November 9, 2020

Gongguan Tutamen Metalwork Co., LTD
% Charles Shen
Official Correspondent
Manton Business and Technology Services
37 Winding Ridge
Oakland, New Jersey 07436

Re: K201431
Trade/Device Name: OGYILI TENS/NMES Stimulator
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator for Pain Relief
Regulatory Class: Class II
Product Code: GZJ, IPF
Dated: August 11, 2020
Received: August 13, 2020

Dear Charles Shen:

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,

Heather Dean, PhD
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

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)*
K201431

Device Name
OGYILI TENS/NMES Stimulator

Indications for Use *(Describe)*
TENS function of the device is indicated for the following use:
Symptomatic relief and management of chronic (long-term), intractable pain and an adjunctive treatment in the management of post-surgical pain and post-traumatic acute pain

NMES function of the device is indicated for the following use:
- Relaxation of muscle spasms
- Prevention or retardation of disuse atrophy
- Increasing local blood circulation
- Muscle re-education
- Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis
- Maintaining or increasing range of motion

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

510(k) Summary:

This summary of 510k safety and effectiveness information is being submitted
In accordance with the requirements of 21CFR 807.92

5.1 Submitter & Foreign Manufacture Identification

Dongguan Tutamen Metalwork Co., LTD.
No.2, HuangGuoTang Rd, Shahu, Tangxia Town
Dongguan, Guangdong Province, 523001 CHINA
Tel: (086) 769 87989845
Submitter's FDA Registration Number：N/A

5.2 Contact Person

Charles Shen
Manton Business and Technology Services
37 Winding Rdg, Oakland, NJ 07436
Tel: 608-217-9358
Email: cyshen@aol.com

5.3 Date of Summary: November 02, 2020

5.4 Device Name:

Proprietary Name:	OGYILI TENS/NMES Stimulator
Device Common Name:	TENS/NMES Stimulator
Classification Regulation:	21 CFR882.5890
Class:	Class 2
Panel:	Neurology
Product Code:	GZJ
Subsequent Product Code	IPF
Prior FDA correspondence:	None

5.5 Predicate Device Information:

The "OGYILI TENS/NMES Stimulator E01" described in this premarket notification is substantially equivalent to:

(1) K193275, "Nerve and Muscle Stimulator (model: XFT-2000)", Manufactured by "Shenzhen XFT Medical Limited"

Reference Device:

(2) K092990, "AMD 6605" manufactured by "Shenzhen Dongdixin Technology Co., Ltd."

(3) K162517, “Electronic Pulse Stimulator”, Manufactured by “JKH Health Co., Ltd.”

5.6 Device Description:

The OGYILI TENS/NMES Stimulator E01 is a 2 channel TENS/NMES stimulator device that is used to help reduce pain, with each channel being isolated from the other. The OGYILI TENS/NMES Stimulator is a programmable device that come equipped with 14 preset programs along with 14 user programs. The user programs are adjustable and can be changed to best help the patient at the doctor's recommendation and prescription settings. The program modes are preset programs that a clinician can conveniently choose from should they desire. This device has a special masking program to make the unwanted programs unavailable to the patients while locking the device in the needed relief setting. This way the patient does not receive the knowledge or ability to change the doctor's prescription settings without a clinician's consent. The OGYILI TENS/NMES Stimulator is programmed to default to program P- 14 which contains the most common setting.

The device gives the clinician ability to store frequencies or to choose from a set of many frequencies that allow quick and easy selection, for prescription of stimulation regimen that can be later stored in any of the many available memory slots. However once the program is set the patients does not have the ability to alter the program from what the doctor or licensed practitioner has deemed to be the most appropriate program for their patient's needs.

The OGYILI TENS/NMES Stimulator has the following specifications: There is pulse mode with a bi-phase rectangular pulse, the pulse frequency is 2Hz to 150Hz, the pulse width is 100-200 μs. The power supply is DC 3.7-volt lithium battery.

OGYILI TENS/NMES Stimulator package is comprised of the following items:

- One TENS/NMES unit powered by DC 3.7-volt lithium battery
- Two UL industry standard wires for electrodes conforming to FDA standards,
- Four standard commercially available round 100 (mm) self adhesive electrodes.
- One UL 110 battery rechargeable unit
- Instruction manual.
- Quick start instruction manual.
- Full package carrying case.

