January 5, 2022

Bozhou Rongjian Medical Appliance Co., Ltd.
% Doris Dong
Manager
Shanghai CV Technology Co., Ltd.
Room 903, No.19 Dongbao Road, Songjiang Area
Shanghai, Shanghai 201613
China

Re: K213879
Trade/Device Name: Self-adhesive Electrode
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous Electrode
Regulatory Class: Class II
Product Code: GXY
Dated: November 24, 2021
Received: December 13, 2021

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 (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 Heather Dean, PhD
Assistant Director, Acute Injury Devices Team
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)*
K213879

Device Name
Self-adhesive Electrode

Indications for Use *(Describe)*
The Self-adhesive Electrode is intended to be used to transmit electrical stimulation current to the patient's skin. Example electrical stimulations for current applications of the electrodes are: TENS and EMS.

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:	K213879
Date:	November 24, 2021
Type of 510(k) Submission:	Traditional 510(k)
Manufacturer/Applicant:	Bozhou Rongjian Medical Appliance Co.,Ltd. Jianghuai Supply Base, Zhongkai Group, Mengcheng County, Bozhou City, 233500 Anhui, China Tel: +86-558-7963368 E-mail: rongjianzl@rjmed.com.cn
Contactor:	Doris Dong (Consultant) Shanghai CV Technology Co., Ltd. Rm. 903, No. 19 Dongbao Rd., Songjiang Area, Shanghai, 201613 China E-mail: doris.d@ceve.org.cn Tel: 86 21-31261348

2. Device Description

Proprietary Name:	Self-adhesive Electrode
Common Name:	Cutaneous electrode
Classification Name:	Electrode, cutaneous
Product Code:	GXY
Device Class:	II
Regulation Number:	21 CFR 882.1320
Review Panel:	Neurology
Indications for use:	The Self-adhesive Electrode is intended to be used to transmit electrical stimulation current to the patient's skin. Example electrical stimulations for current applications of the electrodes are: TENS and EMS.
Device Description:	The Self-adhesive electrode, lead wire type and snap button type, are non-sterile flexible structures, composed of materials commonly used in this application: First layer: Non-woven fabric tape Second layer: Polyurethane (PU) electrically conductive carbon cloth (Hebei Kangshengda Electronic Technology Co., Ltd) Third layer: Biocompatible conductive hydrogel coupling media (ValueTrode Carbon, K970426), which has passed the required skin sensitivity testing criteria as specified in ISO 10993-10 and cytotoxicity testing criteria as specified in ISO 10993-5. The electrodes are designed for single patient / multiple application use. It can be used for low-frequency or medium-frequency nerve or muscle stimulators, as the conduction film adhered to body skin.

There are six shapes of round, rectangle, elliptical, calabash, butterfly and palm shape. For the electrical connection, Rongjian provides lead wire type and snap button type:

Lead wire assembly - at least 40mm long wire with 2mm/2.5mm diameter female socket.

Snap button assembly - with 2.5~5mm diameter male socket.

The lead wire assembly is in compliance with the requirements of FDA performance standard 21 CFR part 898 by testing under ANSI/AAMI ES60601-1, subclause 8.5.2.3.

3. Predicate Device Identification

K090198 - JIAJIAN Self-adhesive Electrode

4. Non-Clinical Test Conclusion

Bench tests were conducted on Self-adhesive Electrode 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:

• ASTM F1980-16, Standard guide for accelerated aging of sterile barrier systems for medical devices. (Sterility)

• ISO 10993-5 Third edition 2009-06-01 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity.

• ISO 10993-10 Third Edition 2010-08-01, Biological evaluation of medical devices - Part 10: Tests for Irritation and Skin Sensitization.

• AAMI / ANSI 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).

• Impedance test, Conformability test and Fluid tolerance test per 201.15.101.6 and 201.15.101.7 of IEC 60601-2-2 Edition 6.0 2017-03.

• Impedance Test (Dispersion Test) according to FDA's requirement.

• Peeling force test and Simulation use test according to manufacturer's requirement.

5. Substantial Equivalent Based on Assessment of Clinical Performance Data

Clinical data was not including in this submission

6. Substantially Equivalent Comparison Conclusion

Parameters		New Device		Predicate Device		Remark
1	510(k) Number	To be assigned		K090198		--
2	510(k) Holder	Bozhou Rongjian Medical Appliance Co.,Ltd.		Wuxi Jiajian Medical Instrument Co., Ltd		--
3	Trade Name	Self-adhesive Electrode		Jiajian Self- adhesive Electrode		--
4	Common Name	Cutaneous electrode		Cutaneous electrode		Same
5	Classification Name	Electrode, cutaneous		Electrode, cutaneous		Same
6	Product Code	GXY		GXY		Same
7	Regulation Number	882.1320		882.1320		Same
8	Medical Specialty	Neurology		Neurology		Same
9	Device Class	II		II		Same
10	Indications for use	The Self-adhesive Electrode is intended to be used to transmit electrical stimulation current to the patient's skin. Example electrical stimulations for current applications of the electrodes are: TENS and EMS.		The self-adhesive electrode is intended to be used to apply electrical stimulation current to the patient's skin. Example electrical stimulations for current applications of the electrodes are: TENS and EMS.		Same
11	Target population	Single patient use and multiple application		Single patient use and multiple application		Same
12	Type of use	OTC and Prescription use		OTC and Prescription use		Same
13	Design (shape & connection)	Round, Rectangle, Elliptical, Calabash, Butterfly, Palm shape according to customized specification. Lead wire with female socket, or snap button with male snap connector.		Round, Rectangle, Oval, Gourd, Butterfly, Saddle according to customized specification. Lead wire with female socket.		Similar
14	Materials	- Non-woven fabric tape - Polyurethane (PU) electrically conductive carbon cloth (Hebei Kangshengda Electronic Technology Co., Ltd) - Biocompatible conductive hydrogel coupling media (ValueTrode Carbon, K970426)		- Non-woven fabric tape - Electrically conductive carbon cloth (ValueTrode Carbon, K970426) - Biocompatible conductive hydrogel coupling media (ValueTrode Carbon, K970426)		Similar
15	Electrode Pad Size	Round	Min.Ø20mm; Max.Ø85mm	Round	Min.Ø20mm; Max.Ø80mm	Similar
		Rectangle	Min.26×26mm; Max.190×110mm	Rectangle	Min.3×10mm; Max.80×130mm	
		Elliptical	Min.85×45mm;	Oval	Min.50×120mm;	

