October 22, 2026

Suzhou Medical Appliance Factory
% Boyle Wang
General Manager
ABMED MEDICAL TECHNOLOGY PTY, Ltd.
48/6 Herbert St.
St Leonards, NSW 2065
Australia

Re: K260230
Trade/Device Name: Needle Stimulator (SDZ-IIB, SDZ-IIC, SDZ-III, SDZ-V)
Regulatory Class: Unclassified
Product Code: BWK
Dated: September 22, 2026
Received: September 22, 2026

Dear Boyle Wang:

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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
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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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K260230

Device Name

Needle Stimulator (SDZ-IIB, SDZ-IIC, SDZ-III, SDZ-V)

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

K260230

In accordance with 21 C.F.R. §807.92(a) the following summary of information is provided:

1.0 Submitter's Information

Name: Suzhou Medical Appliance Factory.
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Tel: +86- 18451500721
Contact: Ms. Yang Zi

Designated Submission Correspondent

Contact: Mr. Boyle Wang
Company Name: ABMED MEDICAL TECHNOLOGY PTY LTD.
Address: 48/6 Herbert Street, St Leonards NSW 2065, Australia
Telephone: + 61 432 758 222
Email: info@abmed.com.au

Date Prepared: October 16, 2026

2.0 Device Information

Trade name: Needle Stimulator(Model: SDZ-IIB, SDZ-IIC, SDZ-III, SDZ-V)
Common name: Electro-Acupuncture
Classification name: Stimulator, electro-acupuncture
Product code: BWK
Device Class: Unclassified
Panel: Neurology

3.0 Predicate Device Information

Manufacturer: Wuxi Jiajian Medical Instrument Co., Ltd.
Trade/Device Name: Needle Stimulator (Model: CMNS6-1)
510(k) number: K202861

4.0 Device Description

The Needle Stimulator is a family of electro-acupuncture stimulation devices

comprising models SDZ-IIB, SDZ-IIC, SDZ-III, and SDZ-V. The devices deliver controlled low-frequency electrical pulses to acupuncture needles through lead wires and alligator-type connectors. All four models share the same intended use and fundamental operating principle, with differences in output channel configuration, user interface, and stimulation sequence timing.

Each device consists of a main console, lead wires, alligator-type connectors, and a power adapter. The console incorporates stimulation control circuitry and software that allows the practitioner to adjust the stimulation mode, pulse frequency, treatment duration, and output intensity. The housing is made of acrylonitrile butadiene styrene (ABS).

The principal model differences are summarized below:

Feature	**SDZ-IIB**	**SDZ-IIC**	**SDZ-III**	**SDZ-V**
Number of output channels	2	6	6	6
Display	LCD	No LCD	LCD	LCD
Mode adjustment	Buttons	Buttons	Rotary control	Buttons
Frequency/Treatment time/ Output intensity adjustment	Buttons	Rotary controls	Rotary controls	Buttons
Interrupted mode timing	15 seconds on / 5 seconds off	15 seconds on / 5 seconds off	15 seconds on / 5 seconds off	9 seconds on / 5 seconds off
Dense-disperse mode timing	5 seconds disperse / 10 seconds dense	5 seconds disperse / 10 seconds dense	5 seconds disperse / 10 seconds dense	5 seconds disperse / 9 seconds dense

SDZ-IIB permits simultaneous operation of up to two channels on a single patient. SDZ-IIC, SDZ-III, and SDZ-V each provide six output channels, with a maximum of three channels permitted to operate simultaneously on a single patient.

All models provide asymmetric biphasic pulse output with three selectable stimulation modes: continuous, interrupted, and dense-disperse. The selectable pulse frequency range is 1–100 Hz ±10%. In dense-disperse mode, the ratio of disperse frequency to dense frequency is 1:5.

The devices include a built-in treatment timer. When the selected treatment time has elapsed, an audible alert indicates the end of treatment and the output intensity returns to zero. All models can be powered by an internal 9 V battery supply or the supplied power adapter, which has an input rating of 100–240 VAC, 50/60 Hz and an output rating of 9 VDC, 0.3 A.

