DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 19, 2017

Guangzhou Xinbo Electronic Co., Ltd.
% Ms. Cecilia Ceng
Manager
Guangzhou Glomed Biological Technology Co., Ltd.
Suite 306, Kecheng Mansion, No.121 Science Road
Guangzhou Science Park
Guangzhou, Guangdong 510000 CN

Re: K163611
Trade/Device Name: Pain Therapy Device
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief, Over The Counter
Regulatory Class: Class II
Product Code: NUH, NYN, NGX
Dated: August 3, 2017
Received: August 9, 2017

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 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); 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 Industry and Consumer Education 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" (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 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 Industry and Consumer Education 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,

Vivek J. Pinto -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)*
K163611

Device Name
Pain Therapy Device

Indications for Use *(Describe)*
To be used for temporary relief of pain associated with sore and aching muscles in the upper and lower back, back of the neck, upper extremities (shoulder and arm), lower extremities (leg and feet) due to strain from exercise or normal household work activities by applying current to stimulate nerve. To be used for symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis (Choose Mode B or C).

To stimulate healthy muscles in order to improve and facilitate muscle performance (Choose Mode A).

To temporarily increase local blood circulation in healthy muscles (Choose Mode A).

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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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. Submitter's Information

510(k) Owner's Name: Guangzhou Xinbo Electronic Co., Ltd.
Establishment Registration Number: Applying
Address: 2nd Building, Juntuo Industry Park, Xingye Dadao, Nancun Town, Panyu District, Guangzhou City, Guangdong Province, China
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Application Correspondent:
Contact Person: Ms. Cecilia Ceng / Ms. Cassie Lee
Guangzhou GLOMED Biological Technology Co., Ltd.
Address: Suite 306, Kecheng Mansion, No.121 Science Road, Guangzhou Science Park, Guangzhou 510663, China
Tel: +86-20-61099984
Email: regulatory@glomed-info.com

2. Subject Device Information

Trade Name: Pain Therapy Device
Common Name: Electronic Stimulator
Classification name: Transcutaneous electrical nerve stimulator for pain relief
Review Panel: Neurology, Physical Medicine
Product Code: NUH, NYN, NGX
Regulation Class: II
Regulation Number: 882.5890, 890.5850

3. Predicate Device Information

Sponsor	Shenzhen OSTO Technology Company Limited	Actegy, Ltd.	Counter Scientific Development (GZ) Ltd.
Device Name and Model	Health Expert Electronic Stimulator, Models: AST-300C and AST-300D	Revitive IX (OTC), Model: MT1101	Pain Therapy System, Model: PTS-II
510(k)	K133929	K143207	K150277

Number			(Primary Predicate)
Product Code	NUH, NGX	NUH, NGX	NUH, NGX, NYN, GZJ
Regulation Number	882.5890, 890.5850	882.5890, 890.5850	882.5890, 890.5850
Regulation Class	II	II	II

4. Device Description

Pain Therapy Device is a household multifunctional device, it can stimulate healthy muscles in order to improve and facilitate muscle performance, and temporary relief of pain associated with sore and aching muscles in the upper and lower back, back of the neck, upper extremities (shoulder and arm), lower extremities (leg and feet) due to strain from exercise or normal household work activities by applying current to stimulate nerve.

Pain Therapy Device has three operation modes and two channels, which can give certain electrical pulse through 2 pairs of electrode pads on the skin.

The electronic stimulatory main units have the operating elements of ON/OFF knob, Mode Selection key and Time Selection key which can be user-friendly controlled.

The device is equipped with accessories of electrode pads and an electrode wire. The electrode wire is used to connect the pads to the main unit. All the accessories can only be changed by local distributor.

"Large Patch Electrode" and "Small Patch Electrode" are cleared in K090198.

"Insole Electrode", "Sole Plant Electrode A" and "Sole Plant Electrode B" are cleared in K151693.

5. Intended Use / Indications for Use

To be used for temporary relief of pain associated with sore and aching muscles in the upper and lower back, back of the neck, upper extremities (shoulder and arm), lower extremities (leg and feet) due to strain from exercise or normal household work activities by applying current to stimulate nerve.

To be used for symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis (Choose Mode B or C).

To stimulate healthy muscles in order to improve and facilitate muscle performance (Choose Mode A).

To temporarily increase local blood circulation in healthy muscles (Choose Mode A).