			Max.240×100mm		Max.100×240mm	
		Calabash	Min.90×47mm; Max.200×88mm	Gourd	Min.85×50mm; Max.170×100mm	
		Butterfly	Min.73×53mm; Max.195×95mm	Butterfly	Min.55×75mm; Max.95×165mm	
		Palm shape	74×47mm	Saddle	Min.75×110mm; Max.150×220mm	
16	Electrode Impedance of Electrode Pad	Round	302~577Ω	Round	290~1000Ω	Similar
		Rectangle	303~646Ω	Rectangle		
		Elliptical	407~676Ω	Oval		
		Calabash	401~602Ω	Gourd		
		Butterfly	402~626Ω	Butterfly		
		Palm shape	402~638Ω	Saddle		
17	--Patient contact area of electrode	Round	Min.3.14cm^2; Max.56.716cm^2	Round	Min.3.14cm^2; Max.50.24cm^2	Similar
		Rectangle	Min.6.76cm^2; Max.209cm^2	Rectangle	Min.0.3cm^2; Max.104cm^2	
		Elliptical	Min.38.25cm^2; Max.240cm^2	Oval	Min.60cm^2; Max.240cm^2	
		Calabash	Min.42.3cm^2; Max.176cm^2	Gourd	Min.42.5cm^2; Max.170cm^2	
		Butterfly	Min.38.69cm^2; Max.185.25cm^2	Butterfly	Min.41.25cm^2; Max.156.75cm^2	
		Palm shape	34.78cm^2	Saddle	Min.82.5cm^2; Max.330cm^2	
18	Max. current Density of Electrode (Use I_{RMS}=10mA for calculation)	Round	3.18mA/cm^2 (Ø20mm: 3.14cm^2)	Round	3.18mA/cm^2 (Ø20mm: 3.14cm^2)	Similar
		Rectangle	1.48mA/cm^2 (26×26mm: 6.76cm^2)	Rectangle	33.3mA/cm^2 (3×10mm: 0.3cm^2)	
		Elliptical	0.52mA/cm^2 (85×45mm/2: 19.13cm^2)	Oval	0.17mA/cm^2 (50×120mm: 60cm^2)	
		Calabash	0.24mA/cm^2 (90×47mm: 42.3cm^2)	Gourd	0.24mA/cm^2 (85×50mm: 42.5cm^2)	
		Butterfly	0.52mA/cm^2 (73×53mm/2: 19.35cm^2)	Butterfly	0.48mA/cm^2 (55×75mm/2: 20.625cm^2)	
		Palm shape	0.29mA/cm^2 (74×47mm: 34.78cm^2)	Saddle	0.24mA/cm^2 (75×110mm/2: 41.25cm^2)	
19	Hydrogel	35mils ± 5mils (0.89mm ±		35mils ± 5mils (0.89mm ±		Same

	thickness	0.13mm)	0.13mm)	
20	Hydrogel pH	4.2 ± 1.0	4.2 ± 1.0	Same
21	Hydrogel volume resistivity	1500 ohm-cm max	1500 ohm-cm max	Same
22	Standards meet	• Lead wires test per 8.5.2.3 of AAMI/ANSI ES 60601-1; • Impedance test, Conformability test and Fluid tolerance test per 201.15.101.6 and 201.15.101.7 of ANSI AAMI IEC 60601-2-2 Edition 6.0 2017-03; • Impedance Test (Dispersion Test) according to FDA's requirement; • Peeling force test and Simulation use test according to manufacturer's requirement; • Shelf life test per ASTM F1980:2016	ISO14971; ISO 13485; EN 980; ANSI/AAMI EC12; IEC 60601-1.	Similar
23	Biocompatibility	ISO10993-5; ISO10993-10	ISO10993-5; ISO10993-10	Same
24	Sterility Status	Non-sterile	Non-sterile	Same
25	Electrical safety	Lead wire meets Clause 8.5.2.3 of AAMI/ANSI ES60601-1	Lead wire meets IEC 60601-1	Same
26	Other Performance	Good electrical conductivity, good adhesive property	Good electrical conductivity, good adhesive property	Same

7. Conclusions

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 devices identified in the submission. Thus the subject device is substantially equivalent to the predicate device K090198.