DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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December 23, 2015

Tohkai Precision Electrical Manufactory (Shenzhen) Limited
c/o Ms. Cecilia Ceng
Guangzhou GLOMED Biological Technology Co., Ltd.
Suite 306, Kecheng Mansion
No. 121 Science Road
Guangzhou Science Park
Guangzhou, Guangdong , 510663
China

Re: K152128
Trade Name: 2-in-1 Abdominal Muscle Training & Back Pain Relief System
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: Class II
Product Code: NUH, NGX
Dated: November 18, 2015
Received: November 23, 2015

Dear Ms. Ceng:

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. 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 27f 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

William J. Heetderks -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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K152128

Device Name
2-in-1 Abdominal Muscle Training & Back Pain Relief System

Indications for Use *(Describe)*
The 2-in-1 Abdominal Muscle Training & Back Pain Relief System has two modes of stimulation; a transcutaneous electrical nerve stimulation (TENS) BP-313 mode and a powered muscle stimulation (PMS) TS-212 mode.

The TENS(BP-313 Mode) is indicated for temporary relief of pain associated with sore and aching muscles in the waist, back, arm, leg due to strain from exercise or normal household and work activities.

The PMS (TS-212 Mode) is indicated for the improvement of abdominal muscle tone, for strengthening of abdominal muscles and for the development of a firmer abdomen. This system is intended to stimulate healthy muscles in order to improve and facilitate muscle performance.

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.

Chapter 5. 510(k) Summary

510(k) Summary

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

1. 510 (k) submitter

- Company Name: Tohkai Precision Electrical Manufactory (Shenzhen) Limited
- Establishment Registration Number: Applying
- Address: No.3 Alley 1,Second Industrial Park, Jia Zi Tang, GongMing Office. GuangMing New Developed Area. ShenZhen.
- Postal Code: 518132
- Phone: 0755-27173101
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- Contact Person (including title): Yuk Wing Li (General Manager)
- E-mail: tohkaip@globalsoures.com

2. Application Correspondent

- Contact Person: Ms. Cecilia Ceng / Mr. Tim Wong
- Guangzhou GLOMED Biological Technology Co., Ltd.
- Tel: +86-20-61099984
- Email: regulatory@glomed-info.com

3. Subject Device Information:

- Common Name: Electronic Stimulator
- Trade Name: 2-in-1 Abdominal Muscle Training & Back Pain Relief System
- Classification Name: Stimulator, Nerve, Transcutaneous, Muscle, Powered, For Muscle Conditioning, Over-The-Counter
- Review Panel: Neurology & Physical Medicine
- Product Code: NUH, NGX
- Regulation Number: 882.5890, 890.5850
- Regulation Class: II

4. Predicate Device Information

Sponsor	LETO ENTERPRISES INCORPORATION	Endurance Therapeutics	Shenzhen OSTO Technology Company Limited
Device Name and Model	X2ABS Dual Channel Fitness Belt	TI040	Health Expert Electronic Stimulator Model: AST-300C and

			AST-300D
510(k) Number	K102295	K060846	K133929
Product Code	NGX	NGX, NUH, GZJ	NUH, NGX
Regulation Number	890.5850	882.5890	882.5890, 890.5850
Regulation Class	II	II	II

5. Device Description

2-in-1 Abdominal Muscle Training & Back Pain Relief System is a portable multifunctional device, offering both Transcutaneous Electronic Nerve Stimulator (TENS) and Powered Muscle Stimulator (PMS) qualities.
2-in-1 Abdominal Muscle Training & Back Pain Relief System has 12 operation modes, which can give certain electrical pulse through 4 of electrode pads placed on the skin to help users to enjoy body stimulation.
The support belt which fastens around your waist provides appropriate stimulation position location for a quick and easy exercise for users of all different waist sizes. The adhesive pads adhere to the belt to conduct the signal from the unit to your abdominal muscles. Snap cables are for connecting the stimulator and the support belt. Each unit comes with one battery (6F22/1604) so you can start exercising right away.

