November 24, 2025

Bozhou Rongjian Medical Appliance Co., Ltd.
℅ Doris Dong
Shanghai CV Technology Co., Ltd.
Room 805, No.19 Dongbao Road, Songjiang Area
Shanghai, Shanghai 201613
China

Re: K252688
Trade/Device Name: Transcutaneous Electrical Nerve Stimulator (RJTENS-2)
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: NUH
Dated: August 25, 2025
Received: August 26, 2025

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Heather L. Dean -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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K252688

Device Name
Transcutaneous Electrical Nerve Stimulator (RJTENS-2)

Indications for Use *(Describe)*
Transcutaneous Electrical Nerve Stimulator (Model: RJTENS-2) 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:	K_ _ _ _ _ _
Date:	August 25, 2025
Type of 510(k) Submission:	Traditional 510(k)
Applicant /Manufacturer:	Bozhou Rongjian Medical Appliance Co., Ltd. Jianghuai Supply Base, Zhongkai Group, Mengcheng County, Bozhou, Anhui, 233500, China E-mail: doris.d@ceve.org.cn Tel: +86-558-7963368
Submitter & Contact:	Doris Dong E-mail: doris.d@ceve.org.cn Tel: 86 21-31261348

2. Device Description

Proprietary Name:	Transcutaneous Electrical Nerve Stimulator
Model:	RJTENS-2
Common Name:	Stimulator, Nerve, Transcutaneous, Over-The-Counter
Regulation Name:	Transcutaneous electrical nerve stimulator for pain relief
Product Code:	NUH
Regulation Number:	882.5890
Device Class:	2
Review Panel:	Neurology
Indications for use:	Transcutaneous Electrical Nerve Stimulator (Model: RJTENS-2) 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 (Model: RJTENS-2) sends gentle electrical current to underlying nerves and muscle groups via electrodes applied onto the skin to relieve pain. The device has 14 programs (11 standard programs and 3 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 (K213879). Size: 50*50mm.

3. Predicate Device Identification

Predicate 510(k) Number:	K231425
Marketing clearance date:	03/27/2024
Product name:	Transcutaneous Electrical Nerve Stimulator (Model: TENS WMPS2-1)
Manufacturer:	Wuxi Jiajian Medical Instrument Co., Ltd

4. Substantially Equivalent Comparison Conclusion

Parameters	**New Device**	**Predicate Device**	**Comparison**
510(k) Number	To be assigned	K231425	--
Device Name	Transcutaneous Electrical Nerve Stimulator	Transcutaneous Electrical Nerve Stimulator	--
Model	RJTENS-2	TENS WMPS2-1	--
Manufacturer	Bozhou Rongjian Medical Appliance Co., Ltd.	Wuxi Jiajian Medical Instrument Co., Ltd	--
Intended use	Transcutaneous Electrical Nerve Stimulator (Model: RJTENS-2) can be used for the symptomatic relief of chronic intractable pain, post traumatic pain adjunctive treatment, and post-surgical pain adjunctive treatment.	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.	Same
Type of use	OTC	OTC	Same
Power Source(s)	DC3.7 V Li-battery powered	DC3.7 V Li-battery powered	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	14	Similar Note 1
Number of Output channels:	2	2	Same
- Synchronous or Alternating?	Alternating	Alternating	Same
- Method of Channel Isolation	By Transformer	By Transformer	Same
Regulated Current or Regulated Voltage?	Current control	Current control	Same
Software/Firmware/Micro processor 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	10~99 min	Similar Note 1
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	Same
Compliance with 21 CFR 898?		Yes	Yes	Same
Weight (grams)		Approx. 106g	Approx.106g	Same
Dimensions (mm) [W x H x D]		140*60*20 mm	140*60*20 mm	Same
Housing Materials & Construction		ABS	ABS	Same
Waveform		Biphasic	Biphasic	Same
Shape		Square	Square	Same
Maximum Output Voltage (volts)		15V±20% @500Ω	15V±20% @500Ω	Same
Maximum Output Current (specify units)		30mA±20% @500Ω	30mA±20% @500Ω	Same
Pulse width (μsec)		75-300μs±20%	75-300μs±20%	Same
Pulse Period (msec)		8.33-1000ms	8.33-1000ms	Same
Max. pulse frequency (Hz) [or Rate (pps)]		1-120Hz±20%	1-120Hz±20%	Same
Net Charge (μC per pulse)		0μC @500Ω(Method: Balanced waveform)	0μC @500Ω(Method: Balanced waveform)	Same
Maximum Phase Charge, (μC)		9μC @500Ω	9μC @500Ω	Same
Maximum Average Current, (mA)		2.16mA @500Ω	2.16mA @500Ω	Same
Maximum Current Density, (mA/cm², r.m.s.)		0.043mA/cm² @500Ω	0.043mA/cm² @500Ω	Same
Maximum Average Power Density, (mW/cm²)		1.30mW/cm² @500Ω	1.30mW/cm² @500Ω	Same
Accessories		Electrodes, cables, adapter	Electrodes, cables, adapter	Same
Comparison in details: **Note 1:** The timer range and number of program 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.				

5. 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:

1) ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021]Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD) [Including Amendment 2 (2021)]

2) ANSI AAMI IEC 60601-1-2:2014 [Including AMD 1:2021]Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests [Including Amendment 1 (2021)]

3) 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.

4) IEC 60601-1-11 Edition 2.1 2020-07 CONSOLIDATED VERSION 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

5) IEC 62133 Edition 2.0 2012-12, IEC 62133 Edition 2.0 2012-12 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 [Including: Corrigendum 1 (2013)]

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.