6. Test Summary

Pain Therapy Device 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
- Usability test according to IEC 62366 standard
- Software verification and validation test according to the requirements of the FDA "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices"
- The electrode wire is compliance with 21 CFR 898 by IEC 60601-1 (version 3.1, clause 8.5.2.3) evaluation.

7. Comparison to predicate device and conclusion

The technological characteristics, features, specifications, materials, mode of operation, and intended use of Electronic Muscle Stimulator 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**
Device Name and Model	Pain Therapy Device, Models: P.T.S-II, P.T.S-IIA, P.T.S-IIB, CP-I	Health Expert Electronic Stimulator Models: AST-300C and AST-300D	Revitive IX (OTC), Model: MT1101	Pain Therapy System, Model: PTS-II (Primary Predicate)	--
510(k) Number	K163611	K133929	K143207	K150277	--
Intended Use & Indications for Use	To be used for temporary relief of pain associated with sore and aching muscles in the upper and lower back, back of the neck, upper extremities (shoulder and arm), lower extremities (leg and feet) due to strain from exercise or normal household work activities by applying current to stimulate nerve. To be used for symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis (Choose Mode B or C). To stimulate healthy muscles in order to improve and facilitate muscle performance (Choose Mode A). To temporarily increase local blood	PMS (Mode 1~8): It is intended to stimulate healthy muscles in order to improve or facilitate muscle performance. TENS (Mode 9~25): To be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, back of the neck, arm, leg, and foot due to strain from exercise or normal household work activities by applying current to stimulate nerve.	To temporarily increase local blood circulation in healthy leg muscles. To stimulate healthy muscles in order to improve and facilitate muscle performance. For temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, upper extremities (arms) and lower extremities (legs) due to strain from exercise or normal household duties.	To be used for temporary relief of pain associated with sore and aching muscles in the upper and lower back due to strain from exercise or normal household work activities (Choose Mode A, B, or C). To be used for temporary relief of pain associated with sore and aching muscles in the upper extremities (Arms) due to strain from exercise or normal household work activities (Choose Mode A, B or C). To be used for temporary relief of pain associated with sore and aching muscles in the lower extremities (Legs) due to strain from exercise or normal household work activities (Choose Mode A, B or C). To be used for	SE Note 4

Elements of Comparison	Subject Device	Predicate Device			Remark
	circulation in healthy muscles (Choose Mode A).			symptomatic relief and management of chronic, intractable pain and relief of pain associated with Arthritis (Choose Mode A). To stimulate healthy muscles in order to improve and facilitate muscle performance (Choose Mode B).	
OTC or Rx	OTC	OTC	OTC	OTC	SE
Basic Unit Characteristics					
Power Source(s)	DC 3.0V, 2 x AAA	Adaptor Input: 100-240Vac, 50-60Hz, 0.1A Main Unit Input: 5Vdc, 1A	Adaptor Input: 100-240Vac, 50/60Hz, 0.18A Main Unit Input: 5.0Vdc, 1.0A	DC 3.0V, 2 x AAA	SE
Method of Line Current Isolation	Type BF Applied Part	Type BF Applied Part	--	--	SE
Patient Leakage Current NC	DC: 0.5 μA	AC: 54.5 μA, DC: 0.5 μA	--	--	SE Note 1
Patient Leakage Current SFC	DC: 0.6 μA	AC: 120.0 μA, DC: 0.6 μA	--	--	
Average DC current through electrodes when device is on but no pulses are being applied	< 0.01 μA	< 0.01 μA	--	--	SE
Number of Output Channels	2 Channels: for models P.T.S-II, P.T.S-IIA, P.T.S-IIB; 1 Channel: for model CP-I	2	2	2	SE Note 1
Number of Output Modes	3	25	1	3	SE
Output Intensity Level	5 steps	99 steps	--	5 steps	SE
Synchronous or Alternating?	Synchronous	Synchronous	--	Synchronous	SE

