February 3, 2021

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

Re: K192568
Trade/Device Name: Jaijian Self-Adhesive Electrode
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous Electrode
Regulatory Class: Class II
Product Code: GXY
Dated: January 4, 2021
Received: January 7, 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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192568

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:	K192568
Date:	December 31, 2020
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) 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:	Cutaneous electrode
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 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 nine shapes of round, rectangle, elliptical, calabash, butterfly, saddle shape, rhombus, meniscus shape and palm shape. For the electrical connection, Jiajian 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:

• 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 IEC 60601-2-2:2009;
• Impedance Test (Dispersion Test) per FDA's requirement;
• Peel strength test according to manufacturer's requirement;
• Shelf life test per ASTM F1980:2016
• Reuse test per FDA's requirement.
• Biocompatibility testing according to ISO 10993-5:2009 and ISO 10993-10:2010.

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	K192568	K090198	--
2	510(k) Holder	Wuxi Jiajian Medical Instrument Co., Ltd	Wuxi Jiajian Medical Instrument Co., Ltd	Same
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, Saddle shape, Rhombus, Meniscus shape, 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 Note 1
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 Note 2

15	Electrode Pad Size	Round	Min.Ø20mm; Max.Ø85mm	Round	Min.Ø20mm; Max.Ø80mm	Similar Note 1
		Rectangle	Min.26×26mm; Max.190×110mm	Rectangle	Min.3×10mm; Max.80×130mm	
		Elliptical	Min.85×45mm; Max.240×100mm	Oval	Min.50×120mm; 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	
		Saddle shape	Min.82×35mm; Max.150×220mm	Saddle	Min.75×110mm; Max.150×220mm	
		Rhombus	Min.136×66mm; Max.200×88mm			
		Meniscus shape	Min.115×40mm; Max.200×88mm			
		Palm shape	74×47mm			
16	Electrode Impedance of Electrode Pad	Round	302~577Ω	Round	290~1000Ω	Similar Note 3
		Rectangle	303~646Ω	Rectangle		
		Elliptical	407~676Ω	Oval		
		Calabash	401~602Ω	Gourd		
		Butterfly	402~626Ω	Butterfly		
		Saddle shape	401~642Ω	Saddle		
		Rhombus	401~648Ω			
		Meniscus shape	403~655Ω			
		Palm shape	402~638Ω			
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 Note 3
		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	
		Saddle shape	Min.14.35cm^2; Max.330cm^2	Saddle	Min.82.5cm^2; Max.330cm^2	
		Rhombus	Min.89.76cm^2; Max.176cm^2			
		Meniscus shape	Min.46cm^2; Max.176cm^2			

		Palm shape	34.78cm^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 Note 3
		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)	
		Saddle shape	0.70mA/cm^2 (82×35mm/2: 14.35cm^2)	Saddle	0.24mA/cm^2 (75×110mm/2: 41.25cm^2)	
		Rhombus	0.11mA/cm^2 (136×66mm: 89.76cm^2)			
		Meniscus shape	0.22mA/cm^2 (115×40mm: 46cm^2)			
		Palm shape	0.29mA/cm^2 (74×47mm: 34.78cm^2)			
19	Hydrogel thickness	35mils ± 5mils (0.89mm ± 0.13mm)		35mils ± 5mils (0.89mm ± 0.13mm)		Same
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 60601-2-2:2009; • Impedance Test (Dispersion Test) per FDA's requirement; • Peel strength test according to manufacturer's requirement; • Shelf life test per ASTM F1980:2016 • Reuse test per FDA's requirement.		ISO14971; ISO 13485; EN 980; ANSI/AAMI EC12; IEC 60601-1.		Similar Note 4
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

Differences between proposed device and predicate device, reference device:

Note 1:

The proposed device has two connection methods: lead wire type and snap button type, while the predicate device only has one lead wire type. The proposed device adds more electrodes of various shapes and sizes than the predicate device.

- Regarding the differences in connection method: Both lead wire type electrodes and snap button type electrodes have passed performance tests.
- Regarding the differences in shape: All shapes of electrodes have passed performance tests.
- Regarding the differences in size: We have selected the maximum and minimum size electrodes of each shape to carry out the performance tests, and all have passed the tests.

In addition, all test samples were drawn from three non-consecutive batches, with 3 samples for each specification. Therefore, these differences will not cause any safety and effectiveness issues.

Note 2:

The conductive carbon cloth of the proposed device is different from the predicate device. The final entire electrodes manufactured have passed biocompatibility tests. So, this difference will not cause any safety and effectiveness issues.

Note 3:

The patient contact area of the proposed device is different from the predicate device. Based on analysis of the maximum current density calculation results, this difference will not cause any safety and effectiveness issues.

The maximum current density of the proposed device is different from the predicate device. According to the calculation results, the maximum current density of all electrodes except for the round shapes does not exceed 2mA/cm^2 (refer to IEC 60601-2-10). The maximum current density of the round electrode of the proposed device is consistent with that of the predicate device. And we have added relevant warning information (warning item 6 & item 11) and warning symbol (see label) in the user manual. Therefore, these differences will not cause any safety and effectiveness issues.

The impedance of the proposed device is between 302~676Ω, within the range of 290~1000Ω of the predicate device. And the impedance on each electrode is well-distribution. Therefore, these differences will not cause any safety and effectiveness issues.

Note 4:

The proposed device has performed more performance tests than the predicate device, including peeling force testing, current distribution testing, accelerated aging testing and simulated use testing etc. All tests comply with the requirements of the FDA. And the test results show that the proposed device can meet the intended requirements. Therefore, these differences will not cause any safety and effectiveness issues.

The Conclusions:

Based on the successful electrode current distribution test results, adhesive performance test results, Self-adhesive Electrode is safe and effective when used as an interface between a user's skin and an approved nerve and muscle stimulation device. 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.