TS-212:
Its technology allows you to exercise ALL of the abdominal muscles using a simple belt. A signal is sent from the belt to the nerves which control the muscles. These nerves are stimulated in the area where they are most concentrated using the model of TS-212, causing a deep, comfortable contraction of the muscles of the abdomen.
You will feel a mild pulsing sensation, followed by some tightening of the skin and muscle between the pads. The muscles should contract smoothly, hold themselves in a tensed position for a few seconds and then gently relax again. If you feel a sharp prickling sensation or no feeling you should refer to the trouble shooting guide it may be that the pads are positioned directly over your hip bones and need repositioning. Once the problem is solved, just continue with your exercise.

BP-313:
The main function of pain relief comes from the continuous stimulation pulse generated from the dual channel stimulator. We cannot ensure that the pain relief is 100% effective for everyone. However, when used according to our instruction, it can be a safe, non-addictive, non-invasive lower back pain reliever.

Transcutaneous Electrical Nerve Stimulation (TENS) relieves pain by sending small electrical impulses through electrodes placed on the skin to underlying nerve fibers. TENS is believed to work by two different mechanisms. First, electrical stimulation of the nerve fibers can block a pain signal from

being carried to the brain. If the signal is blocked, pain is not perceived. Secondly, the body has its own mechanism for suppressing pain. It does this by releasing natural chemicals called endorphins in the brain which act as analgesics. TENS may activate this mechanism.

6. Intended Use

The 2-in-1 Abdominal Muscle Training & Back Pain Relief System has two intended uses;
The powered muscle stimulation (PMS) Mode (TS-212) is intended to deliver electrical stimulation to the muscles of the abdomen.
The transcutaneous electrical nerve stimulation TENS Mode (BP-313) is intended to deliver electrical stimulation to the peripheral nerves of the body.

7. Indications for Use

The 2-in-1 Abdominal Muscle Training & Back Pain Relief System has two modes of stimulation; a transcutaneous electrical nerve stimulation (TENS) BP-313 mode and a powered muscle stimulation (PMS) TS-212 mode.

The TENS(BP-313 Mode) is indicated for temporary relief of pain associated with sore and aching muscles in the waist, back, arm, leg due to strain from exercise or normal household and work activities.

THE PMS (TS-212 Mode) is indicated for the improvement of abdominal muscle tone, for strengthening of abdominal muscles and for the development of a firmer abdomen. This system is intended to stimulate healthy muscles in order to improve and facilitate muscle performance.

8. Design

2-in-1 Abdominal Muscle Training & Back Pain Relief System is a portable multifunctional device, offering both Transcutaneous Electronic Nerve Stimulator (TENS) and Powered Muscle Stimulator (PMS) qualities.
2-in-1 Abdominal Muscle Training & Back Pain Relief System has 12 operation modes, which can give certain electrical pulse through 4 electrode pads placed on the skin to help users to enjoy body stimulation.
It is comprised of a main device for signal generation, belts for fixation, and series electrodes. The electronic stimulatory module has the operating elements of ON/OFF Switch, Model Selection knob, Display screen, Mode Selection key and Intensity Modification keys.
The device is chosen function between TENS(BP-313, Mode 1-8) and PMS(TS-212, Mode 1-4) before turning on the system.
The LCD display screen can show selected mode, output intensity of body, and time remaining of an application mode.
The device is equipped with accessories of electrode pads, snap cable, gel sticks, support belt. The snap cable is used to connect the pads to the main unit. All the accessories, including electrode pads, snap cable, gel sticks, support belt can only be changed by special person.

9. Materials

There are two user directly contracting components in the subject device as the following list.

