August 12, 2026

Hangzhou Ruidi Biotechnology , Ltd.
℅ Xueping Deng
Regulation Affair Specialist
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Beijing, Beijing 100000
China

Re: K253846
Trade/Device Name: Steep Pulse Ablation Instrument (including Disposable Sterile Steep Pulse Probe) (SPA-C02); Disposable Sterile Steep Pulse Probe (NPA-DJ01); Probe connection line (NPA-LX-02)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: OAB
Dated: December 2, 2025
Received: December 2, 2025

Dear Xueping Deng:

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 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,

Colin K. Chen -S

Digitally signed by Colin K. Chen -S
Date: 2026.08.12 09:37:53 -04'00'

Colin K. Chen, Ph.D.
Assistant Director
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Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253846

Please provide the device trade name(s).

Steep Pulse Ablation Instrument (including Disposable Sterile Steep Pulse Probe) (SPA-C02);
Disposable Sterile Steep Pulse Probe (NPA-DJ01);
Probe connection line (NPA-LX-02)

Please provide your Indications for Use below.

Steep Pulse Ablation Instrument is indicated for the surgical ablation of soft tissue.

Please select the types of uses (select one or both, as applicable).

- [x] Prescription Use (Part 21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(K) number is: K253846

Date of Summary：September 4, 2025

1. Submitter

Hangzhou Ruidi Biotechnology Ltd.

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3. Date Prepared: September 4, 2025

4. Proposed Device Information

Trade name: Steep Pulse Ablation Instrument (including Disposable Sterile Steep Pulse Probe)

Model: SPA-C02

Common name: Low Energy Direct Current Thermal Ablation System

Classification name: General & Plastic Surgery

Review Panel: General & Plastic Surgery

Product Code: OAB

Regulation Class: II

Regulation Number: 21 CFR 878.4400

5. Predicate Device Information

Manufacturer	Device Name	510(K) Number
Angiodynamics	NanoKnife System	K183385

6. Device Description

Steep Pulse Ablation Instrument (including Disposable Sterile Steep Pulse Probe) contain steep pulse ablation instrument, Disposable Sterile Steep Pulse Probe and Probe connection line.

Product name	Model Type	Specifications
Steep Pulse Ablation Instrument	SPA-C02	/
Disposable Sterile Steep Pulse Probe	NPA-DJ01	φ1.0x10.0mm
		φ1.0x15.0mm
		φ1.0x20.0mm

Probe connection line	NPA-LX-02	L1.5m

The steep pulse ablation instrument (model: SPA-C02) consists of the main machine and power cord, which is powered by connecting to the external power supply and can be put on the desktop for use. The steep pulse ablation instrument has four fulcrum points, which can be moved in parallel, with a digital display providing a visual running process monitoring and parameter setting for the operator.

The Steep Pulse Ablation Instrument has six pulse output ports, which can connect six Probes at the same time. Any two of six pulse output ports can be combined, and two Probes form a group.

The steep pulse ablation instrument (model: SPA-C02) is designed for non-thermal electric pulse ablation of soft tissue. It transmits the energy of the pulsed electric field to the soft tissue at the target site through a special ablation Probe. This product is used in the medical institutions and is applicable to the surgical soft tissue ablation.

The Steep Pulse Ablation Instrument transfers energy to the ablation target area with the Probe.

7. Intended use

The intended purpose is for the surgical ablation of soft tissue.

8. Indications for Use

The Steep Pulse Ablation Instrument (including Disposable Sterile Steep Pulse Probe) is indicated for the surgical ablation of soft tissue.

9. Comparison to Predicate Device

The Steep Pulse Ablation Instrument (including Disposable Sterile Steep Pulse Probe) have the same intended use, similar technological characteristics as the following predicate device and are substantially equivalent with regards to safety and effectiveness.

K183385 NanoKnife System, manufactured by Angiodynamics.

The following table shows similarities and differences of technological characteristics between our device and the predicate devices.

Comparison Elements			Subject Device	Predicate Device	Comparison
510(k) Number			-	K183385	/
510(k) Submitter			Hangzhou Ruidi Biotechnology Ltd.	Angiodynamics	/
Product name			Steep Pulse Ablation Instrument (including Disposable Sterile Steep Pulse Probe)	NanoKnife System	/
Classification name			878.4400	878.4400	Identical
Product code			OAB	OAB	Identical
Indications for use			The Steep Pulse Ablation Instrument (including Disposable Sterile Steep Pulse Probe) is indicated for the surgical ablation of soft tissue.	The NanoKnife System with six outputs is indicated for the surgical ablation of soft tissue.	Identical
Working mode			Steep pulse mode	Steep pulse mode	Identical
Prescription or OTC			Prescription	Prescription	Identical
Component			Steep Pulse Ablation Instrument, Disposable Sterile Steep Pulse Probe	NanoKnife Generator, Electrode Probes, Foot Pedal	Difference 1. No foot switch of the subject device. Difference will not impact product safety and effectiveness
ESU	Bipolar or monopolar		Bipolar	Bipolar	Identical
	Pulse Amplitude/Voltage output		500~3000V	500~3000V	Identical
	Pulse amplitude precision		±5%	±5%	Identical
	Maximum output current	Pulse mode	~50A	~50A	Identical
	Pulse width	Monophasic pulse mode	10 ~100 μS	20 ~ 100 μs	Difference 2 The difference will not impact product safety and effectiveness.
	Pulse width precision		±2μs	±2μs or ±2% (whichever is larger)	Identical

