March 18, 2022

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

Re: K220153
Trade/Device Name: Needle Stimulator (Model: RJNS6-1)
Regulatory Class: Unclassified
Product Code: BWK
Dated: December 31, 2021
Received: January 19, 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)*
K220153

Device Name
Needle Stimulator (Model: RJNS6-1)

Indications for Use *(Describe)*
Needle Stimulator (Model: RJNS6-1) is an electro-acupuncture stimulator device, which is indicated for use in the practice of acupuncture by qualified practitioners of acupuncture as determined by the states.

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:	K220153
Date：	March 17, 2022
Type of 510(k) Submission:	Traditional 510(k)
Basis for 510(k) Submission:	New device
Submitter/Manufacturer:	Bozhou Rongjian Medical Appliance Co.,Ltd. Jianghuai Supply Base, Zhongkai Group, Mengcheng County, Bozhou City, 233500 Anhui, China
Contact:	Wu Zhifang E-mail: rongjianzl@rjmed.com.cn Tel: +86-558-7662968

2. Device Description

Proprietary Name:	Needle Stimulator (Model: RJNS6-1)
Common Name:	Electro-Acupuncture
Product Code:	BWK
Device Class:	Unclassified
Review Panel:	Neurology
Device Description:	Needle Stimulator (Model: RJNS6-1) is an electro-acupuncture device for acupuncture therapy, powered by 6 pieces of 1.5V batteries or AC 100-240V. It is composed of a LCD, a console and 6 channels of electrode cables with alligator type connectors. Only 3 channels at most could work together on single patient. The console has the operating elements of Channel selecting button, Setting button, Operation suspending switch button, Wave-selecting button, On/off switch, Mute button, Therapy time adjusting button, Output frequency adjusting button, Intensity adjust knobs, and Output indicator light. Needle Stimulator (Model: RJNS6-1) does not equip with acupuncture needles. The practitioners should select 510(k) cleared needles (with minimum diameter of 0.40mm and insertion depth of 16mm) for use.
Indications for use:	Needle Stimulator (Model: RJNS6-1) is an electro-acupuncture stimulator device, which is indicated for use in the practice of acupuncture by qualified practitioners of acupuncture as determined by the states.

3. Predicate Device Identification

Predicate 510(k) Number:	K202861
Marketing clearance date:	August 27, 2021
Product name:	Needle Stimulator (Model: CMNS6-2)
Manufacturer:	Wuxi Jiajian Medical Instrument Co., Ltd

4. Substantial Equivalence to Predicate device

Table 1-

Parameters	**New Device**	**Predicate Device**	**Remark**
510(k) Number	K220153	K202861	--
Marketing clearance date	No	August 27, 2021	--
Device Name	Needle Stimulator (Model: RJNS6-1)	Needle Stimulator (Model: CMNS6-2)	--
Manufacturer	Bozhou Rongjian Medical Appliance Co.,Ltd.	Wuxi Jiajian Medical Instrument Co., Ltd	--
Product Code	BWK	BWK	Same
Intended use	Needle Stimulator is an electro-acupuncture stimulator device, which is indicated for use in the practice of acupuncture by qualified practitioners of acupuncture as determined by the states.	Needle Stimulator is an electro-acupuncture stimulator device, which is indicated for use in the practice of acupuncture by qualified practitioners of acupuncture as determined by the states.	Same
Type of use	Prescription use	Prescription use	Same
Power Source(s)	DC l.5Vx6 Type R14/UM2 or AC 100-240V	DC l.5Vx6 Type R14 or AC 100-240V	Similar Note 1
- Method of Line Current Isolation	Type BF	Type BF	Same
- Patient Leakage Current - Normal Condition (μA) - Single Fault Condition (μA)	-- 2μA ≤50μA	-- 2μA ≤50μA	Same
Average DC current through electrodes when device is on but no pulses are being applied (μA)	N/A	N/A	Same
Number of Output Modes	3 (continuous wave/ interrupted wave/ Dense-disperse wave)	3 (continuous wave/ interrupted wave/ Dense-disperse wave)	Same
Number of Output channels:	6 (3 channels at most work together on single patient)	6 (3 channels at most work together on single patient)	Same
- Synchronous or Alternating?	Synchronous	Synchronous	Same
- Method of Channel Isolation	Transformer	Transformer	Same
Regulated Current or Regulated Voltage?	Voltage Control	Voltage Control	Same
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)		1-99min	1-99min	Same
Compliance with Voluntary Standards?		ANSI AAMI ES60601-1, IEC 60601-2-10, IEC 60601-1-2	IEC 60601-1, IEC 60601-2-10, IEC 60601-1-2	Same
Compliance with 21 CFR 898?		Yes	Yes	Same
Weight (grams)		approx. 657g	approx. 657g	Same
Dimensions [W x H x D]		238*184*75mm	238*184*75mm	Same
Housing Materials & Construction		ABS; Injection molded	ABS; Injection molded	Same
Waveform		Biphasic	Biphasic	Same
Shape		Asymmetric biphasie square wave	Asymmetric biphasie square wave	Same
Maximum Output Voltage (volts)		27V±10% @500Ω	27V±10% @500Ω	Same
		60.4V±10% @2kΩ	60.4V±10% @2kΩ	Same
		75V±10% @10kΩ	75V±10% @10kΩ	Same
Maximum Output Current (specify units)		54mA±10% @500Ω	54mA±10% @500Ω	Same
		30.2mA±10% @2kΩ	30.2mA±10% @2kΩ	Same
		7.5mA±10% @10kΩ	7.5mA±10% @10kΩ	Same
Pulse width (μsec)	Positive	175μs±10%	175μs±10%	Same
	Negative	1051μs (6 x (+Phase))	1051μs (6 x (+Phase))	Same
Pulse Period (msec)		10~1000ms	10~1000ms	Same
Max. pulse frequency (Hz) [or Rate (pps)]		1~100Hz±10%	1~100Hz±10%	Same
Net Charge (μC per pulse)		0μC@500Ω, + and – pulses cancel	0μC@500Ω, + and – pulses cancel	Same
Maximum Phase Charge, (μC)		8.225μC @500Ω	8.225μC @500Ω	Same
Maximum Average Current, (mA)		0.945mA @500Ω	0.945mA @500Ω	Same
Maximum Current Density, (mA/cm², r.m.s.)		8.225mA/cm² @500Ω	8.225mA/cm² @500Ω	Same
Maximum Average Power Density, (W/cm²)		0.1234W/cm²@500Ω	0.1234W/cm²@500Ω	
Biocompatibility		ISO10993-5, ISO 10993-10	ISO10993-5, ISO 10993-10	Same
Accessories		Lead wires, Alligator type connectors	Lead wires, Alligator type connectors	Same
Differences between New device and Predicate Device:				

Note 1:

The proposed device can use more battery types than 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.

5. Test summary

Needle Stimulator (Model: RJNS6-1) is as safe and effective as the predicate device cited above. The new device has passed testing according to the following standards:

1) ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD);

2) 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;

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;

6. Conclusion

Based on 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 K202861.