Patient Contacting Components	Material	Body Contact Location	Contact Duration
Button	ABS PA-757 PMMA-CM211	Surface-contacting device: skin	Less than 30 min
Connect line	SR8000-70N	Surface-contacting device: skin	Less than 30 min

	TPR RN-100PVC03		
Belt	conductive fabric	Surface-contacting device: skin	5 – 30 min (depends on patients' setting)
Electrode Pads	gel	Surface-contacting device: skin	5 – 30 min (depends on patients' settina }
Unit Housing	ABS plastic	Surface-contacting device: skin	Less than 30 min

10. Specification

Power Source	1 x 6F22 battery (9 Volt)
Number of channels	Two channels
Number of programs	TENS (BP-313): 8 PMS (TS-212}: 4
Output intensity level	Blevel
Frequency	2Hz-120Hz
Pulse Duration	16μs -260 μs
Contraction and relaxation time	Adjustable, due to different modes. (See below "Program Specification Table")
Treatment time	5-30 minutes
Indicator display	On/Off Status, Low Battery, Channel, Mode, Time
Electrode size	Electrode pad: 50mm(diameter) • 1.5mm(thickness). gel stick : 48.0*48.0*1.5mm
Control unit dimension	125 x 72 x 39.5mm
Weight	Approx. 150g (battery included)
Environment for operation	Temperature: +41"Fto+104"F (+5'Cto +40'C); Humidity: 15% to 93% RH
Environment for storage	Temperature: -13"Fto+158"F (-25'Cto +70'C); Humidity: ,;93% RH

11. Test Summary

2-in-1 Abdominal Muscle Training & Back Pain Relief System has been evaluated the safety and performance by lab bench testing as following:

- Electrical safety test according to IEC 60601-1 and IEC 60601-2-10 standards
- Electromagnetic compatibility test according to IEC 60601-1-2 standard
- Biocompatibility test according to ISO 10993-5 and ISO 10993-10 standards
- Software verification and validation test according to the requirements of the FDA "Guidance for Pre Market Submissions and for Software Contained in Medical Devices"

- The waveform test report has also been conducted to verify the output specifications of the device according to Guidance for Transcutaneous Electrical Nerve Stimulator for Pain Relief Intended for Over the Counter Use and Guidance for Powered Muscle Stimulator for Muscle Conditioning

12. Comparison to predicate device and conclusion

The technological characteristics, features, specifications, materials, mode of operation, and intended use of 2-in-1 Abdominal Muscle Training & Back Pain Relief System is substantially equivalent to the predicate devices quoted above.

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

Elements of Comparison		**Subject Device**	**Predicate Device**			**Remark**
Manufacturer		Tohkai Precision Electrical Manufactory (Shenzhen) Ltd.	LETO ENTERPRISES INCORPORATION	Endurance Therapeutics	Shenzhen OSTO Technology Company Limited	--
Device Name and Model		2-in-1 Abdominal Muscle Training & Back Pain Relief System	X2ABS Dual Channel Fitness Belt	TI 040	Shenzhen OSTO Technology Company Limited	--
510(k) Number		Applying	K102295	K060846	K133929	--
Basic Unit Characteristics						
Power Source(s)		1 x 6F22 battery （9 Volt）	2 x 1.5V AAA batteries	4.5 Volt battery	Adaptor Input: 100-240Vac, 50-60Hz, 0.1A Output: 5Vdc, 1A Unit Input: 5Vdc, 1A	SE Note1
-Method of Line Current Isolation		Type BF Applied Part	--	Type BF Applied Part	Type BF Applied Part	SE
Patient Leakage Current	NC	Comply with IEC 60601-1 and IEC 60601-2-10	--	--	AC: 54.5μA, DC: 0.5μA	SE Note 1
	SFC	Comply with IEC 60601-1 and IEC 60601-2-10	--	--	AC:120.0μA, DC: 0.6μA	

Average DC current through electrodes when Device is on but no pulses are being delivered.	0A	--	0 A	< 0.01μA	SE Note 1