Acupuncture needles are supplied separately and are not included with the devices that are within the scope of this submission. The manufacturer-recommended needle body dimensions are:

- Diameter of 0.22–0.24 mm with a length of 14–50 mm; or
- Diameter of 0.25–0.45 mm with a length of 14–75 mm.

The smallest needle body diameter is 0.22 mm, and the smallest needle body length is 14 mm.

The devices are intended for use in hospitals and clinics by qualified practitioners of acupuncture as determined by the states.

5.0 Indications for Use Statement

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.

6.0 Technological Characteristic Comparison Table

Table 1 Comparison of Technology Characteristics

Item	Subject Device	Predicate Device	Comparison
510(k) No.	K260230	K202861	--
Manufacturer	Suzhou Medical Appliance Factory	Wuxi Jiajian Medical Instrument Co., Ltd.	--
Product Name	Needle Stimulator	Needle Stimulator	--
Model	SDZ-IIB, SDZ-IIC, SDZ-III, SDZ-V	CMNS6-1	--
Product Code	BWK	BWK	Identical
Classification	Class II	Class II	Identical
Intended Use/ Indication 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.	Identical
Patient Population	Adults aged 22 years and older	Not publicly available	The subject device is intended for use in adults aged 22 years and older, which does not raise increased safety and/or effectiveness concerns compared to the predicate device.
Power Source(s)	SDZ-V/ SDZ-III: DC 9V Type R14/UM2 ×6 or AC 100-240V; SDZ-IIC: DC 9V Type AA/UM3 or AC 100-240V; SDZ-IIB: DC 9V Type 6F22 or AC 100-240V	DC l.5Vx6TypeR14 or AC 100-240V	The power source between the subject and predicate device are similar and do not raise increased concerns of safety and/or effectiveness compared to the predicate device.
Method of Line Current Isolation	Type BF	Type BF	Identical

- Patient Leakage Current - Normal Condition(μA) - Single Fault Condition(μA)	-- 2μA ≤50μA	-- 2μA ≤50μA	Identical
Average DC current through electrodes when device is on but no pulses are being applied(μA)	N/A	N/A	Identical
Number of Output Modes	3 (continuous wave/ interrupted wave/ Dense-disperse wave)	3 (continuous wave/ interrupted wave/ Dense-disperse wave)	Identical
Number of Output channels	SDZ-IIB: 2 (2 channels at most work together on single patient) SDZ-IIC/ SDZ-III/ SDZ-V: 6 (3 channels at most work together on single patient)	6 (3 channels at most work together on single patient)	Different for SDZ-IIB; identical for SDZ-IIC, SDZ-III, and SDZ-V. SDZ-IIB provides two output channels, compared with six channels for the predicate device. The lower channel count limits the number of needle pairs that can be stimulated simultaneously, but does not alter the intended use, operating principle, or stimulation delivered through each active channel. SDZ-IIB does not claim the ability to provide the same simultaneous

			treatment coverage as a three-channel configuration. Electrical performance testing supports that its output meets the predefined specifications. Therefore, the lower channel count does not raise different questions of effectiveness.
- Synchronous or Alternating?	Synchronous	Synchronous	Identical
- Method of Channel Isolation	Transformer	Transformer	Identical
Regulated Current or Regulated Voltage?	Voltage Control	Voltage Control	Identical
Software/Firmware/ Microprocessor Control?	Yes	Yes	Identical
Automatic Overload Trip?	No	No	Identical
Automatic No-Load Trip?	No	No	Identical
Automatic Shut Off?	Yes	Yes	Identical
User Override Control?	No	Yes	Different The user override control of the subject device is different from the

				predicate device. However, both devices adopt the same fundamental stimulation output technology and provide similar therapeutic effects. In addition, the stimulation can be immediately stopped by the operator. Therefore, the difference do not raise new questions of safety or effectiveness.
Indicator Display	On/Off Status?	Yes	Yes	Identical
	Low Battery?	No	Yes	Different The subject devices do not have a dedicated low-battery indicator but use the same fundamental stimulation technology as the predicate device. All models also support operation with the supplied power adapter. All device models have been evaluated for electrical safety, EMC, and software verification. Therefore, this difference does not raise increased safety and/or effectiveness concerns compared to the predicate device.

