May 22, 2023

Jiangxi Royall Smart Technology Co., Ltd.
℅ Cassie Lee
Manager
Share Info (Guangzhou) Medical Consultant Ltd.
No. 1919-1920, Building D3, Minjie Plaza, Shuixi Road
Huangpu District
Guangzhou, Guangdong
China

Re: K230443
Trade/Device Name: TENS & EMS Device (LY-ET-01, LY-ET-02, LY-ET-04)
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: NUH, NGX, NYN
Dated: February 21, 2023
Received: February 21, 2023

Dear Cassie Lee:

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,

Robert Kang -S

for Pamela Scott
Assistant 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230443

Device Name
TENS & EMS Device (Model: LY-ET-01, LY-ET-02, LY-ET-04)

Indications for Use *(Describe)*
TENS & EMS Device (Model: LY-ET-01, LY-ET-02, LY-ET-04):
- 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.
- To stimulate healthy muscles in order to improve and facilitate muscle performance .
- To temporarily increase local blood circulation in healthy muscles.

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 of K230443

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 801.92.

1. Submitter's Information

Sponsor Name: Jiangxi Royall Smart Technology Co., Ltd.
Establishment Registration Number: Applying
Address: Workshop 3#, Shangyou Lefeng Technology Co., Ltd., Huangbu Town, Ganzhou City, Jiangxi Province
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Application Correspondent:
Contact Person: Ms. Cassie Lee
Share Info (Guangzhou) Medical Consultant Ltd.
Address: No. 1919-1920, Building D3, Minjie Plaza, Shuixi Road, Huangpu District, Guangzhou, China
Tel: +86 20 8266 2446
Email: regulatory@share-info.com

2. Date of the summary prepared: May 18, 2023

3. Subject Device Information

Classification Name: Stimulator, Nerve, Transcutaneous, Over-The-Counter
Trade Name: TENS & EMS Device
Model Name: LY-ET-01, LY-ET-02, LY-ET-04
510(K) Number: K230443
Review Panel: Neurology
Product Code:
- Primary product code: NUH
- Secondary product code: NGX, NYN

Regulation Number: 882.5890
Regulatory Class: II

4. Predicate Device Information

Predicate Device:
Sponsor: Guangzhou Xinbo Electronic Co., Ltd.

Trade Name: Pain Therapy Device, Models: P.T.S-II, P.T.S-IIA, P.T.S-IIB, CP-I

Common Name: TENS, EMS, Stimulator for pain relief

Classification Name: Stimulator, Nerve, Transcutaneous, Over-The-Counter

510(K) Number: K163611

Review Panel: Neurology

Product Code:

Primary product code: NUH

Secondary product code: NGX, NYN

Regulation Number: 21 CRF 882.5890

Regulation Class: II

Reference device:
Sponsor: Counter Scientific Development (GZ) Ltd

Trade/Device Name: Pain Therapy System, Model PTS-II

Common Name: TENS, EMS, Stimulator for pain relief

Classification Name: Stimulator, Nerve, Transcutaneous, Over-The-Counter

510(K) Number: K150277

Review Panel: Neurology

Product Code:

Primary product code: NUH

Secondary product code: NGX, NYN GZJ

Regulation Number: 21 CRF 882.5890

Regulatory Class: II

5. Device Description

TENS & EMS Device is a pain management device with a combination of TENS and EMS therapy technology.

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.

TENS & EMS Device (Model: LY-ET-01, LY-ET-04) has 3 modes (Model LY-ET-02 has 5 modes) and one channel, which provide electrical pulse stimulation through the electrode pads to the treatment area. The

TENS & EMS Device has the operating elements of ON/OFF knob, Mode Selection button, Intensity adjustment Dial (or Intensity Increase button and Intensity decrease button) and Time Selection button which is user-friendly and easy to control.

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

6. Intended Use / Indications for Use

TENS & EMS Device (Model: LY-ET-01, LY-ET-02, LY-ET-04):

- 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.
- To stimulate healthy muscles in order to improve and facilitate muscle performance.
- To temporarily increase local blood circulation in healthy muscles.