Elements of Comparison	**Subject Device**	**Predicate Device**			**Remark**
device is on but no pulses are being applied					
Number of Output Channels:	2	2	1	2	SE Note 1
Number of Output Modes	TENS (BP-313): 8 PMS (TS-212): 4	8	10	25	SE Note 2
Output Intensity Level	8 steps	28 steps	--	99 steps	SE Note 2
Synchronous or Alternating	Synchronous	Synchronous	Synchronous	Synchronous	SE Note 2
Method of Channel Isolation	Voltage Transform Isolation	Up / down button of left or right channel	On/Off Switch	Voltage Transform Isolation “BODY▼” and “ BODY▼” buttons for body channel, “ SOLE▲” and “SOLE▼” buttons for feet channel	SE Note 2
Regulated Current or Regulated Voltage	Voltage Control	Regulated Voltage	Voltage Control	Voltage Control	SE
Software/Firmware/Microprocessor Control?	Yes	--	Yes	Yes	SE
Automatic Overload Trip	No	No	No	No	SE

Automatic No-Load Trip	Yes. The unit will not work and the icon of the corresponding unit will twinkle if no load is connected.	Yes. The unit will not work and the unit will sound a beeping alarm if no load is connected.	No	No	SE Note 2

Elements of Comparison		**Subject Device**	**Predicate Device**			**Remark**
Automatic Shut Off		Yes	After approximately 10 minutes, the AUTO OFF function will turn off the unit, if it is not in use.	No	Yes	SE
User Override Control		Yes	Yes	Yes	Yes	SE
Indicator Display	On/Off Status	Yes	Yes	Yes	Yes	SE
	Low Battery	Yes	Yes	Yes	No	SE Note 2
	Voltage/ Current Level	Yes	Yes	No	Yes	SE Note 2
Timer Range		adjustable from 5 - 30 minutes	Default time is 10 minutes, minimum time is 5	--	Yes	SE Note 2
Weight		Approx. 150g (battery included)	81.2g (with battery)	14.4 oz	2Kg (Without accessories)	SE Note 2
Dimensions		125 x 72 x 39.5mm	82 mm (L) X 62 mm (W) X 23 mm (H)	6 in(W)*1 in(H)*2.8 in(D)	428mm x 428.8mm x 185mm	SE Note 2
Housing Materials and Construction		Main unit: ABS plastic	--	ABS	Main unit: ABS plastic	SE
Output Specifications						
Waveform		TENS (BP-313): Monophasic PMS (TS-212): Biphasic	Biphasic	Biphasic	Pulsed, symmetric, biphasic	SE

Sponsor: Tohkai Precision Electrical Manufactory (Shenzhen) Limited
Subject Device: 2-in-1 Abdominal Muscle Training & Back Pain Relief System

510(k) Summary

Shape	Rectangular	Rectangular	Rectangular	Rectangular, with interphase interva	SE
Maximum Output Voltage	42V±10% @ 500Ω	From 0 to 60 mA (From 0 to 1000 Ω)	40.7V±20% @ 500 Ω	44V±10% @ 500Ω	SE Note 3
	78V±10% @ 2kΩ		105.1V±20% @ 2 kΩ	80V±10% @ 2KΩ	
	94V±10% @ 10KΩ		154.1V±20% @10 kΩ	112V±10% @10KΩ	
Maximum Output Current	84mA±10% @ 500Ω	--	81.4mA±20% @ 500 Ω	88mA±10% @ 500Ω	SE Note 3
	39mA±10% @ 2KΩ		47.8mA±20% @ 2 kΩ	40mA±10% @ 2KΩ	
	9.4mA±10% @ 10KΩ		15.4mA±10% @10 kΩ	11.2mA±10% @ 10KΩ	
Pulse Duration	16μs ~260μs	200μs	4.1—500ms	120μs	SE Note 3
Pulse frequency	2Hz-120Hz	8.5~64Hz	245Hz	77.3Hz	SE Note 3
Net charge	21.84μC @ 500Ω	--	4.07μC @ 500Ω	0μC @ 500Ω Method: Balanced waveform	SE Note 3
Maximum Phase Charge	21.84μC @ 500Ω	--	16.90μC @ 500Ω	12.78μC @ 500Ω	SE Note 3
Maximum Average Current	2.25mA @ 500Ω	--	4.25 mA	0.968mA @ 500Ω	SE Note 3
Maximum Current Density (r.m.s)	0.153mA/ cm2 (without DC current)	0.032 (for the smallest size electrode 32.0 cm²)	2.71mA/cm^2 @500Ω	0.235mA/cm² @ 500Ω	SE Note 3
Maximum Average Power Density	0.232mW/cm² @ 500Ω	0.23W/cm² @ 500Ω	5.35mW/ cm^2	1.38mW/cm² @ 500Ω	SE Note 3
ON Time	1s	1s	--	0.6s	SE Note 3
OFF Time	10ms	2s	--	0.6s	SE Note 3
Additional Features					
Environment for operating	Temperature: +41℉ to+104℉ (+5℃to +40℃) ; Humidity: 15% to 93% RH	Temperature: 5 ~ 40° C Humidity: 20 ~ 65% RH	--	Temperature: 5 ~ 45°C Humidity: 20 ~ 65% RH	SE Note 1