	Voltage/ Current Level?	Yes	Yes	Identical
Timer Range (minutes)		1-60min	0-60min	Similar
Compliance with Voluntary Standards?		IEC60601-1, IEC60601-2-10, IEC60601-1-2	IEC60601-1, IEC60601-2-10, IEC60601-1-2	Identical
Housing Materials& Construction		ABS; Injection molded	ABS;Injection molded	Identical
Waveform		Biphasic	Biphasic	Identical
Shape		Asymmetric biphasic square wave	Asymmetric biphasice square wave	Identical
Maximum Output Voltage(volts)		**SDZ-IIB:** Continuous: 24.4V @500Ω, 70.4V@2kΩ, 102V@10kΩ Interrupted: 24.4V @500Ω,70.4V@2kΩ, 102V@10kΩ Dense-Disperse: 24.4 V @500 Ω ,70.4V@2kΩ, 102V@10kΩ **SDZ-IIC:** Continuous: 24.8V @500Ω;70.4V@2kΩ; 102V@10kΩ; Interrupted:24.4V @500Ω;70.4V@2kΩ; 104V@10kΩ; Dense-Disperse: 24.4V @500Ω;70.4V@2kΩ;	27V±10%@500Ω; 60.4V±10%@2kΩ; 75V±10%@10kΩ;	Similar The measured maximum output voltages of the subject device models were 24.4–24.8 V at 500 Ω , 69.6–70.4 V at 2 kΩ, and 102–104 V at 10 kΩ across all output modes, The predicate device specifies 27 V ±10%, 60.4 V ±10%, and 75 V ±10% at the corresponding loads. The subject device's output voltage is within the predicate specification at 500 Ω but is larger at 2 kΩ and 10 kΩ. However, each subject device model has comparable stimulation

	104V@10kΩ.		output waveform, frequency, pulse duration, maximum output current, and maximum phase charge to the predicate device. Verification testing confirmed that all models and modes of the subject device met the predefined output specifications. Therefore, these difference does not raise different questions of safety or effectiveness.
	SDZ-III: Continuous: 24.4V @500Ω;69.6V@2kΩ; 102V@10kΩ; Interrupted: 24.4V @500Ω;70.4V@2kΩ; 102V@10kΩ; Dense-Disperse: 24.4V @500Ω;69.6V@2kΩ; 102V@10kΩ;		
	SDZ-V: Continuous: 24.4V @500Ω;70.4V@2kΩ; 102V@10kΩ. Interrupted: 24.4V @500Ω;70.4V@2kΩ; 102V@10kΩ; Dense-Disperse: 24.4V @500Ω;70.4V@2kΩ; 102V@10kΩ;		