7. Comparison to predicate device and conclusion

Compare with predicate device, the subject device is very similar in design principle, intended use, indications for use, functions, material and the applicable standards. The differences between subject device and predicate device do not raise and new questions of safety or effectiveness.

Elements of Comparison	**Subject Device**	**Predicate Device**	**Reference device**	**Remark**
Company	Jiangxi Royall Smart Technology Co., Ltd.	Guangzhou Xinbo Electronic Co., Ltd.	Counter Scientific Development (GZ) Ltd	--
Trade Name	TENS & EMS Device	Pain Therapy Device,	Pain Therapy System	--
510(k) Number	K230443	K163611	K150277	--
Classification Name	Transcutaneous Electrical Nerve Stimulator For Pain Relief, Over The Counter	Transcutaneous Electrical Nerve Stimulator For Pain Relief, Over The Counter	Transcutaneous Electrical Nerve Stimulator For Pain Relief, Over The Counter	Same
Classification Product Code	NUH	NUH	NUH	Same
Subsequent Product Code	NYN, NGX	NYN, NGX	GZJ, NGX, NYN	Same

Elements of Comparison		Subject Device	Predicate Device	Reference device	Remark
Intended Use / Indications for Use		TENS & EMS Device (Model: LY-ET-01, LY-ET-02, LY-ET-04): - 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. - To stimulate healthy muscles in order to improve and facilitate muscle performance . - To temporarily increase local blood circulation in healthy muscles.	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).	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 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)	Same
Regulatory Class		Class II	Class II	Class II	Same
OTC or Rx		OTC	OTC	OTC	Same
Power Source(s)		DC 3.0V, 2 x AAA	DC 3.0V, 2 x AAA	DC 3.0V, 2 x AAA	Same
Method of Line Current Isolation		Type BF Applied Part	Type BF Applied Part	Use resistance to isolate	Same
Patient Leakage Current	NC	DC: <1 μA	DC: 0.5 μA	N/A	Similar Note 1
	SFC	DC: <1 μA	DC: 0.6 μA	N/A	
Average DC		< 0.01 μA	< 0.01 μA	0 μA	Same

Elements of Comparison		Subject Device	Predicate Device	Reference device	Remark
current through electrodes when device is on but no pulses are being applied					
Number of Output Channels		1	2 Channels: for models P.T.S-II, P.T.S-IIA, P.T.S-IIB; 1 Channel: for model CP-I	2 Synchronous	Similar Note 2
Output Intensity Level		LY-ET-01: 5 intensity levels LY-ET-02: 5 intensity levels LY-ET-04: 15 intensity levels	5 steps	Not published	Different Note 2
Synchronous or Alternating?		Synchronous	Synchronous	Synchronous	Same
Method of Channel Isolation		Parallel connection	Parallel connection	Parallel connection	Same
Software/Firmware /Microprocessor Control?		Yes	Yes	Yes	Same
Automatic Overload Trip		No	No	Not published	Same
Automatic Shut Off		Yes	Yes	Not published	Same
User Override Control		Yes	Yes	Not published	Same
Indicator Display	On/Off Status	Yes	Yes	Not published	Same
	Low Battery	No	No	Not published	Same
	Voltage/ Current Level	No	No	Not published	Same
Timer Range		LY-ET-01: 10min, 20min, 40min LY-ET-02: 10min, 20min, 30min LY-ET-04: 10min, 20min, 40min	10, 20, 40 min	Not published	Similar Note 2
Weight		LY-ET-01: 95g LY-ET-02: 82g LY-ET-04: 90g Electrode: Gel Pad: 10g Electrode Foot Pad: 98g	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	Not published	Similar Note 3

