March 1, 2024

Shenzhen Yiran Intelligent Co., Ltd
℅ Tulin Li
Regulatory Manager
Huide Medical Technology Service (Shenzhen) Group Co., Ltd.
Room 703, Building 16, South Bank Plaza,
Exhibition Bay, Zhancheng Community, Fuhai Street,
Shenzhen, Guangdong 518053
China

Re: K231648
Trade/Device Name: Muscle Stimulator
Regulation Number: 21 CFR 882.5890, 21 CFR 890.5850
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: Class II
Product Code: NUH, NGX
Dated: February 26, 2024
Received: February 27, 2024

Dear Tulin Li:

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)*
K231648

Device Name
Muscle Stimulator

Indications for Use *(Describe)*
TENS(Transcutaneous Electric Nerve Stimulation):
To be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, upper extremities (arm), and lower extremities (leg) due to strain from exercise or normal household work activities.
PMS(Powered Muscle Stimulation):
It is intended to be used 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.

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510(K) Summary

510(k) number: K231648

Date of Summary Preparation: Feb 29, 2024

Applicant

Name: Shenzhen Yiran Intelligent Co., Ltd
Address: Floor 6, No. 531 Nanpu Road, Huangpu Community, Xinqiao Street, Bao'an District, Shenzhen, Guangdong, China

Official Correspondent:
Huide Medical Technology Service (Shenzhen) Group Co., Ltd.
Name: Tulin Li
Tel: 0086-186067546446
Mail: yiranintelligent@gmail.com

Device

Trade Name:	Muscle Stimulator
Common Name:	Stimulator, Nerve, Transcutaneous, Over-The-Counter; Power Muscle Stimulator
Model Name:	YR-U80-PRO-MAX,YR-U80-PRO, YR-U8-PRO, YR-U8
Regulation Classification	21 CFR 882.5890, 21 CFR 890.5850
Product Code:	NUH, NGX
Classification Panel:	Physical Medicine
Device Class:	II

Predicate Device

510(k) number: K143268

Trade Name:	TENS AND POWERED MUSCLE STIMULATOR
Common Name:	Stimulator, Nerve, Transcutaneous, Over-The-Counter; Power Muscle Stimulator
Model Name:	AS-TEC
Regulation Classification	21 CFR 882.5890, 21 CFR 890.5850
Product Code:	NUH, NGX
Classification Panel:	Physical Medicine
Device Class:	II

Reference Device

510(k) number: K121719

Trade Name:	SM TENS&PMS
Common Name:	Stimulator, Nerve, Transcutaneous, Over-The-Counter; Power Muscle Stimulator
Model Name:	NA

Regulation Classification	21 CFR 882.5890, 21 CFR 890.5850
Product Code:	NUH, NGX
Classification Panel:	Physical Medicine
Device Class:	II

Device Description:

Muscle Stimulator is a portable and DC 3.7V battery powered multifunction device, offering both Transcutaneous Electrical Nerve Stimulation (TENS) and Powered Muscle Stimulation (PMS) qualities in one device.

Muscle Stimulator can give certain electrical pulses through electrode adhesive pads to the suggested area of the body where the electrodes are placed. The electrodes to be used with the device have already been cleared under K182111.

The electronic stimulatory module has the operating elements of an On/Off Switch, Intensity buttons, Output channel buttons, T button, Output ports, and USB port for battery charging.

The LCD display screen can show time remaining of an application program, battery power, program icons, output channel and intensity, etc.

The device is equipped with accessories of electrode pads, electrode cables, a battery charger, and one USB cable. The electrode cables are used to connect the pads to the device; the USB cable is used to connect the charger and the built-in lithium battery. All accessories, including USB cables, electrode pads, electrode cables, chargers can only be changed or replaced by a qualified person.

Indications for use:

TENS (Transcutaneous Electric Nerve Stimulation):

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

PMS (Powered Muscle Stimulation):

It is intended to be used to stimulate healthy muscles in order to improve and facilitate muscle performance.