The device has physical dimensions of 92 x 60 x 18 mm, and weighs 90 grams with battery.

5.7 Indications for Use:

TENS function of the device is indicated for the following use:

Symptomatic relief and management of chronic (long-term), intractable pain and an adjunctive treatment in the management of post-surgical pain and post-traumatic acute pain

NMES function of the device is indicated for the following use:

- Relaxation of muscle spasms
- Prevention or retardation of disuse atrophy
- Increasing local blood circulation
- Muscle re-education
- Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis
- Maintaining or increasing range of motion

5.8 Performance Testing Summary:

Design control activities for this modification were performed and bench tests have been done. Those performance tests, risk management, and design verification tests provide demonstration that the device does not raise any new questions of safety and effectiveness.

The subject device conforms to the following standards:

- **IEC 60601-2-10**, Particular requirements for the basic safety and essential performance of nerve and muscle stimulators
- **IEC 60601-1-6**, General Requirements For Basic Safety And Essential Performance - Collateral Standard: Usability
- **IEC60601-1,** Electrical safety;
- **IEC60601-1-2,** Electromagnetic compatibility
- **ISO 10993-1**, Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process

5.9 Technological Comparison with Predicate Device

Table 5.1 below shows similarities and differences of use, mechanism, and labeling between our device and the predicate devices.

Table 5.1: Comparison of Intended Use, Mechanism, and Labeling

Description	Subject Device	Primary Predicate Device (K193275)	Reference Device (K092990)	Remark
Product Code	GZJ	GZJ	GZJ	SE
Regulation Number	21 CFR882.5890	21 CFR882.5890	21 CFR882.5890	SE
Indication For Use	TENS function of the device is indicated for the following use: Symptomatic relief and management of chronic (long-term), intractable pain and an adjunctive treatment in the management of post-surgical pain and post-traumatic acute pain NMES function of the device is indicated for the following use: • Relaxation of muscle spasms • Prevention or retardation of disuse atrophy • Increasing local blood circulation • Muscle re-education • Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis • Maintaining or increasing range of motion	Over-The-Counter Use: TENS[(Program 1~9, Program 15 (Frequency＜5Hz or ＞15Hz)]: XFT-2000 is used for temporary relief of pain associated with sore and aching muscles due to strain from exercise or normal household and work activities. XFT-2000 is also intended for the symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis. NMES[(Program 10~14, Program 15(5Hz≤Frequency≤50Hz)]: XFT-2000 is used to stimulate healthy muscles in order to improve and facilitate muscle performance. To be used for the improvement of muscle tone and firmness, and for strengthening muscles in the arms, abdomen, legs, and buttocks. Not intended for use in any therapy or for the treatment of any medical conditions or diseases. Prescription Use: XFT-2000 is intended for the following use: - Relaxation of muscle spasms - Prevention or retardation of disuse atrophy - Increasing local blood circulation - Muscle re-education - Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis - Maintaining or increasing range of motion	TENS function of the device is indicated for the following use: Symptomatic relief and management of chronic (long-term), intractable pain and an adjunctive treatment in the management of post-surgical pain and post-traumatic acute pain NMES function of the device is indicated for the following use: • Relaxation of muscle spasms • Prevention or retardation of disuse atrophy • Increasing local blood circulation • Muscle re-education • Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis • Maintaining or increasing range of motion	SE

		- Adjunctive treatment in the management of post-surgical and post-traumatic acute pain		
Target Population	18 years and older	Adult Population	18 years and older	SE
Components	Control unit and electrode	Control unit and electrode	Control unit and electrode	SE
Contradictions	**Never use** your **TENS/NMES** on: Atrophied muscles. Muscles with spasms. Muscles associated with an impaired joint or limb. Muscles with undiagnosed pain. **Never use** the **TENS/NMES** when pregnant or if you think you are pregnant. **Do not use** your **TENS/NMES** With cardiac pacemakers, defibrillators, or other implanted metallic or electronic devices. Over or around the neck/carotid sinus. Over the neck, mouth or face. Over the carotid sinus nerves. Trans cerebrally (over the head). Over/around the eyes. Over the heart or chest. When there is a possibility to haemorrhage following acute trauma or fracture. After surgical procedures when muscle contraction may affect the healing process. On areas of skin which lack normal sensation	Not available as public information	Patients with pacemakers and heart conditions Patients with pacemakers and heart conditions TENS/NMES: should NOT use should NOT use Do NOT use stimulation over the carotids Do NOT use stimulation over the carotids sinus nerves, the larynx or throat muscles sinus nerves, the larynx or throat muscles Do NOT use stimulation trans-cerebrally. Do NOT use stimulation trans-cerebrally. Do NOT use on undiagnosed pain or until Do NOT use on undiagnosed pain or until I etiology is established.	Similar

The subject device are predicate devices are essentially identical in terms of use, and mechanism. They have minor different wording in the descriptions of contradictions, but the actual contents are very similar.