Elements of Comparison	Subject Device	Predicate Device	Reference device	Remark
		Insole Electrode: 200g Sole Plant Electrode A (only for CP-I): 900g Sole Plant Electrode B: 920g		
Dimensions	LY-ET-01: 102.84*72.84*20.27mm LY-ET-02: 103*59*20mm LY-ET-04: 79*79*23.8mm Electrode: Gel Pad: 25 cm^2 Electrode Foot Pad: 228.8 cm^2	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	Not published	Similar Note 3
Waveform	Pulsed, symmetric, biphasic	Pulsed, symmetric, biphasic	Positive-going, Reverse and Biphasic	Same as the predicate
Shape	Rectangular, with interphase interval	Rectangular, with interphase interval	Square wave	Same as the predicate
Maximum Output Voltage	LY-ET-01: 94Vp@ 500Ω LY-ET-02: 93V@ 500Ω LY-ET-04: 40V@ 500Ω	40Vp @ 500Ω	88Vp @ 500Ω	Similar Note 4
	LY-ET-01: 116Vp@ 2kΩ LY-ET-02: 113V@ 2kΩ LY-ET-04: 61.6V@ 2kΩ	80Vp @ 2kΩ	102Vp @ 2kΩ	
	LY-ET-01: 122Vp@ 10kΩ LY-ET-02: 123V@ 10kΩ LY-ET-04: 65.6V@ 10kΩ	95Vp @ 10kΩ	106Vp @ 10kΩ	
Maximum Output Current	LY-ET-01: 188mA@ 500Ω LY-ET-02: 186mA@ 500Ω	80mA @ 500Ω	176mA @ 500Ω	Similar Note 4

Elements of Comparison	Subject Device	Predicate Device	Reference device	Remark
	LY-ET-04: 80mA@ 500Ω			
	LY-ET-01: 58mA@ 2kΩ LY-ET-02: 56.5mA@ 2kΩ LY-ET-04: 30.8mA@ 2kΩ	40mA @ 2kΩ	51.0mA @ 2kΩ	
	LY-ET-01: 12.2mA@ 10kΩ LY-ET-02: 12.3mA@ 10kΩ LY-ET-04: 6.56mA@ 10kΩ	9.5mA @ 10kΩ	10.6 mA @ 10kΩ	
Pulse Duration	200μs	200μs	170μs	Same as the predicate
Pulse Frequency	LY-ET-01: 1-136 Hz LY-ET-02:1-136 Hz LY-ET-04: 1-100 Hz	13.7~48.5 Hz	1-136 Hz	Similar Note 4
Net Charge (per pulse)	0μC @ 500Ω, Method: Balanced waveform	0μC @ 500Ω, Method: Balanced waveform	1.63 μC @500Ω	Same as the predicate
Maximum Phase Charge	LY-ET-01: 37.60 μC@ 500Ω LY-ET-02: 37.20 μC@ 500Ω LY-ET-04: 16.00 μC@ 500Ω	19.2 μC @ 500Ω	29.9μC @500Ω	Similar Note 4
Maximum Average Current	LY-ET-01: 2.70 mA@ 500Ω LY-ET-02: 3.34 mA@ 500Ω LY-ET-04: 3.10 mA@ 500Ω	1.53 mA @ 500Ω	2.22mA @ 500Ω	Similar Note 4
Maximum Current Density	LY-ET-01: 7.52 mA/cm^2@ 500Ω LY-ET-02: 7.44 mA/cm^2@ 500Ω LY-ET-04: 3.20 mA/cm^2@ 500Ω	0.073 mA/cm^2 @ 500Ω	8.31 mA/cm^2@ 500Ω	Similar Note 4
Maximum Average Power Density	LY-ET-01: 0.1461 mW/cm^2 @ 500Ω LY-ET-02: 0.2227 mW/cm^2 @ 500Ω LY-ET-04: 0.1927 mW/cm^2 @ 500Ω	0.056 mW/cm^2 @ 500Ω	0.115 mW/cm^2 @ 500Ω	Similar Note 4
Operating Environment	Temperature: 5~40°C, Humidity: ≤80%RH, Atmospheric Pressure: 86~106kPa	Temperature: 5~40°C, Humidity: ≤80%RH, Atmospheric Pressure: 86~106kPa	Not published	Same
Storage Environment	Temperature: Main Unit: -20 ~ 55°C,	Temperature: Main Unit: -20 ~ 55°C, Electrode	Not published	Same

Elements of Comparison	Subject Device	Predicate Device	Reference device	Remark
	Electrode Pad: 10 ~ 20°C Humidity: 10~95% RH, Atmospheric Pressure: 50~106 kPa	Pad: 10 ~ 20°C Humidity: 10~95% RH, Atmospheric Pressure: 50~106 kPa		
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.	Same
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	Same
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	Same

Comparison in Detail(s):

Note 1:

Although the "Patient Leakage Current" of the subject device is different from the predicate device, they are all in compliance with IEC 60601-1requirements for the product. So, the difference will not raise any safety or effectiveness issue.