Comparison table

		New Device	**Predicate Device**	**Reference device**	**Same/Different**
1.	510(k) Number	K231648	K143268	K121719	
2.	Marketing clearance date	/	07/21/2015	10/23/2012	
3.	Device Name	Muscle Stimulator	TENS AND POWERED MUSCLE STIMULATOR	SM TENS & PMS	
4.	Model	YR-U80-PRO-MAX,YR-U80-PRO, YR-U8-PRO,YR-U8	AS-TEC	NA	
5.	Manufacturer	Shenzhen Yiran Intelligent Co., Ltd	Shenzhen Technology Co.,	Hong Qiangxing (Shen Zhen) Electronics	

			Ltd.	Limited	
6.	Intended use	TENS (Program 3, 4)： To be used for temporary sore and aching muscles in relief of pain associated with the shoulder, waist, back, upper extremities (arm),and lower extremities (leg) due to strain from exercise or normal household work activities. PMS (Program 1, 2, 5,6)： It is intended to be used to stimulate healthy muscles in Order to improve and Facilitate muscle performance.	TENS (Mode 1, 3, 4, 5, 6): To be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, upper extremities (arm), and lower extremities (leg) due to strain from exercise or normal household work activities. PMS (Mode 1, 2, 3, 5): It is intended to be used to stimulate healthy muscles in order to improve and facilitate muscle performance	TENS: To be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, neck, upper extremities (arm), and lower extremities (leg) due to strain from exercise or normal household work activities. PMS: It is intended to be used to stimulate healthy muscles in order to improve and facilitate muscle performance.	Same Note 1

7.	Type of use	OTC	OTC	OTC	Same
7.8.	Power Source(s)	DC 3.7V lithium battery	DC 3.7V lithium battery	DC 3.7V lithium battery	Same
	- Method of Line Current Isolation	Type BF	Type BF	Type BF	Same
	- Patient Leakage Current - Normal Condition (μA) - Single Fault Condition (μA)	-- 0.1μA 0.1μA	-- 0.1μA 0.1μA	2 μA ＜ 10 μA	Same
9.	Average DC currentthrough electrodes when device is on	< 0.01μA	< 0.01μA	< 0.01μA	Same

	but no pulses are being applied (μA)				
10.	Number of Output Modes	6	6	6	Same
11.	Number of Output channels:	2	2	2	Same
	- Synchronous or Alternating?	Synchronous	Synchronous	Synchronous	Same
	- Method of Channel Isolation	Voltage transformer Isolation	Voltage transformer Isolation	Voltage transformer isolation	Same
12.	Regulated Currentor Regulated Voltage?	Voltage control	Voltage control	Voltage control	Same
13.	Software/Firmware/ Microprocessor Control?	Software	Software	Software	Same
14.	Automatic Overload Trip?	No	No	No	Same
15.	Automatic No-Load Trip?	Yes	No	No	Same Note 2
16.	Automatic Shut Off?	Yes	Yes	Yes	Same
17.	User Override Control?	Yes	Yes	Yes	Same
18.	Indicator Display — On/Off Status?	Yes	Yes	Yes	Same
	Indicator Display — Low Battery?	Yes	Yes	Yes	Same
	Indicator Display — Voltage Current Level?	Yes	Yes	Yes	Same
19.	Timer Range (minutes)	10 ~ 60 min 10 min/step	10 ~ 60 minute 10 min/step	10-60 minutes, 10 min/step	Same

20.	Compliance with Voluntary Standards?	Yes. AAMI/ANSI ES 60601-1, IEC 60601-1-2, IEC 60601-2-10, IEC 62133,IEC 60601-1-11	Yes. AAMI/ANSI ES60601-1,IEC 60601-1-2, IEC 60601-2-10, IEC 62133, IEC 60601-1-11	Yes. AAMI/ANSI ES60601-1,IEC 60601-1-2, IEC 60601-2-10, IEC 62133,IEC 60601-1-11	Same
21.	Compliance with 21 CFR 8988?	Yes	Yes	Yes	Same
22.	Weight (grams)	262g	170g	NA	Same
23.	Dimensions (mm) [W x H x D]	110mm*108mm*58mm	93*50*9mm	NA	Note 1
24.	Housing Materials & Construction	ABS	ABS	ABS	
25.	Waveform	Pulsed, symmetric, biphasic	Pulsed, symmetric, biphasic	Pulsed, symmetric, biphasic	
26.	Shape	Oval, spike	Rectangular, with interphase interval	Rectangular, with interphase interval	
27.	Maximum Output Voltage (volts)	37.2V ±20% @500Ω	53.5V±20% @500Ω	42V±10%@500Ω	
		74.2V±20% @2kΩ	67V±20% @2kΩ	84V±10%@2kΩ	
		138.6V ±20% @10kΩ	68V±20% @10kΩ	130V±10%@10kΩ	
28.	Maximum Output Current (specify units)	74.4mA±20% @500Ω	107mA±20% @500Ω	84mA±10% @500Ω	
		37.1mA±20% @2kΩ	33.5mA±20% @2kΩ	42mA±10% @2kΩ	
		13.86mA±20% @10kΩ	6.8±20% @10kΩ	13mA±10% @10kΩ	
29.	Pulse width (μsec)	Positive phase: 200μs±10% Negative phase: 200μs±10% Interphase interval: 200μs±10%	Positive phase: 225μs Negative phase: 225μs Interphase interval: 225μs	100μs	
30.	Pulse Period (msec)	20-1000ms	8.9~617ms	NA	
31.	Pulse frequency	1-50Hz±10%	1.62Hz~113Hz	110Hz	