Elements of Comparison		Subject Device	Predicate Device			Remark
Method of Channel Isolation		Parallel connection	--	--	Parallel connection	SE
Regulated Current or Regulated Voltage?		Regulated Voltage	Regulated Voltage	--	Regulated Voltage	SE
Software/Firmware/Microprocessor Control?		Yes	Yes	Yes	Yes	SE
Automatic Overload Trip		No	No	--	No	SE
Automatic No-Load Trip		No	No	--	No	SE
Automatic Shut Off		Yes	Yes	--	Yes	SE
User Override Control		Yes	Yes	--	Yes	SE
Indicator Display	On/Off Status	Yes	Yes	--	Yes	SE
	Low Battery	No	No	--	No	SE
	Voltage/ Current Level	Yes	Yes	--	Yes	SE
Timer Range		10, 20, 40 min	25 min	1 to 60 min	10, 20, 40 min	SE
Weight		Main Unit: P.T.S-II: 75g P.T.S-IIA: 100g P.T.S-IIB: 100g CP-I: 66g Electrode: Big Patch Electrode: 40g Small Patch Electrode:10g Insole Electrode: 200g Sole Plant Electrode A (only for CP-I): 900g Sole Plant Electrode	2kg (Without accessories)	1.725kg (Without PSU)	75g	SE Note 2

Elements of Comparison	Subject Device	Predicate Device			Remark
	B: 920g				
Dimensions	Main Unit: P.T.S-II: 110 x 78 x 20 mm P.T.S-IIA: 135 x 82 x 20 mm P.T.S-IIB: 135 x 82 x 20 mm CP-I: 92 x 78 x 20 mm Electrode: Large Patch Electrode: 120 x 80 mm Small Patch Electrode: 46 x 46 mm Insole Electrode: 260 x 110 mm Sole Plant Electrode A (only for CP-I): 450 x 450 x 90 mm Sole Plant Electrode B: 450 x 450 x 90 mm	428mm x 428.8mm x 185mm	Ø360mm x 75mm	110 x 78 x 20 mm	SE Note 2
Housing Materials and Construction	Main unit: ABS plastic	Main unit: ABS plastic	Casing/body: ABS, Footpads: NBR	Main unit: ABS plastic	SE
Output Specifications					
Waveform	Pulsed, symmetric, biphasic	Pulsed, symmetric, biphasic	Pulsed, symmetric, biphasic	Positive-going, Reverse	SE
Shape	Rectangular, with interphase interval	Rectangular, with interphase interval	Rectangular and bipolar	Square wave	SE
Maximum Output Voltage	40Vp @ 500Ω	44V±10% @ 500Ω	--	88Vp @ 500Ω	SE Note 3
	80Vp @ 2kΩ	80V±10% @ 2kΩ	--	102Vp @ 2kΩ	
	95Vp @ 10kΩ	112V±10% @ 10kΩ	--	106Vp @ 10kΩ	
Maximum Output Current	80mA @ 500Ω	88mA±10% @ 500Ω	--	176mA @ 500Ω	SE Note 3
	40mA @ 2kΩ	40mA±10% @ 2kΩ	--	51.0mA @ 2kΩ	
	9.5mA @ 10kΩ	11.2mA±10% @10kΩ	--	10.6mA @ 10kΩ	
Pulse Duration	200μs	120μs	--	170μs	SE Note 3

Elements of Comparison	Subject Device	Predicate Device			Remark
Pulse frequency	13.7~48.5 Hz	77.3Hz	--	--	SE Note 3
Net Charge (per pulse)	0μC @ 500Ω, Method: Balanced waveform	0μC @ 500Ω, Method: Balanced waveform	--	1.63μC @ 500Ω	SE Note 3
Maximum Phase Charge	19.2μC @ 500Ω	12.78μC @ 500Ω	--	29.9μC @ 500Ω	SE Note 3
Maximum Average Current	1.53mA @ 500Ω	0.968mA @ 500Ω	--	2.22mA	SE Note 3
Maximum Current Density (r.m.s)	0.073mA/cm^2 @ 500Ω	0.235mA/cm^2 @ 500Ω	--	8.31mA/cm^2 @ 500Ω	SE Note 3
Maximum Average Power Density	0.056mW/cm² @ 500Ω	1.38mW/cm^2 @ 500Ω	--	0.115mW/cm² @ 500Ω	SE Note 3
ON Time	2s	0.6s	--	--	SE Note 3
OFF Time	2s	0.6s	--	--	SE Note 3
Additional Features					
Operating Environment	Temperature: 5~40°C, Humidity: ≤80%RH, Atmospheric Pressure: 86~106kPa	Temperature: 5~45°C, Humidity: 20~65% RH	--	--	SE Note 1
Storage Environment	Temperature: Main Unit: -20 ~ 55°C, Electrode Pad: 10 ~ 20°C Humidity: 10~95% RH, Atmospheric Pressure: 50~106 kPa	Temperature: 0~45°C, Humidity: 10~90% RH, Electrode Pad: 10~20°C	--	--	SE Note 1
Standards					
Biocompatibility	All user directly contacting materials are compliance with ISO10993-5 and ISO10993-10 requirements. "Large Patch	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

