device is also safe and effective with its output voltage, and at the meantime, the proposed device was also demonstrated electrical safety by passing ANSI AAMI ES60601-1 and IEC 60601-2-10 tests. Therefore, the difference does not raise the issue of product's safety and effectiveness.

		165 V @ 10 kΩ **TENS:** <u>- Pain Relief TENS:</u> 60 V @ 500 Ω 152 V @ 2 kΩ 165 V @ 10 kΩ	
Maximum Output Current (± 10%)	**NMES:** 100 mA @ 500 Ω 58 mA @ 2 kΩ 13 mA @ 10 kΩ **TENS:** <u>- Normal:</u> 100 mA @ 500 Ω 58 mA @ 2 kΩ 13 mA @ 10 kΩ <u>- Random:</u> 100 mA @ 500 Ω 58 mA @ 2 kΩ 13 mA @ 10 kΩ <u>- Sweep:</u> 100 mA @ 500 Ω 58 mA @ 2 kΩ 13 mA @ 10 kΩ <u>- Alternation</u> 100 mA @ 500 Ω 58 mA @ 2 kΩ 13 mA @ 10 kΩ	**NMES:** <u>- Endurance:</u> 120 mA @ 500 Ω 82 mA @ 2 kΩ 16 mA @ 10 kΩ <u>- Resistance:</u> 120 mA @ 500 Ω 82 mA @ 2 kΩ 16 mA @ 10 kΩ <u>- Strength:</u> 120 mA @ 500 Ω 82 mA @ 2 kΩ 16 mA @ 10 kΩ <u>- Explosive Strength:</u> 120 mA @ 500 Ω 82 mA @ 2 kΩ 16 mA @ 10 kΩ <u>- Potentiation:</u> 120 mA @ 500 Ω 82 mA @ 2 kΩ 16 mA @ 10 kΩ <u>- Training Recovery:</u> 120 mA @ 500 Ω 82 mA @ 2 kΩ 16 mA @ 10 kΩ <u>- Competition Recovery:</u> 120 mA @ 500 Ω 82 mA @ 2 kΩ 16 mA @ 10 kΩ <u>- Pre Warmup</u> 120 mA @ 500 Ω 82 mA @ 2 kΩ 16 mA @ 10 kΩ <u>- Muscle Relaxation:</u> 120 mA @ 500 Ω 82 mA @ 2 kΩ 16 mA @ 10 kΩ **TENS:** <u>- Pain Relief TENS:</u> 119[mA] peak@500 Ω 76[mA] peak@2 kΩ	**Similar** The output current of proposed device is smaller than predicate device, the predicate device is safe and effective with its output current range which means the proposed device is also safe and effective with its output current, and at the meantime, the proposed device was also demonstrated electrical safety by passing ANSI AAMI ES60601-1 and IEC 60601-2-10 tests. Therefore, the difference does not raise the issue of product's safety and effectiveness.

		12[mA] peak @10 kΩ	
Pulse Width	**NMES:** 50 to 400 μs **TENS:** - Normal: 50 to 400 μs - Random: 50 to 400 μs - Sweep: 50 to 400 μs - Alternation 50 to 400 μs	**NMES:** - 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 200 to 400 [μs] - Muscle Relaxation: 200 to 400 [μs] **TENS:** - Pain Relief TENS: 70 to 300[μs] (measured at 50% of positive pulse)	**Similar** Risk arises with lager Pulse Width, since the largest Pulse Width of proposed device is same the predicate device, this tiny differences will not affect the safety and effectiveness of the proposed device
Frequency	**NMES:** 1 to 120 Hz **TENS:** - Normal: 1 to 120 Hz - Random 1 to 120 Hz - Sweep: 1 to 120 Hz - Alternation 1 to 120 Hz	**NMES:** - Endurance: 10 Hz - 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:	**Similar** The different frequency will finally cause different feelings, as for NMES mode, the frequency range of the proposed device is 1~120Hz and the equivalent device is 1~100Hz, both of them have similar frequency range and the parameter of the proposed device can be adjusted to the same with the proposed device, as for TENS mode, the frequency range of the proposed device is 1~120Hz, and the equivalent device is 5~122Hz, both of them have similar frequency range and are Frequency Modulation, therefore, these tiny difference existed in Frequency between proposed device and predicate device are acceptable. The difference will not raise the issue of product's safety and