	(Hz) [or Rate (pps)]				
32.	Net Charge (μC per pulse)	0μC @500Ω; Method: Balanced waveform	0μC@500Ω; Method: Balanced waveform	0μC @500 Ω; Method: Balanced waveform	
33.	Maximum Phase Charge, (μC)	15.87μC@500Ω	48μC @500Ω	16.8μC@500 Ω	Note 3
34.	Maximum Average Current, (mA)	0.793mA@500 Ω	2.72mA @500Ω	0.924mA@500Ω	
35.	Maximum Current Density, (mA/cm², r.m.s.)	0.06mA/cm2 area 25cm2)	1.36mA/cm2 (Smallest electrode area = 4cm2)	0.462mA/cm 2@500Ω	
36.	Maximum Average Power Density, (mW/cm²)	1.57mW/cm2 area 25cm2)	36.4mW/cm2 (Smallest electrode area = 4cm2)	9.702mW/cm2@ 500Ω	
37.	Battery charge	① The Lithium battery can be recharged throughboth AC adaptor and computer USB input. ② When Charging is finished, the LCD will show full cell of battery.	① The Lithium battery can be recharged through both AC adaptor and computer USB input. ② When charging show full cell of battery.	NA	
38.	Accessories	Self-adhesive electrodes, electrode wires, Battery charger, USB cable	Self-adhesive electrodes, electrode wires, Battery charger, USB cable	NA	

	Differences between proposed device and predicate device: **Note 1:** The proposed device has more treatment programs than the predicate device K143268, but allof the treatment programs have passed the IEC 60601-2-10 test codes. So this difference doesn't raise any safety issues. And the weight, dimensions, housing material, appearance of proposed device are a little different from predicate device K143268. Consider the same intended use, components, working principle, test standards, these differences are insignificant in the terms of safety or effectiveness. **Note 2:** The maximum phase charge of the proposed device (15.87μC@500Ω) is less than the predicate device (48μC @500Ω), but the cleared device K121719, which is the predicate device of K143268, has the maximum phase charge of 16.8μC@500Ω. The value of the proposed device is similar to that of the 510K clearance device K121719, therefore this difference doesn't raise any new safety and effectiveness issues. The maximum average current, maximum current density, maximum average power density have some differences between proposed device and predicate device due to they are calculated by different electrode area. Both of them meet maximum current density <2mA/cm² and maximum average power density <0.25W/cm². Therefore these differences don't raise any new safety and effectiveness issues. **Note 3** The reference device is being included to demonstrate that the different technological parameters do not have an effect on the safety and effectiveness of the subject device

Muscle Stimulator is safe and effective as the predicate devices cited above. The new devices have passed testing according to the safety standards:

Non-Clinical Testing

1) ANSI AAMI ES60601-1: 2005/(R)2012 And A1:2012, C1:2009/(R)2012 And A2:2010/(R)2012 (Consolidated Text) Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance (IEC 60601-1:2005, MOD);

2) IEC 60601-2-10 Edition 2.1 2016-04, Medical Electrical Equipment - Part 2-10: Particular Requirements For The Basic Safety And Essential Performance Of Nerve And Muscle Stimulators

3) ANSI AAMI IEC 60601-1-2:2014, Medical Electrical Equipment -- Part 1-2: General Requirements For Basic Safety And Essential Performance -- Collateral Standard: Electromagnetic Disturbances -- Requirements And Tests;

4) IEC 62133-2 Edition1.0 2017-02 Secondary Cells And Batteries Containing Alkaline Or Other Non-Acid Electrolytes - Safety Requirements For Portable Sealed Secondary Cells, And For Batteries Made From Them, For Use In Portable Applications - Part 2: Lithium Systems

5) IEC 60601-1-11 Edition 2.0 2015-01, 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 . (General II (ES/EMC))

Clinical Testing

No clinical testing was performed on the device.

The conclusion drawn from the safety testing is that the new devices are substantially equivalent to the predicate devices. Furthermore, the new devices comply with the recognized standards and perform its intended tasks as well as the legally marketed predicate devices.

Conclusion

In accordance with the Federal Food, Drug and Cosmetic Act 21, CFR Part 807 and based on the Intended Use, Technological Characteristics, Performance data and non-clinical tests performed, the subject device is substantially equivalent and is as safe and as effective as the legally marketed predicate device.