August 27, 2021

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

Re: K202861
Trade/Device Name: Needle Stimulator
Regulatory Class: Unclassified
Product Code: BWK
Dated: August 9, 2021
Received: August 13, 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,

Jitendra V. Virani -S

For 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)*
K202861

Device Name
Needle Stimulator

Indications for Use *(Describe)*
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.

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:	K202861
Date:	April 1st, 2021
Type of 510(k) Submission:	Traditional
Basis for 510(k) Submission:	Modified device
Submitter/Manufacturer:	Wuxi Jiajian Medical Instrument Co., Ltd No. 35 Baiqiao Rd., Ehu Town, Xishan District, Wuxi, Jiangsu, China 214116
Contact:	Doris Dong [Consultant, from Shanghai CV Technology Co., Ltd.] Add: Room 903, No. 19 Dongbao Road, Songjiang Area, Shanghai, 201613 China E-mail: doris.d@ceve.org.cn Tel: 86 21-31261348 / Fax: 86 21-57712250

2. Device Description:

Proprietary Name:	Needle Stimulator
Model:	CMNS6-1, CMNS6-2
Common Name:	Electro-Acupuncture
Product Code:	BWK
Device Class:	Unclassified
Review Panel: Device	Neurology
Description:	Needle Stimulator 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 console and 6 channels of electrode cables with alligator type connectors. The console has the operating controls including function knobs or buttons. Needle Stimulator does not equip with acupuncture needles. The practitioners should select legally marketed needles.
Indications for 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.

3. Substantial Equivalence to Predicate device:

Detailed comparison data is included in “Section 10.1 - Substantial Equivalence Discussion” of this 510(k) submission.

Table 1-

Parameters		**Modified Device**	**Predicate Device**	**Remark**
1	510(k) Number:	K202861	K130768	--
2	Marketing clearance date:	No	August 16, 2013	--
3	Device Name	Needle Stimulator	Jiajian® CMN Stimulator	--
4	Model	CMNS6-1	/	--

5	Manufacturer	Wuxi Jiajian Medical Instrument Co.,Ltd	Wuxi Jiajian Medical Instrument Co.,Ltd	Same
6	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.	Jiajian® CMN 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
7	Type of use	Prescription use	Prescription use	Same
8	Power Source(s)	DC 1.5Vx6 Type R14 or AC 100-240V	DC 1.5Vx6 Type R14	Same 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
9	Average DC current through electrodes when device is on but no pulses are being applied (μA)	N/A	N/A	Same
10	Number of Output Modes	3 (continuous wave/ interrupted wave/ Dense-disperse wave)	3 (continuous wave/ interrupted wave/ Dense-disperse wave)	Same
11	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
12	Regulated Current or Regulated Voltage?	Voltage Control	Voltage Control	Same
13	Software/Firmware/Microprocessor Control?	Yes	Yes	Same
14	Automatic Overload Trip?	No	No	Same
15	Automatic No-Load Trip?	No	No	Same
16	Automatic Shut Off?	Yes	Yes	Same
17	User Override	Yes	Yes	Same

	Control?				
18	Indicator Display:	On/Off Status?	Yes	Yes	Same
		Low Battery?	Yes	Yes	Same
		Voltage/Current Level?	Yes	Yes	Same
19	Timer Range (minutes)		0-60min	0-60min	Same
20	Compliance with Voluntary Standards?		IEC 60601-1, IEC 60601-2-10, IEC 60601-1-2	IEC 60601-1, IEC 60601-2-10, IEC 60601-1-2	Same
21	Compliance with 21 CFR 898?		Yes	Yes	Same
22	Weight (grams)		740g	740g	Same
23	Dimensions [W x H x D]		230*155*55mm	230*155*55mm	Same
24	Housing Materials & Construction		ABS; Injection molded	ABS; Injection molded	Same
25	Waveform		Biphasic	Biphasic	Same
26	Shape		Asymmetric biphasie square wave	Asymmetric biphasie square wave	Same
27	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
28	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
29	Pulse width (μsec)	Positive	200μs±10%	200μs±10%	Same
		Negative	1030μs (5.15 x (+Phase))	1030μs (5.15 x (+Phase))	Same
30	Pulse Period (msec)		10~1000ms	10~1000ms	Same
31	Max. pulse frequency (Hz) [or Rate (pps)]		1~100Hz±10%	1~100Hz±10%	Same
32	Net Charge (μC per pulse)		0μC@500Ω, + and – pulses cancel	0μC@500Ω, + and – pulses cancel	Same
33	Maximum Phase Charge, (μC)		9.4μC @500Ω	9.4μC @500Ω	Same
34	Maximum Average Current, (mA)		1.08mA @500Ω	1.08mA @500Ω	Same
35	Maximum Current Density, (mA/cm², r.m.s.)		9.4mA/cm² @500Ω	13.3mA/cm² @500Ω	Same Note 2
36	Maximum Average		0.141W/cm²@500Ω	0.2W/cm²@500Ω	

	Power Density, (W/cm^2)			
37	Biocompatibility	ISO10993-5, ISO 10993-10	ISO10993-5, ISO 10993-10	Same
38	Accessories	Lead wires, Alligator type connectors	Lead wires, Alligator type connectors	Same
Note 1: Compared with the predicate device, the proposed device can be connected to AC power. Both of the AC power and DC power of the proposed device have passed IEC 60601-1 and EMC tests, and the description of AC power supply has been added to user manual. Therefore, this difference doesn't raise any safety and effectiveness issues. **Note 2:** The maximum current density and maximum power density are different between the proposed device and the predicate device because they are calculated by different needle surface areas. After calculation, both of them are within the safety limit. Therefore, this difference doesn't raise any safety and effectiveness issues.				