			4 Hz <u>- Muscle Relaxation:</u> 1 Hz **TENS:** <u>- Pain Relief TENS:</u> 5 to 122Hz	effectiveness.
For interferential modes only: - Beat Frequency [Hz]		N/A	N/A	**Same**
For multiphasic waveforms only	Symmetrical phases?	Yes	Yes	**Same**
	Phase Duration (include units) (state range, if applicable) (both phases, if asymmetrical)	**NMES:** Symmetrical, 50 - 400 µs **TENS:** <u>- Normal:</u> Symmetrical, 50 - 400 µs <u>- Random</u> Symmetrical, 50 - 400 µs <u>- Sweep:</u> Symmetrical, 50 - 400 µs <u>- Alternation</u> Symmetrical, 50 - 400 µs	**NMES:** <u>- Endurance:</u> Symmetrical, 280 - 400 µs <u>- Resistance:</u> Symmetrical, 280 - 400 µs <u>- Strength:</u> Symmetrical, 280 - 400 µs <u>- Explosive Strength:</u> Symmetrical, 280 - 400 µs <u>- Potentiation:</u> Symmetrical, 280 - 400 µs <u>- Training Recovery:</u> Symmetrical, 280 - 400 µs <u>- Competition Recovery:</u> Symmetrical, 280 - 400 µs <u>- Pre Warmup:</u> Symmetrical, 280 - 400 µs <u>- Muscle Relaxation:</u> Symmetrical, 280 - 400 µs **TENS:** <u>- Pain Relief TENS:</u> Symmetrical, 70 - 300 µs	**Similar** Risk arises with lager Pulse Width, since the largest Pulse Width of proposed device is same the predicate device, this tiny differences will not affect the safety and effectiveness of the proposed device
Net Charge (µC/pulse)		**NMES:**	**NMES:**	**Same**

	0 µC @ 500Ω **TENS:** <u>- Normal:</u> 0 µC @ 500Ω <u>- Random</u> 0 µC @ 500Ω <u>- Sweep:</u> 0 µC @ 500Ω <u>- Alternation</u> 0 µC @ 500Ω	<u>- Endurance:</u> 0 [µC] @ 500Ω Excitation pulse fully Compensated <u>- Resistance:</u> 0 [µC] @ 500Ω Excitation pulse fully Compensated <u>- Strength:</u> 0 [µC] @ 500Ω Excitation pulse fully Compensated <u>- Explosive Strength:</u> 0 [µC] @ 500Ω Excitation pulse fully Compensated <u>- Potentiation:</u> 0 [µC] @ 500Ω Excitation pulse fully Compensated <u>- Training Recovery:</u> 0 [µC] @ 500Ω Excitation pulse fully Compensated <u>- Competition Recovery:</u> 0 [µC] @ 500Ω Excitation pulse fully Compensated <u>- Pre Warmup</u> 0 [µC] @ 500Ω Excitation pulse fully Compensated <u>- Muscle Relaxation:</u> 0 [µC] @ 500Ω Excitation pulse fully Compensated **TENS:** <u>- Pain Relief TENS:</u> 0 [µC] @ 500Ω Excitation pulse fully compensated	
Maximum Phase Charge (µC)	NMES:48.24 µC @ 500Ω TENS: 46.73 µC @ 500Ω	48 (µC) @ 500Ω	**Similar** The tiny difference existed in Maximum Phase Charge between proposed device and predicate device are acceptable and the proposed device was demonstrated electrical safety by passing ANSI AAMI ES60601-1

				and IEC 60601-2-10 tests. The difference does not raise the issue of product's safety and effectiveness.
Maximum Current Density, (mA / cm^2, r.m.s.)		TENS: 1.94mA/cm^2 @ 500Ω NMES: 2.00mA/cm^2 @ 500Ω	4.8 (mA/cm^2) @ 500Ω	**Similar** The proposed device has a smaller maximum current density than predicate device. The proposed device was also demonstrated electrical safety by passing ANSI AAMI ES60601-1 and IEC 60601-2-10 tests. The difference does not raise the issue of product's safety and effectiveness.
Maximum Average Power Density (mW/cm^2)		TENS: 30.15 mW/cm^2 @500Ω NMES: 32.28 mW/cm^2 @500Ω	27.6 (mW/cm^2) @500Ω	**Similar** The tiny difference existed in Maximum Average Power between proposed device and predicate device are acceptable and the proposed device was demonstrated electrical safety by passing ANSI AAMI ES60601-1 and IEC 60601-2-10 tests. The difference does not raise the issue of product's safety and effectiveness.
Burst Mode (i.e., pulse trains)	Pulses per burst	N/A, no burst mode	N/A, no burst mode	**Same**
	Bursts per second			
	Burst duration (seconds)			
	Duty Cycle [Line (b) x Line (c)			
ON Time (seconds)		Depends on your own settings, Once started, the output is active until user manually stops the unit	Depends on the selected program	**Same** Both device is depended on the user's selection
OFF Time (seconds)		Depends on your own settings 1-60min	Depends on the selected program	**Same** Both device is depended on the user's selection
Additional Features (if applicable)		N/A	N/A	**Same**

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-231 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-231 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:

ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
ISO 10993-10:2010 Biological evaluation of medical devices. Tests for irritation and skin sensitization
ANSI AAMI ES60601-1:2005+A1:2012 Medical electrical equipment. General requirements for basic safety and essential performance
ANSI AAMI ES60601-1-2:2014 Medical electrical equipment - part 1-2: general requirements for safety - collateral standard: electromagnetic compatibility - requirements and tests
IEC 60601-2-10:2012 Medical Electrical equipment - Part 2-10: Particular requirements for the safety of nerve and muscle stimulators
ANSI AAMI ES60601-1-11:2015 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. Discussion of Clinical Tests Performed:
Longest determined that bench and non-clinical testing were sufficient to demonstrate that Portable Electro-Stimulation Therapy Device, model: LGT-231 is as safe and effective as the predicate device.

10. 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-231 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-231 is substantially equivalent to the predicate device Compex Sport Elite.