June 18, 2021

Wuxi Jiajian Medical Instrument Co., Ltd
Caihong Sun
Regulatory Assurance
No. 35 Baiqiao Rd., Ehu Town, Xishan District,
Wuxi, Jiangsu 214116
China

Re: K202893
Trade/Device Name: Transcutaneous Electrical Nerve Stimulator
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: GZJ
Dated: April 25, 2021
Received: May 17, 2021

Dear Caihong Sun:

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,

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)*
K202893

Device Name
Transcutaneous Electrical Nerve Stimulator

Indications for Use *(Describe)*
The Transcutaneous Electrical Nerve Stimulator is an electrical nerve stimulator indicated for use for pain relief by applying an electrical current to electrodes on a patient's skin to treat pain. In particular, this device is indicated for use for symptomatic relief of chronic intractable pain and adjunctive treatment in the management of post surgical and post traumatic pain.

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

[As required by 21 CFR 807.92]

1. Submission Information:

510(k) Number:	K202893
Date:	April 15, 2021
Type of 510(k) Submission:	Special
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 903, 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
Common Name:	TENS (Transcutaneous Electrical Nerve Stimulator)
Classification Name:	Transcutaneous electrical nerve stimulator for pain relief
Product Code:	GZJ
Device Class:	II
Regulation Number:	21 CFR 882.5890
Review Panel:	Neurology
Indications for use:	Transcutaneous Electrical Nerve Stimulator is an electrical nerve stimulator indicated for use for pain relief by applying an electrical current to electrodes on a patient's skin to treat pain. In particular, this device is indicated for use for symptomatic relief of chronic intractable pain and adjunctive treatment in the management of post surgical and post traumatic pain.
Device Description:	Transcutaneous Electrical Nerve Stimulator is Transcutaneous Electrical Nerve Stimulator for pain relief. The stimulator sends gentle electrical current to underlying nerves and muscle group via electrodes applied on the skin. The device has standard programs and edit programs. It is a battery-powered portable device, comprising electronic stimulatory module and accessories of lead wires, electrodes and battery. Two outlet sockets are used to connect skin electrodes by lead wires. The accessories of electrodes is 510(k) cleared device (K192568), Size: 50*50mm.

3. Substantially Equivalent Comparison Conclusion

Table 1 - TENStem eco basic Parameters

Parameters	Modified Device	Predicate Device	Remark
510(k) Number	K202893	K112288	--
Device Name	Transcutaneous Electrical Nerve Stimulator	Jiajian® TENS	--
Model	TENStem eco basic	/	--
Manufacturer	Wuxi Jiajian Medical Instrument Co., Ltd	Wuxi Jiajian Medical Instrument Co., Ltd	Same
Intended use	Transcutaneous Electrical Nerve Stimulator is an electrical nerve stimulator indicated for use for pain relief by applying an electrical current to electrodes on a patient's skin to treat pain. In particular, this device is indicated for use for symptomatic relief of chronic intractable pain and adjunctive treatment in the management of post surgical and post traumatic pain.	Jiajian® TENS is an electrical nerve stimulator indicated for use for pain relief by applying an electrical current to electrodes on a patient's skin to treat pain. In particular, this device is indicated for use for symptomatic relief of chronic intractable pain and adjunctive treatment in the management of post surgical and post traumatic pain.	Same
Type of use	Prescription use	Prescription use	Same
Power Source(s)	1.5Vx4 AAA alkaline battery	9V Battery type 6F22	Similar Note 1
- Method of Line Current Isolation	N/A	NA	Same
- Patient Leakage Current - Normal Condition (μA) - Single Fault Condition (μA)	-- 2μA NA	-- 2μA NA	Same
Average DC current through electrodes when device is on but no pulses are being applied (μA)	<0.01μA	<0.01μA	Same
Number of program	16	12	Similar Note 1
Number of Output channels:	2	2	Same
- Synchronous or Alternating?	Synchronous	Synchronous	Same

