March 27, 2024

Wuxi Jiajian Medical Instrument Co., Ltd
% Doris Dong
General manager
Shanghai CV Technology Co., Ltd.
Room 602, No.19 Dongbao Road, Songjiang Area,
Shanghai, Shanghai 201613
China

Re: K231425
Trade/Device Name: Transcutaneous Electrical Nerve Stimulator (TENS WMPS2-1)
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: Class II
Product Code: NUH
Dated: December 28, 2023
Received: December 28, 2023

Dear Doris Dong:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Pamela D. Scott -S

Pamela Scott
Assistant Director
DHT5B: Division of Neuromodulation
and Rehabilitation 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)*
K231425

Device Name
Transcutaneous Electrical Nerve Stimulator(TENS WMPS2-1)

Indications for Use *(Describe)*
Transcutaneous Electrical Nerve Stimulator (Model:TENS WMPS2-1) can be used for the symptomatic relief of chronic intractable pain, post traumatic pain adjunctive treatment, and post-surgical pain adjunctive treatment.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

[As required by 21 CFR 807.92]

1. Submission Information

510(k) Number:	K231425
Date:	May 10, 2023
Type of 510(k) Submission:	Traditional 510(k)
Submitter/Manufacturer:	Wuxi Jiajian Medical Instrument Co., Ltd. No. 35 Baiqiao Rd., Ehu Town, Xishan District, Wuxi, Jiangsu, China 214116 E-mail：sch@jjmed.com.cn Tel: 86 510-88745788
Contactor:	Doris Dong [Consultant, from Shanghai CV Technology Co., Ltd.] Add: Room 602, No. 19 Dongbao Road, Songjiang Area, Shanghai, 201613 China E-mail: doris.d@ceve.org.cn Tel: 86 21-31261348 / Fax: 86 21-57712250

2. Device Description

Proprietary Name:	Transcutaneous Electrical Nerve Stimulator
Model:	TENS WMPS2-1
Common Name:	Stimulator, Nerve, Transcutaneous, Over-The-Counter
Classification Name:	Transcutaneous electrical nerve stimulator for pain relief
Product Code:	NUH
Device Class:	2
Regulation Number:	21 CFR 882.5890
Review Panel:	Neurology
Indications for use:	Transcutaneous Electrical Nerve Stimulator (Model:TENS WMPS2-1) can be used for the symptomatic relief of chronic intractable pain, post traumatic pain adjunctive treatment, and post-surgical pain adjunctive treatment.
Device Description:	Transcutaneous Electrical Nerve Stimulator sends gentle electrical current to underlying nerves and muscle groups via electrodes applied onto the skin to relieve pain. The device has 16 programs (12 standard programs and 4 editable programs). It is a lithium battery-powered device comprising the electronic stimulatory module, the accessories of lead wires, the electrodes and the adapter. Two outlet sockets are used to connect skin electrodes by lead wires. The accessories of electrodes are 510(k) cleared devices (K192568). Size: 50*50mm.

3. Predicate Device Identification

Predicate 510(k) Number:	K210223
Marketing Clearance Date:	December 15,2021
Product Name:	Transcutaneous Electrical Nerve Stimulator
Manufacturer:	Top-Rank Health Care Co.,Ltd.
Reference Predicate 510(k) Number:	K123958
Marketing clearance date:	October 28,2013
Product name:	Jiajian® Pointoselect Digital
Manufacturer:	Wuxi Jiajian Medical Instrument Co., Ltd

