March 28, 2025

Wuxi Jiajian Medical Instrument Co., Ltd.
% Doris Dong
Official Correspondent
Shanghai CV Technology Co., Ltd.
Room 805, No.19 Dongbao Road, Songjiang Area
Shanghai, Shanghai 201613
China

Re: K244030
Trade/Device Name: Needle Stimulator (CMNS6-1 PLUS, CMNS6-3)
Regulatory Class: Unclassified
Product Code: BWK
Dated: December 2, 2024
Received: December 30, 2024

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,

Amber T. Ballard -S

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)*
K244030

Device Name
Needle Stimulator (CMNS6-1 PLUS, CMNS6-3)

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:	K244030
Date:	March 24, 2025
Type of 510(k) Submission:	Traditional
Basis for 510(k) Submission:	New 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 805, 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 PLUS, CMNS6-3
Common Name:	Electro-Acupuncture
Classification Name:	Stimulator, Electro-Acupuncture
Product Code:	BWK
Device Class:	Unclassified
Review Panel:	Neurology
Device 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. Predicate Device Identification

Predicate 510(k) Number:	K202861
Marketing Clearance Date:	08/27/2021
Product Name:	Needle Stimulator
Manufacturer:	Wuxi Jiajian Medical Instrument Co., Ltd

4. Substantial Equivalence to Predicate device:

Detailed comparison data is included in “Substantial Equivalence Discussion - CMNS6-1 PLUS” of this 510(k) submission.

Table 1-

Parameters		Subject Device	Predicate Device	Remark
1	510(k) Number:	K244030	K202861	--
2	Marketing clearance date:	--	08/27/2021	--
3	Device Name	Needle Stimulator	Needle Stimulator	--
4	Model	CMNS6-1 PLUS	CMNS6-1	--
5	Manufacturer	Wuxi Jiajian Medical Instrument Co.,Ltd	Wuxi Jiajian Medical Instrument Co.,Ltd	Same
6	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.	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
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 or AC 100-240V	Same
	- 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?		Yes	No	Similar Note 1
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?	No	Yes	Similar Note 1
		Voltage/ Current Level?	No	Yes	
19	Timer Range (minutes)		1-60min	0-60min	Similar Note 3
20	Compliance with Voluntary Standards?		IEC 60601-1,IEC 60601-1-2	IEC 60601-1, IEC 60601-2-10, IEC 60601-1-2	Similar Note 2
21	Compliance with 21 CFR 898?		Yes	Yes	Same
22	Weight (grams)		740g	740g	Same
23	Dimensions [W x H x D]		234*160*76mm	230*155*55mm	Similar Note 3
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)		35V±20%@500Ω	27V±10% @500Ω	Similar Note 4
			60.4V±20%@2kΩ	60.4V±10% @2kΩ	
			75V±20%@10kΩ	75V±10% @10kΩ	
28	Maximum Output Current (specify units)		70mA±20%@500Ω	54mA±10% @500Ω	
			30.2mA±20%@2kΩ	30.2mA±10% @2kΩ	
			7.5mA±20%@10kΩ	7.5mA±10% @10kΩ	
29	Pulse width (μsec)	Positive	175μs±20%	200μs±10%	
		Negative	1051μs (6 x (+Phase))	1030μs (5.15 x (+Phase))	
30	Pulse Period (msec)		10~1000ms	10~1000ms	Same
31	Max. pulse frequency (Hz) [or		1~100Hz±20%	1~100Hz±10%	Similar Note 4

	Rate (pps)]			
32	Net Charge (μC per pulse)	0μC@500Ω, + and – pulses cancel	0μC@500Ω, + and – pulses cancel	Same
33	Maximum Phase Charge, (μC)	8.6μC @500Ω	9.4μC @500Ω	Similar Note 5
34	Maximum Average Current, (mA)	1.17mA @500Ω	1.08mA @500Ω	
35	Maximum Current Density, (mA/cm², r.m.s.)	8.6mA/cm² @500Ω	9.4mA/cm² @500Ω	
36	Maximum Average Power Density, (W/cm²)	0.135W/cm²@500Ω	0.141W/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:
The proposed device's average DC current at overload, low battery and voltage/current level are different from those of the primary predicate device. As the proposed device and the predicate device adopt the same fundamental output technology and similar treatment effect, therefore, the proposed device is considered to be substantially equivalent. Also, the proposed device had passed AAMI / ANSI ES60601-1 and IEC 60601-1-2 tests, so these differences will not raise any new safety and effectiveness issues.

Note 2:
The IEC 60601-2-10 for testing of predicate device is specific to neuromuscular stimulation, and the BWK product code does not appear in the FDA's testing standards, so we do not believe that this test is required for the proposed device.

Note 3:
The dimensions and appearance 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.

Note 4:
There are some differences in the maximum output voltage, maximum output current, pulse width, pulse period and frequency between the proposed device and the predicate device. Based on the calculation of maximum current density, maximum average power density, these parameters don't exceed the safety limit. Also, the worst cases have been considered in risk analysis report. Therefore, these differences do not raise new questions of safety and effectiveness.