Table 5.2 shows similarities and differences of mechanism and design between our device and the predicate devices.

Table 5.2: Comparison of Mechanism and Design

Characteristic	**Subject device (K201431)**	**Primary Predictive Device** (K193275)	**Reference Device** (K092990)	**Reference Device** (K162517)	**Remarks**
Unit Name:	**OGYILI TENS/NMES UNIT**	**XFT - 2000**	**AMD 6605**	**PL-029K12**	
Manufacturer	Tutamen Metal Co., LTD	Shenzhen XFT Medical Limited	Shenzhen Dongdixin Technology Co., Ltd.	JKH USA LLC	
Power source	Use a Lithium-ion battery	DC4.5V, 3xAAA batteries; DC adaptor	Battery	Rechargeable or non-rechargeable battery	SE
a. **Method of Line Current isolation**	N/A battery operated	N/A battery operated	N/A battery operated	N/A battery Operated	SE
b. **Patient Leakage current**	N/A battery operated	N/A battery operated	N/A battery operated	N/A battery operated	SE
a. **Normal condition**	N/A battery operated	N/A battery operated	N/A battery operated	N/A battery operated	SE
b. **Single Fault Condition**	N/A battery operated	N/A battery operated	N/A battery operated	N/A battery operated	SE
Average DC current through electrodes when device is on but no pulses are being applied	User pure AC, No DC current used	User pure AC, No DC current used	User pure AC, No DC current used	User pure AC, No DC current used	SE
Number of output modes	14 programs	15 programs	Information not available	8 programs	Similar
Output channels	2 output Channels	2 output channels	2 output channels	1 output channel	SE
a. **Method of current isolation**	Individually isolated circuits, and transistors	Individually isolated circuits, and transistors	Individually isolated circuits, and transistors	NA	SE
Regulated Current or Regulated Voltage?	Regulated Voltage	Regulated Current	Information not available	Regulated voltage	SE

Indicator Display: On/OFF Status? Low Battery? Voltage/Current Level?	 Yes, Shows On/off status Yes, Shows Low Battery Yes, shows output level 1-15 (1 being low 15 being high)	 Shows On/Off Status Yes shows battery low Shows voltage level	Shows On/Off Status	 Shows On/Off Status Yes shows battery low Shows voltage level	SE
Software firmware, microprocessor control Automatic overload trip Automatic No load trip Automatic Shut Off User Override control Timer Range (minutes)	 MCU: PIC16F1937 Edition V1.0 Yes Yes Yes Yes, pause button 15min – 60min	 MCU Yes Yes Yes Yes, pause button 60min	 MCU NO, Battery operated NO, Battery Operated Yes Yes (anytime) 15min – 60min	 MCU NO Yes Yes Yes, pause button 10- 540min	SE
Hardware and materials Housing construction material Size: Weight:	 ABS 92 x 60 x 18mm 0.07 kg. without battery, 0.09kg. with battery	 ABS 108 x 62 x 26mm 96g with battery	 ABS 141 (L) x 60(W) X 18(H) mm 115 grams	 ABS n/a 25g	SE
Electrode Lead wires Length Construction Materials Electrode connectors 510K number:	 1.m Strand Copper wire PVC Coating 2x2mm Pin connector K171722	 K132588	 2' round self-adhering reusable Amgel based electrodes, FDA approved		SE

The subject device is essentially identical to the predicate device in terms mechanism and design. The differences in number of programs, dimension and weight does not raise safety and effectiveness issues. The electrode leas wire is FDA 510(K) cleared, as the predicate devices.

Table 5.3 shows similarities and differences of output performance between our device and the predicate devices.

