May 25, 2022

Bozhou Rongjian Medical Appliance Co., Ltd.
Wu Zhifang
General Manager
Jianghuai Supply Base, Zhongkai Group, Mengcheng County
Bozhou, Anhui 233500
China

Re: K220578
Trade/Device Name: Transcutaneous Electrical Nerve Stimulator (Model RJTENS-1)
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: GZJ
Dated: February 18, 2022
Received: February 28, 2022

Dear Wu Zhifang:

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,

Amber Ballard, PhD
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)*
K220578

Device Name
Transcutaneous Electrical Nerve Stimulator (Model RJTENS-1)

Indications for Use *(Describe)*
The Transcutaenous Electrical Nerve Stimulator (Model RJTENS-1) 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:	K220578
Date:	April 25, 2022
Type of 510(k) Submission:	Traditional 510(k)
Submitter/Manufacturer:	Bozhou Rongjian Medical Appliance Co.,Ltd. Jianghuai Supply Base, Zhongkai Group, Mengcheng County, Bozhou City, 233500 Anhui, China
Contactor:	Wu Zhifang E-mail: doris.d@ceve.org.cn Tel: +86-558-7662968

2. Device Description

Proprietary Name:	Transcutaneous Electrical Nerve Stimulator (Model RJTENS-1)
Common Name:	TENS (Transcutaneous Electrical Nerve Stimulator)
Classification Name:	Transcutaneous electrical nerve stimulator for pain relief
Product Code:	GZJ
Device Class:	2
Regulation Number:	21 CFR 882.5890
Review Panel:	Neurology
Indications for use:	Transcutaneous Electrical Nerve Stimulator (Model RJTENS-1) 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 (Model RJTENS-1) sends gentle electrical current to underlying nerves and muscle group via electrodes applied on the skin to relieve pain. The device has 16 programs (12 standard programs and 4 editable programs). It is a battery-powered portable device, comprising electronic stimulatory module and accessories of lead wires, electrodes and 4×1.5V AAA alkaline batteries. Two outlet sockets are used to connect skin electrodes by lead wires. The accessories of electrodes is 510(k) cleared device (K213879), Size: 50*50mm.

3. Predicate Device Identification

Predicate 510(k) Number:	K202893
Marketing clearance date:	June 18, 2021
Product name:	Transcutaneous Electrical Nerve Stimulator
Manufacturer:	Wuxi Jiajian Medical Instrument Co., Ltd

4. Substantially Equivalent Comparison Conclusion

Parameters	New Device	Predicate Device	Comparison
510(k) Number	K220578	K202893	--
Device Name	Transcutaneous Electrical Nerve Stimulator (Model RJTENS-1)	Transcutaneous Electrical Nerve Stimulator	--
Manufacturer	Bozhou Rongjian Medical Appliance Co.,Ltd.	Wuxi Jiajian Medical Instrument Co., Ltd	--
Indication for Use	Transcutaneous Electrical Nerve Stimulator ((Model RJTENS-1) 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.	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.	Same
Type of use	Prescription use	Prescription use	Same
Power Source(s)	1.5Vx4 AAA alkaline battery	1.5Vx4 AAA alkaline battery	Same
- Method of Line Current Isolation	N/A	N/A	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	16	Same
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	Current control	Same
Software/Firmware/	Yes	Yes	Same

Microprocessor Control?				
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	10~90 min	Same
Compliance with Voluntary Standards?		ANSI AAMI ES60601-1, IEC 60601-1-2, IEC 60601-2-10	ANSI AAMI ES60601-1, IEC 60601-1-2, IEC 60601-2-10	Same
Compliance with 21 CFR 898?		Yes	Yes	Same
Weight (grams)		Approx.96g without battery	Approx.96g without battery	Same
Dimensions (mm) [W x H x D]		140*64*28 mm	140*64*28 mm	Same
Housing Materials & Construction		ABS	ABS	Same
Waveform		Monophasic	Monophasic	Same
Shape		Rectangular pulse	Rectangular pulse	Same
Maximum Output Voltage (volts)		30V±10% @500Ω	30V±20% @500Ω	Similar Note 1
Maximum Output Current (specify units)		60mA±10% @500Ω	60mA±20% @500Ω	
Pulse width (μsec)		75-300μs±10%	75-300μs±20%	
Pulse Period (msec)		8.33-1000ms	8.33-1000ms	
Max. pulse frequency (Hz) [or Rate (pps)]		1-120Hz±10%	1-120Hz±20%	
Net Charge (μC per pulse)		0.65μC @500Ω	0.65μC @500Ω	Same
Maximum Phase Charge, (μC)		18μC @500Ω	18μC @500Ω	
Maximum Average Current, (mA)		2.16mA @500Ω	2.16mA @500Ω	
Maximum Current		0.09mA/cm² @500Ω	0.09mA/cm² @500Ω	

Density, (mA/cm², r.m.s.)			
Maximum Average Power Density, (mW/cm²)	2.59mW/cm² @500Ω	2.59mW/cm² @500Ω	
Accessories	Electrodes, cables, battery	Electrodes, cables, battery	Same
Comparison in details: **Note 1:** The deviation from the amplitude, frequency and pulse width of the proposed device are different from those of the predicate device. The proposed device has less deviation than the predicate device, which means that its output is more stable. And both the proposed device and predicate device passed ANSI AAMI ES60601-1, IEC 60601-1-2, IEC 60601-2-10 standards tests. Therefore, this difference will not raise any safety or effectiveness issue.			

5. Non-Clinical Test Conclusion

Bench tests were conducted on Transcutaneous Electrical Nerve Stimulator (Model RJTENS-1) 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;

6. Clinical Test

Clinical data was not including in this submission.

7. Conclusions

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