Note 5:
The net charge, maximum phase charge, maximum average current, maximum current density, maximum average power density have some differences between the proposed device and the predicate device. The differences are minor and do not raise new questions of safety and effectiveness.

Detailed comparison data is included in “Substantial Equivalence Discussion - CMNS6-3” of this 510(k) submission.

Table 2-

Parameters		Modified Device	Predicate Device	Remark
1	510(k) Number:	K244030	K202861	--
2	Marketing clearance date:	--	08/27/2021	--
3	Device Name	Needle Stimulator	Needle Stimulator	--
4	Model	CMNS6-3	CMNS6-2	--
5	Manufacturer	Wuxi Jiajian Medical Instrument Co.,Ltd	Wuxi Jiajian Medical Instrument Co.,Ltd	Same
6	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.	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
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 or AC 100-240V	Same
	- 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?		Yes	No	Similar Note 1
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?	No	Yes	Similar Note 1
		Voltage/ Current Level?	Yes	Yes	Same
19	Timer Range (minutes)		1-100min	1-99min	Similar Note 3
20	Compliance with Voluntary Standards?		IEC 60601-1, IEC 60601-1-2	IEC 60601-1, IEC 60601-2-10, IEC 60601-1-2	Similar Note 2
21	Compliance with 21 CFR 898?		Yes	Yes	Same
22	Weight (grams)		740g	approx. 657g	Similar Note 3
23	Dimensions [W x H x D]		234*160*76mm	238*184*75mm	
24	Housing Materials & Construction		ABS; Injection molded	ABS; Injection molded	Same
25	Waveform		Biphasic	Biphasic	Same
26	Shape		Asymmetric, square wave	Asymmetric, square wave	Same
27	Maximum Output Voltage (volts)		35V±20%@500Ω	27V±10% @500Ω	Similar Note 4
			60.4V±20%@2kΩ	60.4V±10% @2kΩ	
			75V±20%@10kΩ	75V±10% @10kΩ	
28	Maximum Output Current (specify units)		70mA±20%@500Ω	54mA±10% @500Ω	
			30.2mA±20%@2kΩ	30.2mA±10% @2kΩ	
			7.5mA±20%@10kΩ	7.5mA±10% @10kΩ	
29	Pulse width (μsec)	Positive	175μs±20%	175μs±10%	
		Negative	1051μs (6 x (+Phase))	1051μs (6 x (+Phase))	

30	Pulse Period (msec)	10~1000ms	10~1000ms	Same
31	Max. pulse frequency (Hz) [or Rate (pps)]	1~100Hz±20%	1~100Hz±10%	Similar Note 4
32	Net Charge (μC per pulse)	0μC@500Ω, + and – pulses cancel	0μC@500Ω, + and – pulses cancel	Same
33	Maximum Phase Charge, (μC)	8.6μC @500Ω	8.225μC @500Ω	Similar Note 5
34	Maximum Average Current, (mA)	1.17mA @500Ω	0.945mA @500Ω	
35	Maximum Current Density, (mA/cm², r.m.s.)	8.6mA/cm² @500Ω	8.225mA/cm² @500Ω	
36	Maximum Average Power Density, (W/cm²)	0.135W/cm²@500Ω	0.1234W/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:

The proposed device's average DC current at no load and voltage/current level are different from those of the primary predicate device. As the proposed device and the predicate device adopt the same fundamental output technology and similar treatment effect, therefore, the proposed device is considered to be substantially equivalent. Also, the proposed device had passed AAMI / ANSI ES60601-1 and IEC 60601-1-2 tests, so these differences will not raise any new safety and effectiveness issues.

Note 2:

The IEC 60601-2-10 for testing of predicate device is specific to neuromuscular stimulation, and the BWK product code does not appear in the FDA's testing standards, so we do not believe that this test is required for the proposed device.

Note 3:

The time range, weight, dimensions and appearance 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 thesed ifferences are insignificant in terms of safety or effectiveness.

Note 4:
There are some differences in the maximum output voltage, maximum output current, pulse width, pulse ~~period,~~ and frequency between the proposed device and the predicate device. Based on the calculation of maximum current density, maximum average power density, these parameters don't exceed the safety limit. Also, the worst cases have been considered in risk analysis report. Therefore, these differences do not raise new questions of safety and effectiveness.

Note 5:
The net charge, maximum phase charge, maximum average current, maximum current density, maximum ~~average~~ power density have some differences between the proposed device and the predicate device. The differences are minor and do not raise new questions of safety and effectiveness.

5. Test summary:

Needle Stimulator is safe and effective as the predicate device cited above. The new devices have passed testings according to the following standards:

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) IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard:
Electromagnetic disturbances - Requirements and tests;
3) IEC TS 60601-4-2 Edition 1.0 2024-03 Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems

6. Clinical Test

Clinical data were not included in this submission.

7. Conclusion

The conclusion drawn from the non-clinical tests demonstrates that the device performs as intended and is as safe, and effective as the legally marketed device identified in the submission. Thus, the subject device is substantially equivalent to the predicate device.