Environment for storage	Temperature: -13℉ to+158℉ (-25℃to +70℃);	Temperature: 0 ~ 40° C Humidity: 10 ~ 90%	--	Temperature: 0 ~ 45°C, Humidity: 10 ~ 90%	SE Note 1

Elements of Comparison	**Subject Device**	**Predicate Device**			**Remark**
	Humidity: ≤93% RH	RH		RH Electrode Pad: 10~20°C	
Standards					
Biocompatibility	All user directly contacting materials are compliance with ISO10993-5 and ISO10993-10 requirements.	All user directly contacting materials are compliance with ISO10993-5 and ISO10993-10 requirements.	--	All user directly contacting materials are compliance with ISO10993-5 and ISO10993-10 requirements.	SE
Electrical Safety	Comply with IEC 60601-1 and IEC 60601-2-10	Comply with IEC 60601-1 and IEC 60601-2-10	--	Comply with IEC 60601-1 and IEC 60601-2-10	SE
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	--	Comply with IEC 60601-1-2	SE

Programs

	Program	Maximum	Phase Duration	Rate
BP-313(TENS)	1	84mA	260μs	16Hz
	2	84mA	260μs	100Hz
	3	50mA	260μs	120Hz
	4	80mA	260~160μs	2Hz~100Hz
	5	54mA	260~160μs	100Hz
	6	80mA	260μs	80<->10 Hz
	7	52mA	260~160μs	120Hz
	8	84mA	P1～P7	Cycle
TS-212(PMS)	1	52mA	200μs	70Hz
	2	52mA	200μs	60Hz
	3	52mA	200μs	50Hz
	4	52mA	200μs	50Hz

Comparison in Detail(s):

Note 1:

Although the " Power Source(s)", " Patient Leakage Current", "Average DC current through electrodes when device is on but no pulses are being applied", "Operating Environment", "Storage Environment" are a little different from the predicate devices, they all comply with IEC 60601-1 requirements. So the differences will not raise any safety or effectiveness issue.

Note 2:

Although the " Number of Output Modes" "Output Intensity Level", " Method of Channel Isolation", " Timer Range", "Weight" and "Dimensions" of subject device are different from the predicate devices, they are all comply with IEC 60601-1 and IEC 60601-2-10 requirements. So the differences of the function specifications will not raise any safety or effectiveness issue.

Note 3:

Although the "Maximum Output Voltage", "Maximum Output Current", "Pulse Duration", "Maximum pulse frequency", "Net Charge (per pulse)", "Maximum Phase Charge", "Maximum Average Current", "Maximum Current Density", "Maximum Average Power Density of subject device", "ON Time" and "OFF Time" are a little different from the predicate devices, they all comply with IEC 60601-1, IEC 60601-2-10 requirement, FDA guidance requirement for Transcutaneous Electrical Nerve Stimulator for Pain Relief and FDA guidance requirement for Powered Muscle Stimulator for Muscle Conditioning. So the differences of function specification will not raise any safety or effectiveness issue.

Finial Conclusion:

The subject device 2-in-1 Abdominal Muscle Training & Back Pain Relief System has all features of the predicate devices. The differences between them do not affect the safety and effectiveness. Thus, the subject device is substantially equivalent to the predicate devices.

13. Date of the summary prepared: December 16, 2015