Maximum Output Current	**SDZ-IIB:** Continuous: 48.8mA @500Ω; 35.20mA @2kΩ; 10.2mA @10kΩ. Interrupted: 48.8mA @500Ω;35.20mA @2kΩ; 10.2mA @10kΩ. Dense-Disperse: 48.8mA @500Ω;35.20mA @2kΩ; 10.2mA @10kΩ.	54mA±10%@500Ω; 30.2mA±10%@2kΩ; 7.5mA±10%@10 kΩ	Similar The measured maximum output currents across all subject device models and output modes were 48.8–49.6 mA at 500 Ω, 34.0–35.2 mA at 2 kΩ, and 10.2–10.4 mA at 10 kΩ. The predicate device specifies 54 mA ±10%, 30.2 mA ±10%, and 7.5 mA ±10% at the corresponding loads. The subject device's output current is within the predicate specification at 500 Ω but slightly larger at 2 kΩ and 10 kΩ. The waveform, pulse duration, frequency, maximum phase charge, and maximum current and maximum power densities were evaluated as part of the waveform output evaluation to demonstrate that each subject device model met its pre-specified output parameters. Therefore, this minor difference in maximum output current does not raise increased concerns of safety and effectiveness compared to the
	SDZ-IIC: Continuous: 49.6mA @500Ω;35.20mA @2kΩ; 10.2mA @10kΩ. Interrupted: 48.8mA @500Ω;35.20mA @2kΩ; 10.4mA @10kΩ. Dense-Disperse: 48.8mA @500Ω;35.20mA @2kΩ; 10.2mA @10kΩ.		
	SDZ-III: Continuous: 48.8mA @500Ω;34.0mA @2kΩ; 10.4mA @10kΩ. Interrupted: 48.8mA @500Ω;35.20mA @2kΩ; 10.2mA @10kΩ. Dense-Disperse: 48.8mA @500Ω;34.80mA @2kΩ;		

	10.2mA @10kΩ.		predicate device.
	SDZ-V: Continuous: 48.8mA @500Ω;35.20mA @2kΩ; 10.2mA @10kΩ. Interrupted: 48.8mA @500Ω;35.20mA @2kΩ; 10.2mA @10kΩ. Dense-Disperse : 48.8mA@500Ω;35.20mA @2kΩ; 10.2mA @10kΩ.		
Maximum Phase Charge	**SDZ-IIB:** Continuous: 9.42μC @500Ω Interrupted: 9.41 μC @500Ω Dense-Disperse: 9.42 μC @500Ω	9.4μC@500Ω	Different The maximum phase charge of the subject device ranges from 9.41 μC to 9.56 μC per phase at a 500 Ω load across all models and operating modes, compared with 9.4μC per phase for the predicate device. This small difference results from minor variations in the measured output current and pulse width and does not change the biphasic stimulation waveform or the charge-balancing characteristics of the output. The subject device uses a
	SDZ-IIC: Continuous: 9.56μC @500Ω Interrupted: 9.42μC @500Ω Dense-Disperse: 9.42μC @500Ω		
	SDZ-III: Continuous: 9.418μC @500Ω		

	Interrupted: 9.418μC @500Ω Dense-Disperse: 9.42μC @500Ω		charge-balanced biphasic waveform consistent with its design specification. This difference does not raise different questions of safety or effectiveness.
	SDZ-V: Continuous: 9.42μC @500Ω Interrupted: 9.42 μC @500Ω Dense-Disperse: 9.41μC @500Ω		
Maximum Average Current	**SDZ-IIB:** Continuous: 1.033 mA @500Ω Interrupted: 1.071 mA @500Ω Dense-Disperse: 1.068 mA @500Ω	1.08mA@500Ω	Different The maximum average current of the subject device ranges from 0.757 to 1.107 mA at 500 Ω, compared with 1.08 mA for the predicate device. The variation results from differences in waveform timing among models and modes. The subject device maintains comparable maximum output current and phase charge, and output waveform bench testing verified that the subject device delivers output with the predefined output specifications. Therefore, the difference does not
	SDZ-IIC: Continuous: 1.067mA @500Ω Interrupted: 1.054mA @500Ω Dense-Disperse: 1.0505mA @500Ω		
	SDZ-III: Continuous: 0.764mA @500Ω Interrupted: 0.769mA @500Ω		