4. Substantially Equivalent Comparison Conclusion

Parameters	**New Device**	**Predicate Device**	**Reference Predicate Device**	**Comparison**
510(k) Number	K231425	K210223	K123958	--
Device Name	Transcutaneous Electrical Nerve Stimulator	Transcutaneous Electrical Nerve Stimulator	Jiajian® Pointoselect Digital	--
Model	TENS WMPS2-1	TOPTENS-01	--	--
Manufacturer	Wuxi Jiajian Medical Instrument Co., Ltd	Top-Rank Health Care Co.,Ltd.	Wuxi Jiajian Medical Instrument Co., Ltd	--
Indications for use	Transcutaneous Electrical Nerve Stimulator (Model:TENS WMPS2-1) can be used for the symptomatic relief of chronic intractable pain, post traumatic pain adjunctive treatment, and post-surgical pain adjunctive treatment.	The TOPTENS-01 can be used for the symptomatic relief of chronic intractable pain, post traumatic pain adjunctive treatment, and post-surgical pain adjunctive treatment.	Jiajian® Pointoselect Digital is intended for use in the symptomatic relief of chronic intractable pain, postoperative pain, and acute pain.	Same
Type of use	OTC	OTC	Prescription use	Same
Power Source(s)	DC3.7 V Li-battery powered	DC 4.5V, 3 AAA batteries	DC 9V battery, Type 6F22	Similar Note 1
- Method of Line Current Isolation	N/A	N/A	N/A	Same
- Patient Leakage Current	--	--	--	Same
- Normal Condition	2μA	2μA	20μA	

(μA)					
- Single Fault Condition (μA)		N/A	N/A	N/A	
Average DC current through electrodes when device is on but no pulses are being applied (μA)		<0.01μA	Not Published	Not Published	Similar Note 2
Number of program		16	9	1	Similar Note 2
Number of Output channels:		2	2	1	Same
- Synchronous or Alternating?		Alternating	Synchronous	N/A	Similar Note 2
- Method of Channel Isolation		By Transformer	By enclosure	N/A	Similar Note 2
Regulated Current or Regulated Voltage?		Current control	Voltage control	Current control	Similar Note 1
Software/Firmware/ Microprocessor Control?		Yes	Yes	Yes	Same
Automatic Overload Trip?		No	No	No	Same
Automatic No-Load Trip?		No	Yes	No	Similar Note 2
Automatic Shut Off?		Yes	Yes	Yes	Same
User Override Control?		Yes	No	No	Similar Note 2
Indicator Display	On/Off Status?	Yes	Yes	Yes	Same
	Low Battery?	Yes	Yes	Yes	Same
	Voltage/ Current Level?	Yes	Yes	Yes	Same
Timer Range (minutes)		10~99 min	50~60 min (5,10,15,20,25,30,35 ,40, 45,50,55and 60 min selectable)	Manually controlled	Similar Note 3
Compliance with Voluntary Standards?		AAMI/ANSI ES 60601-1, IEC 60601-1-2, IEC 60601-2-10, IEC 60601-1-11	AAMI/ANSI ES 60601-1, IEC 60601-1-2, IEC 60601-2-10, IEC 60601-1-11	AAMI/ANSI ES 60601-1, IEC 60601-1-2, IEC 60601-2-10	Same

Compliance with 21 CFR 898?	Yes	Yes	Yes	Same
Weight (grams)	Approx.106g	0.18 (Battery Excluded).lbs	123g	Similar Note 3
Dimensions (mm) [W x H x D]	140*60*20mm	2.32*4.96*1.18 mm	115*60*30mm	Similar Note 3
Housing Materials & Construction	ABS	Plastic (ABS) enclosure	ABS; Injection molded	Same
Waveform	Biphasic	Biphasic	Biphasic	Same
Shape	Square	Square	Asymmetric biphasic square wave	Same
Maximum Output Voltage (volts)	Program 1 15V±20% @500Ω 60V±20% @2kΩ 85V±20% @10kΩ	Mode 4 23V @500Ω 60V@2kΩ 100V @10kΩ	-- 6.6V±15%@500Ω 26.0 ±15%@2kΩ 125V ±15% @10kΩ	Similar Note 4
Maximum Output Current (specify units)	Program 1 30mA±20% @500Ω 30mA±20% @2kΩ 8.5mA±20% @10kΩ	Mode 4 46mA @500Ω 30mA @2kΩ 10mA @10kΩ	-- 13.2mA ±15% @500Ω 13.0mA ±15% @2kΩ 12.5mA ±15% @10kΩ	
Pulse width (μsec)	75-300μs±20%	100-260μs	60-120μs	
Pulse Period (msec)	8.33-1000ms	6.67-16.67ms	55.6-500ms	
Max. pulse frequency (Hz) [or Rate (pps)]	1-120Hz±20%	60-150Hz	2-18Hz	
Net Charge (μC per pulse)	0μC @500Ω(Method: Balanced waveform)	0μC @500Ω(Method: Balanced waveform)	0μC @500Ω，+ and – pulses cancel	Same
Maximum Phase Charge, (μC)	9μC @500Ω	17.16μC @500Ω	2.4μ C@500Ω	
Maximum Average Current, (mA)	2.16mA @500Ω	2.22mA @500Ω	Not Published	