Detailed comparison data is included in "Section 10.2 - Substantial Equivalence Discussion" of this 510(k) submission.

Table 2-

Parameters		**Modified Device**	**Predicate Device**	**Remark**
1	510(k) Number:	K202861	K130768	--
2	Marketing clearance date:	No	August 16, 2013	--
3	Device Name	Needle Stimulator	Jiajian® CMN Stimulator	--
4	Model	CMNS6-2	/	--
5	Manufacturer	Wuxi Jiajian Medical Instrument Co.,Ltd	Wuxi Jiajian Medical Instrument Co.,Ltd	Same
6	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.	Jiajian® CMN 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
7	Type of use	Prescription use	Prescription use	Same
8	Power Source(s)	DC 1.5Vx6 Type R14 or AC 100-240V	DC 1.5Vx6 Type R14	Same 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
9	Average DC current	N/A	N/A	Same

	through electrodes when device is on but no pulses are being applied (μA)				
10	Number of Output Modes		3 (continuous wave/ interrupted wave/ Dense-disperse wave)	3 (continuous wave/ interrupted wave/ Dense-disperse wave)	Same
11	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
12	Regulated Current or Regulated Voltage?		Voltage Control	Voltage Control	Same
13	Software/Firmware/Microprocessor Control?		Yes	Yes	Same
14	Automatic Overload Trip?		No	No	Same
15	Automatic No-Load Trip?		No	No	Same
16	Automatic Shut Off?		Yes	Yes	Same
17	User Override Control?		Yes	Yes	Same
18	Indicator Display:	On/Off Status?	Yes	Yes	Same
		Low Battery?	Yes	Yes	Same
		Voltage/Current Level?	Yes	Yes	Same
19	Timer Range (minutes)		1-99min	0-60min	Same Note 2
20	Compliance with Voluntary Standards?		IEC 60601-1, IEC 60601-1-10, IEC 60601-1-2	IEC 60601-1, IEC 60601-1-10, IEC 60601-1-2	Same
21	Compliance with 21 CFR 898?		Yes	Yes	Same
22	Weight (grams)		approx. 657g	740g	Same Note 2
23	Dimensions [W x H x D]		238*184*75mm	230*155*55mm	
24	Housing Materials & Construction		ABS; Injection molded	ABS; Injection molded	Same
25	Waveform		Biphasic	Biphasic	Same
26	Shape		Asymmetric biphasie square	Asymmetric biphasie square	Same

			wave	wave	
27	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
28	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
29	Pulse width (μsec)	Positive	175μs±10%	200μs±10%	Same
		Negative	1051μs (6 x (+Phase))	1030μs (5.15 x (+Phase))	Note 3
30	Pulse Period (msec)		10~1000ms	10~1000ms	Same
31	Max. pulse frequency (Hz) [or Rate (pps)]		1~100Hz±10%	1~100Hz±10%	Same
32	Net Charge (μC per pulse)		0μC@500Ω, + and – pulses cancel	0μC@500Ω, + and – pulses cancel	Same
33	Maximum Phase Charge, (μC)		8.225μC @500Ω	9.4μC @500Ω	Same Note 4
34	Maximum Average Current, (mA)		0.945mA @500Ω	1.08mA @500Ω	
35	Maximum Current Density, (mA/cm², r.m.s.)		8.225mA/cm² @500Ω	13.3mA/cm² @500Ω	
36	Maximum Average Power Density, (W/cm²)		0.1234W/cm²@500Ω	0.2W/cm²@500Ω	
37	Biocompatibility		ISO10993-5, ISO 10993-10	ISO10993-5, ISO 10993-10	Same
38	Accessories		Lead wires, Alligator type connectors	Lead wires, Alligator type connectors	Same

Note 1:

Compared with the predicate device, the proposed device can be connected to AC power. Both of the AC power and DC power of the proposed device have passed IEC 60601-1 and EMC tests, and the description of AC power supply has been added to user manual. Therefore, this difference doesn't raise any safety and effectiveness issues.

Note 2:

The weight, dimensions and appearance of the proposed device are a little different from the predicate device K130768, but these differences are insignificant in the terms of safety or effectiveness. Besides, there is a difference in treatment time range between the proposed device and predicate device. The treatment time can be adjusted by user as they want. So, the difference of treatment time range will not raise any safety or effectiveness issue.

Note 3:

There is a difference in the pulse width between the proposed device and predicate device. Based on the calculation of maximum current density, maximum power density, these parameters don't exceed the safety limit. All deviation and the worst case have been considered in risk analysis report, and all parameters have passed IEC 60601-2-10 test codes. So, the difference doesn't raise any new safety and effectiveness issues.

Note 4:

The Maximum Phase Charge of the proposed device are similar to the predicate device, and both of them comply with IEC 60601-1 and IEC 60601-2-10 requirements. So, the differences will not raise any safety or effectiveness issue.The maximum average current of the proposed device is smaller than that of the predicate device which means the better safety. The maximum current density and maximum power density are different between the proposed device and the predicate device because they are calculated by different needle surface areas. After calculation, both of them are within the safety limit. Therefore, this difference doesn't raise any safety and effectiveness issues.

4. Test summary:

Needle Stimulator is safe and effective as the predicate devices cited above. The new devices have passed testings 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;

The conclusion drawn from the testings are that the new devices are substantially equivalent to the predicate device. Furthermore, the new device complies with the recognized standards and performs its intended tasks as well as the legally marketed predicate device.