	Dense-Disperse: 0.757mA @500Ω		raise different questions of safety or effectiveness compared to the predicate device.
	SDZ-V: Continuous: 1.082 mA @500Ω Interrupted: 1.050mA @500Ω Dense-Disperse: 1.107mA @500Ω		
Maximum Current Density, (mA/cm²)	**SDZ-IIB:** Continuous: 10.598 mA/cm² @500Ω Interrupted: 10.988 mA/cm² @500Ω Dense-Disperse: 10.957 mA/cm² @500Ω	9.4mA/cm²@500Ω	Different The maximum average current density of the subject device ranges from 7.766 to 11.353 mA/cm² at 500 Ω, compared with 9.4 mA/cm² for the predicate device, CMNS6-1. The subject and predicate devices employ asymmetric biphasic waveforms. FDA has cleared other electro-acupuncture devices, such as K122812, with current density of 17.6 mA/cm², which is larger than the maximum current densities reported for the subject device. Therefore, these differences will not
	SDZ-IIC: Continuous: 10.947mA/cm² @500Ω Interrupted: 10.855 mA/cm² @500Ω Dense-Disperse: 10.778 mA/cm² @500Ω		
	SDZ-III: Continuous: 7.891mA/cm² @500Ω Interrupted: 7.945 mA/cm² @500Ω		

	Dense-Disperse: 7.766mA/cm² @500Ω		raise any increased safety and effectiveness concerns compared to the predicate device.
	SDZ-V: Continuous: 11.101mA/cm² @500Ω Interrupted: 10.947mA/cm² @500Ω Dense-Disperse :11.353mA/cm² @500Ω		
Maximum Average Power Density	**SDZ-IIB:** Continuous: 0.229 W/cm² @500Ω Interrupted: 0.237 W/cm² @500Ω Dense-Disperse: 0.229 W/cm² @500Ω	0.141W/cm^2@500Ω	Different The maximum average power density of the subject devices ranges from 0.229 to 0.239 W/cm² at a 500 Ω load, compared with 0.141 W/cm² for the predicate device. Although higher than the predicate value, all subject device values remain below the established safety threshold. So the difference in maximum average power density does not raise increased thermal safety concerns compared to the predicate device.
	SDZ-IIC: Continuous: 0.239 W/cm² @500Ω Interrupted: 0.237 W/cm² @500Ω Dense-Disperse: 0.237 W/cm² @500Ω		
	SDZ-III: Continuous: 0.237 W/cm² @500Ω Interrupted: 0.237 W/cm² @500Ω		

		Dense-Disperse: 0.237 W/cm² @500Ω		
		SDZ-V: Continuous: 0.237 W/cm² @500Ω Interrupted: 0.237 W/cm² @500Ω Dense-Disperse: 0.237 W/cm² @500Ω		
Pulse width (μsec)	Positive	**SDZ-IIB:** Continuous: 193.00 μs @500Ω Interrupted: 192.80 μs @500Ω Dense-Disperse: 193.80 μs @500Ω	200μs±10%	Similar The positive phase duration of the subject device ranges from 192.8 to 193.8 μs at 500 Ω, which is within the predicate device specification of 200 μs ±10%. Therefore, the minor variation does not affect the stimulation waveform or raise different questions of safety or effectiveness.
		SDZ-IIC: Continuous: 193.60us @500Ω Interrupted: 193.75us @500Ω Dense-Disperse: 193.65us @500Ω		
		SDZ-III: Continuous: 193us @500Ω Interrupted: 193us @500Ω		

		Dense-Disperse: 192.9us @500Ω		
		SDZ-V: Continuous: 193.70us @500Ω Interrupted: 193.00us @500Ω Dense-Disperse: 193.70us @500Ω		
	Negative	**SDZ-IIB:** Continuous: 1034 μs @500Ω Interrupted: 1034 μs @500Ω Dense-Disperse: 1024 μs @500Ω	1030μs(5.15x(+Phase))	Similar. The negative phase duration of the subject device ranges from 1024 to 1054 μs at 500 Ω, compared with 1030 μs for the predicate device. The minor variation maintains the intended asymmetric biphasic waveform and does not adversely affect charge balance. Therefore, it does not raise different questions of safety or effectiveness.
		SDZ-IIC: Continuous: 1034us @500Ω Interrupted: 1036us @500Ω Dense-Disperse: 1030us @500Ω		
		SDZ-III: Continuous: 1038us @500Ω Interrupted: 1036us @500Ω Dense-Disperse: 1036us @500Ω		