Note 2:

Although the "Number of Output Channels", "Output Intensity Level" and "Timer Range" of the subject device are little different from the predicate device, the time range of the subject device is included in the time range of the predicate device, and other only the design of the device itself. So, the difference will not raise any safety or effectiveness issue.

Note 3:

Although the "Dimensions" and "Weight" of the subject device are little different from the predicate device, the difference will not raise any safety or effectiveness issue.

Note 4:

For the “Pulse Frequency”, although the predicate device does differ, the reference device is included to demonstrate that the frequency range of subject device has been used before.

And although the "Maximum Phase Charge", "Maximum Output Voltage", "Maximum Output Current", "Maximum Average Current", "Maximum Current Density" and "Maximum Average Power Density" of the subject device are little different from the predicate device, they are all in compliance with IEC 60601-2-10 requirements for the product. Also, the reference device demonstrates that more similar values have been cleared for TENS/EMS devices.

Therefore, the difference will not raise any safety or effectiveness issue.

8. Test Summary

8.1 Summary of Non-Clinical Performance Testing

1) Performance Testing Summary
The TENS & EMS Device (Model: LY-ET-01, LY-ET-02, LY-ET-04) has been evaluated the safety and performance by lab bench testing as following:

Title of the test	Device Description /Sample Size	Test Method/Applicable Standards	Acceptance criteria	Unexpected Results/ Significant Deviations	Test results
General requirements for basic safety and essential performance	The test sample is the final, finished product. Model: LY-ET-01, LY-ET-02, LY-ET-04	IEC 60601-1:2005/AMD 1:2012/AMD 2:2020	The test is carried out under the test method specified in the standard, and the test result is within the test acceptance range of the standard.	NA	Pass
Electromagnetic disturbances	The test sample is the final, finished product. Model: LY-ET-01, LY-ET-02, LY-ET-04	IEC 60601-1-2: 2014+A1:2020	No degradation of performance was found during test or Lower than limits of measurement	NA	Pass
Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.	The test sample is the final, finished product. Model: LY-ET-01, LY-ET-02, LY-ET-04	IEC 60601-1-11: 2015/AMD1: 2020	The device operates normally, and can provide basic safety and essential performance.	NA	Pass
Particular requirements for the basic safety and essential performance of nerve and	The test sample is the final, finished product. Model: LY-	IEC 60601-1-10 Edition 1.2 2020-07	The test is carried out under the test method specified in the standard, and	NA	Pass

muscle stimulators	ET-01, LY-ET-02, LY-ET-04		the test result is within the test acceptance range of the standard.		

2) Biocompatibility testing

- ISO 10993-1: 2018 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management.
- ISO 10993-5:2009 Biological Evaluation of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity
- ISO 10993-10:2010 Third Edition 2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

3) Usability Testing

Usability testing was conducted on the TENS & EMS Device (Model: LY-ET-01, LY-ET-02, LY-ET-04), the device complies with

IEC 62366-1 Edition 1.1 2020-06 CONSOLIDATED VERSION Medical device- Part 1: Application of usability

and IEC 60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION Medical electrical equipment-Part 1-6: General requirements for basic safety and essential performance-Collateral standard: Usability.

4) Software verification and validation testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA'S Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate" level concern, since a malfunction of, or a latent design flaw in, the Software Device leads to an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to Minor Injury.

5) Cybersecurity

The subject device no any external interfaces, according to FDA guidance "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices", no need cybersecurity evaluation.

8.2 Clinical Performance

Clinical testing was not performed on the device.

9. Final Conclusion：

The subject device TENS & EMS Device has similar features as the predicate device, and the few differences do not affect the safety and effectiveness of the subject device. Thus, the subject device is substantially equivalent to the predicate device K163611.