Table 5.3: Comparison of Output Performance

Characteristic	**Subject device (K201431)**	**Primary Predictive Device** (K193275)	**Reference Device** (K162517)	**Remarks**
Shape	Rectangular	Rectangular	Rectangular	SE
Maximum Output Voltage (V) (+/-___%)	17-20v +/-20%@ 500kΩ 48-60v +/-20%@ 2kΩ 95-125v +/-20%@ 10kΩ	29.7-39v +/-20%@ 500kΩ 89.1-90.6v +/-20%@ 2kΩ 123-125v +/-20%@ 10kΩ	29.6-57.6v +/-20%@ 500kΩ 80.8-86.4v +/-20%@ 2kΩ 108-134v +/-20%@ 10kΩ	SE
Maximum Output Current (mA) (+/-___%)	36-40mA +/-20%@ 500Ω 24-30mA +/-20%@ 2kΩ 9-12.5mA +/-20%@ 10kΩ	59-60mA +/-20%@ 500Ω 44-45.3mA+/-20% @ 2kΩ 12.3-12.5mA +/-20%@ 10kΩ	59.2-115.2mA +/-20%@ 500Ω 33.2-48mA+/-20% @ 2kΩ 10.8-13.4mA +/-20%@ 10kΩ	SE
Pulse duration† (µs)	100-200 µS @ 500Ω	150-350 µS 500Ω	100 µS	SE
Frequency (Hz) {or Rate (pps)}	2-150 Hz	2-125 Hz	1.9-104.1 Hz	SE
Net Charge (microcoulombs (µC) per pulse)	12-21 [µC] @ 500Ω	5.9-21 [µC] @ 500Ω	11.8-23 [µC] @ 500Ω	SE
Maximum Phase Charge (µC)	12-21 [µC] @ 500Ω	5.9-21 [µC] @ 500Ω	11.8-23 [µC] @ 500Ω	SE
Maximum Current density ††(mA/cm2, r.m.s.)	0.16-0.54mA/cm2@500Ω	0.15-0.72mA/cm2@500Ω	1.64-3.26mA/cm2@500Ω	SE
Maximum Average Power Density†† (W/cm2)	0.0002-0.0026mA/cm2 @500Ω	0.0002-0.0045mA/cm2 @500Ω	0.00004-0.00101mA/cm2 @500Ω	SE
Burst Mode	Yes/No	Yes/No	n/a	
Pulses per Burst	9	15-840	n/a	SE
Bursts per Second	2	0.07-0.33	n/a	SE
Burst duration (seconds)	175 µs – 5s	3-14	n/a	SE
ON Time (seconds)	5-8	3-14	3.4-20	SE
OFF time (seconds)	5-12	2-10	1-2.5	SE

The output performances of the subject device are either within the range covered by the predicate device, or in the close proximity of the range covered by the predicate device. The subject device essentially has the same performance as that of the predicate device. Our device is essentially identical to the predicate device in terms of indications for use, design, and mechanism, between subject device and the predicate device.

The following table shows similarities and differences of the key performance between the subject device and the predicate devices. Tests were conducted following applicable procedures outlined in the internal procedures and FDA recognized consensus standards, and results met all relevant requirements in the test standards, and are comparable to the predicate device in performance.

Table 5.4: Comparison of Device Performance

Description	Subject Device	Primary Predicate Device (K193275)	Reference Device (K092990)	Comparison
Biocompatibility	Biocompatible per ISO 10993-1	Biocompatible per ISO 10993-1	Biocompatible per ISO 10993-1	SE
Electric Safety	The proposed device was tested to demonstrate compliance with IEC 60601-1	Compliance with IEC 60601-1	Compliance with IEC 60601-1	SE
EMC	The proposed device was tested to demonstrate compliance with IEC 60601-1-2	Compliance with IEC 60601-1-2	Compliance with IEC 60601-1-2	SE
Performance Standards	The proposed device was tested to demonstrate compliance with IEC 60601-2-10	Compliance with IEC 60601-2-10	Compliance with IEC 60601-2-10	SE

The above table shows that the performance is either same or very similar between the subject and predicate device. The subject device is as safe and effective, and its performance meets the requirements of its pre-defined acceptance criteria and intended uses.

5.10 Substantial Equivalence Conclusion

Based on the comparison of intended use, design, and performance, "OGYILI TENS/NMES" manufactured by "Dongguan Tutamen Metalwork Co., LTD." is substantial equivalent to its predicate devices.