Elements of Comparison	Subject Device	Predicate Device			Remark
	Electrode" and "Small Patch Electrode" are cleared in K090198. "Insole Electrode", "Sole Plant Electrode A" and "Sole Plant Electrode B" are cleared in K151693.				
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	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	Comply with IEC 60601-1-2	SE

Comparison in Detail(s):

Note 1:

Although the "Patient Leakage Current", "Number of Output Channels", "Operating Environment", and "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 "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 some output specifications "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.

Note 4:

Although the Indication for Use (IFU) of subject device is a little different from that of predicate, its combines from 3 predicate devices' IFU, so the differences between them will not raise any safety or effectiveness issue.

Additional Modes Comparison Table:

Elements of Comparison	Subject Device (K163611)	Predicate Device (K133929)	Remark

Elements of Comparison	Subject Device (K163611)	Predicate Device (K133929)	Remark
Device Name	Pain Therapy Device, Models: P.T.S-II, P.T.S-IIA, P.T.S-IIB, CP-I	Health Expert Electronic Stimulator	--
Mode Comparison Group 1	**Mode A**	**Mode 2**	--
- Indications for Use Claim	PMS claims	PMS claims	SE
- Waveform	Pulsed, Rectangular, Symmetric, Biphasic	Pulsed, Rectangular, Symmetric, Biphasic	SE
- Pulse Width	200μs	120μs	SE Note (a)
- Pulse Frequency	48.5Hz	77.3Hz	SE Note (a)
- Pulse Cycle Number (T) for One Burst	200T ~ 206T	200T	SE Note (a)
- Maximum Output Voltage	40Vpk @ 500Ω 80Vpk @ 2kΩ 95Vpk @ 10kΩ	44Vpk @ 500Ω 80Vpk @ 2kΩ 112Vpk @ 10kΩ	SE Note (b)
Mode Comparison Group 2	**Mode B**	**Mode 20**	--
- Intended Use Claim	TENS claims	TENS claims	SE
- Waveform	Pulsed, Rectangular, Symmetric, Biphasic	Pulsed, Rectangular, Symmetric, Biphasic	SE
- Pulse Width	200μs	120μs	SE Note (a)
- Pulse Frequency	13.7Hz / 19.0Hz	77.3Hz	SE Note (a)
- Pulse Cycle Number (T) for One Burst	82T ~ 113T	100T	SE Note (a)
- Maximum Output Voltage	40Vpk @ 500Ω 80Vpk @ 2kΩ 95Vpk @ 10kΩ	44Vpk @ 500Ω 80Vpk @ 2kΩ 112Vpk @ 10kΩ	SE Note (b)
Mode Comparison Group 3	**Mode C**	**Mode 14**	--
- Intended Use Claim	TENS claims	TENS claims	SE
- Waveform	Pulsed, Rectangular, Symmetric, Biphasic	Pulsed, Rectangular, Symmetric, Biphasic	SE
- Pulse Width	200μs	120μs	SE Note (a)
- Pulse Frequency	46.1Hz / 38.6Hz / 29.4Hz	77.3Hz	SE Note (a)
- Pulse Cycle	150T ~ 184T	200T	SE

Elements of Comparison	Subject Device (K163611)	Predicate Device (K133929)	Remark
Number (T) for One Burst			Note (a)
- Maximum Output Voltage	40Vpk @ 500Ω 80Vpk @ 2kΩ 95Vpk @ 10kΩ	44Vpk @ 500Ω 80Vpk @ 2kΩ 112Vpk @ 10kΩ	SE Note (b)

Comparison in Detail(s):

Note (a):
Although the "Pulse Duration", "Pulse Frequency" and "Pulse Cycle Number for One Burst" of subject device are different from the predicate device, they are very similar in waveform group, and 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 (b):
Although the "Maximum Output Voltage" of subject device is little different from the predicate device, their maximum peak voltage are very similar, and 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.

Finial Conclusion:
The subject device "Pain Therapy Device" is Substantial Equivalent to the predicate devices.

8. Date of the summary prepared: September 19, 2017