Maximum Current Density, (mA/cm², r.m.s.)	0.043mA/cm² @500Ω	0.14mA/cm² @500Ω	12.08mA/cm^2@500 Ω	Similar Note 5
Maximum Average Power Density, (mW/cm²)	1.30mW/cm² @500Ω	1.50mW/cm² @500Ω	0.0036W/cm^2@500 Ω	
Accessories	Electrodes, cables, adapter	Electrodes, cables	1 pcs. of hand probe for stimulation with lead wire; 1 pcs. of hand electrode with lead wire	Similar Note 3
Comparison in details:				

Note 1:

Although the proposed device's power source(s) and output intensity control are a little different from those of the predicate device, they all comply with IEC 60601-1 requirements. So the differences will not raise any safety or effectiveness issues.

Note 2:

The proposed device's average DC current at no load, number of output modes, channel output design and isolation methods,automatic no trip and user override control are different from those of the primary predicate device. As the proposed device and predicate device adopt the same fundamental output technology and have similar treatment effect, therefore, the proposed device is considered to be substantially equivalent. Also, the proposed device had passed AAMI / ANSI ES60601-1 and IEC 60601-2-10 tests, so these differences will not raise any new safety and effectiveness issues.

Note 3:

The time range, weight, dimensions and accessories of the proposed device are a little different from those of the predicate device, depending on the design and sales requirements of the product. But these differences are insignificant in terms of safety or effectiveness.

Note 4:

There are some differences in the maximum output voltage and maximum output current between the proposed device and the predicate device. Based on the calculation of maximum current density, maximum average power density, these parameters don't exceed the safety limit. Also, these parameters have passed IEC 60601-2-10 test codes and all deviation and the worst cases have been considered in risk analysis report..So these differences will not raise any new safety and effectiveness issues. Although the pulse width, pulse period and frequency of the proposed device are a little different from those of the predicate device, but they are all in compliance with IEC 60601-2-10 requirements. The minor differences of function specification will not raise any safety or effectiveness issue, either.

Note 5:

The net charge and maximum phase charge of the proposed device are different from those of the predicate device, but both of them comply with IEC 60601-1 and IEC 60601-2-10 requirements, so the differences will not raise any safety or effectiveness issues. The maximum average current, maximum current density, maximum average power density have some differences between the proposed device and the predicate device. But both of them meet the maximum average current of <10mA, the maximum current density of <2mA/cm² and the maximum average power density of <0.25W/cm². Also, all programs have passed AAMI/ANSI ES 60601-1 and IEC 60601-2-10 tests. Therefore, these differences will not raise any new safety and effectiveness issues.

5. Non-Clinical Test Conclusion

Bench tests were conducted on Transcutaneous Electrical Nerve Stimulator (TENS WMPS2-1) to verify that the proposed device met all design specifications and was Substantially Equivalent (SE) to the predicate devices. The following tests were performed on the proposed device:

• 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);

• 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;

• IEC 60601-1-2 Edition 4.0 2014-02 Medical electrical equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements and Tests;

• 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 Equipment and Medical Electrical Systems Used in Home Healthcare Environment

6. Clinical Test

Clinical data were not included in this submission.

7. Conclusion

The conclusion drawn from the non-clinical tests demonstrates that the device performs well and is as safe, and effective as the legally marketed device identified in the submission. Thus, the subject device is substantially equivalent to the predicate device.