- Method of Channel Isolation		By Transformer	By Transformer	Same
Regulated Current or Regulated Voltage?		Current control	Voltage control	Similar Note 2
Software/Firmware/Microprocessor Control?		Yes	Yes	Same
Automatic Overload Trip?		No	No	Same
Automatic No-Load Trip?		No	No	Same
Automatic Shut Off?		Yes	Yes	Same
User Override Control?		Yes	Yes	Same
Indicator Display	On/Off Status?	Yes	Yes	Same
	Low Battery?	Yes	Yes	Same
	Voltage/Current Level?	Yes	Yes	Same
Timer Range (minutes)		10~90 min	1~99 min	Similar Note 2
Compliance with Voluntary Standards?		ANSI AAMI ES60601-1, IEC 60601-1-2, IEC 60601-2-10	IEC 60601-1, IEC 60601-1-2, IEC 60601-2-10	Same
Compliance with 21 CFR 898?		Yes	Yes	Same
Weight (grams)		Approx.96g without battery	170g without battery	Similar Note 1
Dimensions (mm) [W x H x D]		140*64*28 mm	114 x 59 x 27 mm	
Housing Materials & Construction		ABS	ABS	Same
Waveform		Monophasic	Monophasic	Same
Shape		Rectangular pulse	Rectangular	Same
Maximum Output Voltage (volts)		30V±20% @500Ω	35V @500Ω	Similar Note 3
Maximum Output Current (specify units)		60mA±20% @500Ω	70mA @500Ω	
Pulse width (μsec)		75-300μs±20%	60-300μs±20%	
Pulse Period (msec)		8.33-1000ms	8.33-2000ms	
Max. pulse frequency (Hz) [or Rate (pps)]		1-120Hz±20%	0.5-120Hz±20%	
Net Charge (μC per pulse)		0.65μC @500Ω	0.83μC @500Ω	Similar Note 4

Maximum Phase Charge, (μC)	18μC @500Ω	23.04μC @500Ω	
Maximum Average Current, (mA)	2.16mA @500Ω	2.76mA @500Ω	
Maximum Current Density, (mA/cm², r.m.s.)	0.09mA/cm² @500Ω	0.35mA/cm² @500Ω	
Maximum Average Power Density, (mW/cm²)	2.59mW/cm² @500Ω	13.27mW/cm² @500Ω	
Accessories	Electrodes, cables, battery	Electrodes, cables, battery	Same

Comparison in details:

Note 1:

The proposed device has more treatment programs than the predicate device K112288, but all of the treatment programs have passed the IEC 60601-2-10 and IEC 60601-1 test codes. So, this difference will not raise any safety or effectiveness issue.

The weight, dimensions of the proposed device are a little different from the predicate device K112288, but these differences are insignificant in the terms of safety or effectiveness. Besides, the battery used is different from the predicate device, but the battery used by the proposed device is commonly used in the market. Therefore, this difference will not raise any safety or effectiveness issue.

Note 2:

The "Regulated Current or Regulated Voltage" between the proposed device and the predicate device has slight difference. But both of them have passed IEC 60601-1 test code, so this difference won't raise any new safety and effectiveness issues.

There is a little difference on treatment time range between proposed device and predicate device. But the treatment time can be adjusted by user as they want. So, the difference of treatment time range will not raise any safety or effectiveness issue.

Note 3:

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

Note 4:

The "Net Charge" and "Maximum Phase Charge" of the proposed device are very similar to the predicate device, and both of them comply with IEC 60601-1 and IEC 60601-2-10 requirements. So, the differences will not raise any safety or effectiveness issue.

The maximum average current of the proposed device is smaller than that of the predicate device which means the better safety. The 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. However, the Maximum current density complies with IEC 60601-2-10 requirements and the

Maximum average power density is within 0.25W/cm^2 limit.Therefore, these differences will not raise any new safety and effectiveness issues.
Final conclusion: The proposed device TENStem eco basic is substantial Equivalent to the predicate device K112288.

4. Non-Clinical Test Conclusion

Bench tests were conducted on Transcutaneous Electrical Nerve Stimulator to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. 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;

5. Clinical Test

Clinical data was not including in this submission.

6. Conclusions

The conclusions drawn from the non-clinical tests demonstrate that the subject device is substantially equivalent to the predicate device.