		SDZ-V: Continuous: 1040us @500Ω Interrupted: 1040us @500Ω Dense-Disperse: 1054us @500Ω		
Pulse Period(msec)		10~1000ms	10~1000ms	Identical
Max. pulse frequency(Hz) [or Rate(pps)]		1~100Hz±10%	1~100Hz±10%	Identical
Net Charge (μC per pulse)		0μC@500Ω, + and– pulses cancel	0μC@500Ω, + and– pulses cancel	Identical
Burst Mode		N/A	N/A	Identical
Accessories		Lead wires, Alligator type connectors	Lead wires, Alligator type connectors	Identical
OTC or Rx		Rx	Rx	Identical
Compliance with 21 CFR Part 898		Yes	Yes	Identical
Weight (g)		SDZ-IIB: Approx. 190 (Without battery) SDZ-IIC: Approx. 650 (Without battery) SDZ-III: Approx. 700 (Without battery) SDZ-V: Approx. 500 (Without battery)	approx.657	Different Differences in weight do not alter the intended use or fundamental stimulation principle. Therefore, these physical differences do not adversely affect safety or

			effectiveness.
Dimensions (mm)	SDZ-IIB: 157 × 79 × 33; SDZ-IIC: 275 × 160 × 54; SDZ-III: 286 × 180 × 64; SDZ-V: 258 × 169 × 45	230*155*55	Different The differences in external dimensions reflect differences in enclosure design among the subject device models. These dimensional differences do not alter the intended use or fundamental stimulation principle. Therefore, the differences in external dimensions do not raise different questions of safety or effectiveness.

Substantial Equivalence Discussion:
The subject device (Needle Stimulator, models SDZ-IIB, SDZ-IIC, SDZ-III, SDZ-V) and the K202861 predicate device have the same intended use. Both the subject and predicate devices employ charge-balanced asymmetric biphasic waveforms and operate within comparable pulse-duration and frequency ranges. Minor differences in channel configuration, maximum output voltage and maximum output current, maximum phase charge, maximum average current, maximum average current density, maximum average power density, and phase durations do not raise increased concerns of safety and/or effectiveness compared to the predicate device.

7.0 Summary of Non-Clinical Testing

Non-clinical tests were conducted to verify that the subject devices met all design specifications to be considered substantially equivalent to the predicate device:

Electrical Safety and Electromagnetic Compatibility:

- IEC 60601-1: 2020, Medical electrical equipment – Part 1: General requirements for basic safety, and essential performance
- IEC 60601-1-2: 2020, Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic Compatibility
- IEC TS 60601-4-2:2024, Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems

Software Verification

- Software was evaluated at basic documentation level in accordance with 2023 FDA Guidance: Content of Premarket Submissions for Device Software Functions.

The following non-clinical tests were conducted：

- Oscilloscope tracings of the output waveforms at loads of 500 Ω, 2,000 Ω, and 10,000 Ω for each output mode (continuous, interrupted, and dense-disperse) of each subject device model (SDZ-IIB, SDZ-IIC, SDZ-III, and SDZ-V).
- Values and calculation methodologies for the output parameters of Maximum Output Voltage, Maximum Output Current, Maximum Phase Charge (μC), Maximum Average Current (mA), Maximum Current Density (mA/cm²); Maximum Average Power Density (W/cm²) and Maximum Charge Density (μC/cm²).

  The test results demonstrated that the subject devices (SDZ-IIB, SDZ-IIC, SDZ-III, SDZ-V)met the predefined output specifications. The results demonstrate that the SDZ-IIB, SDZ-IIC, SDZ-III, and SDZ-V subject device models do not raise increased safety and/or effectiveness concerns compared

with the predicate device.

8.0 Conclusion

The comparison and analysis above demonstrate that the proposed device is as safe and effective as the K202861 predicate device. Thus, the subject device is substantially equivalent to the predicate device.