Comparison Elements			Subject Device	Predicate Device	Comparison
	Number of pulse(s)		10 ~ 200	10 ~ 100	Difference 3 The minimum number of pulses is the same with predicate device. The number of pulses can be increased to achieve a more thorough and uniform ablation within the area, without affecting the safety and effectiveness of clinical use.
	Volts/cm		500~3000	500 ~ 3000	Identical
	Maximum probes		6	6	Identical
	Pulse frequency, Un-sync		90PPM/every 10 pulse	240PPM/every 10 pulse 90PPM/every 10 pulse	Identical
	Pulse frequency, Sync		ECG, frequency varies depending on heart rate	ECG, frequency varies depending on heart rate	Identical
	ECG synchronization triggering		Yes	Yes	Identical
	Impedance monitor		Yes	Yes	Identical
	Continuity monitor		Yes	Yes	Identical
	RF Output frequency		N/A (refer to Pulse frequency)	N/A (refer to Pulse frequency)	Identical
	Waveform	monophasic	Square wave with steep edge (one direction)	Square wave with steep edge (one direction)	Identical
	Maximum Energy per Pulse (normal)		15J	15J	Identical
	Physical dimension		547mm(L)x524mm(W)x 192mm(H)	680mm(L)x560mm(W)x 1490mm(H)	Different 4 Different product dimension will not impact product safety and effectiveness.
Active access	Monopolar or bipolar		Monopolar	Monopolar	Identical

Comparison Elements		Subject Device	Predicate Device	Comparison
ory	Physical dimension	Monopolar Probe lengths: 15cm. Working length is 1cm, 1.5cm, 2cm. Probe needle size: 1mm.	Monopolar length: 15 cm, 25cm, working length is adjustable in 0.5 cm increments from 0 -4 cm via the thumbslide. Probe needle size: 19G Bipolar: not available.	Different 5 Difference will not impact product safety and effectiveness.
	Connector type	6 pins	6 pins	Identical
	Patient contact Materials	Stainless steel, Parylene C	Stainless steel, PI	Different 6 Difference will not impact product safety and effectiveness.

Our device and the predicate device differ in the following areas.

The features of the Steep Pulse Ablation Instrument (including Disposable Sterile Steep Pulse Probe) are compared to predicate devices in the form of above tables.

Our device and the predicate device differ in the following areas.

(1) Different 1: Component

The start-up and shutdown of the subject device, as well as the energy output, can be controlled by the button and screen of instrument. The operation of buttons and screens can achieve the same effect as Foot Pedal. Waveform and Output Test and Animal test can prove product safety and effectiveness. So, different of Foot Pedal will not impact product safety and effectiveness.

(2) Different 2: Pulse width

The minimum pulse width of this product is 10μs, with higher precision. It provides an additional option for pulse ablation in a small range. The pulse energy within the 10μs-20 μs range is smaller, without increasing the safety risk for clinical application. Since the typical pulse width for clinical application is 90μs, the recommended effective ablation pulse width is within the 50μs-100μs range. Therefore, it does not

bring any new risks to effectiveness. Waveform and Output Test Report and animal test result can prove product safety and effectiveness. So, different product pulse width will not impact product safety and effectiveness.

(3) Different 3: Pulse number

During the soft tissue ablation process using the steep pulse ablation instrument, when the probe spacing is 10-20mm, due to the voltage pitch ratio setting range being 1500V/cm to 3000V/cm, 70-100 pulses within the pulse ablation range can form a continuous irreversible electroporation ablation area, and no additional pulse count is required. In some larger soft tissue ablation application cases, when the electrode spacing exceeds 20mm, the voltage pitch ratio is less than 1500V/cm, and it is prone to form a discontinuous irreversible electroporation ablation area. At this time, increasing the pulse count is necessary to enhance the continuity and uniformity of the pulse ablation area. Setting the pulse count between 100 and 200 will form a better ablation area. These application scenarios do not increase the safety risk of clinical application nor pose a risk to effectiveness.

(4) Different 4: Physical dimension of ESU

Steep Pulse Ablation Instrument is active device host; the external size will not affect the effectiveness and safety of device.

(5) Different 5: Physical dimension of Active accessory

Probe: The subject device probe length is 15cm, predicate device monopolar probe has 15cm length probe, they are same. Predicate device also has the probe length is 25cm. Predicate device working length is 0-4cm, adjustable in 0.5cm, subject device probe working length is 1cm, 1.5cm, 2cm. subject device probe working length included in the scope of Predicate device and reference device working length.

Needle: The way of needle diameter is expressed for Subject device and Predicate device is different, Predicate device needle diameter is 19G=1.067mm, it’s nearly the same with Subject device 1mm diameter. Different diameter will not impact product safety and effectiveness.

We conducted contrast animal test on subject device and predicate device, the ablation effect is the same.

(6) Different 6: Patient contact Materials of Active accessory

The subject device probe contact person materials are stainless steel and Parylene C, the predicate device and reference device contact person materials are stainless steel and PI, the different material is insulating layer Parylene C. Compare with PI, Parylene C has higher chemical stability and electrical insulation. The probes have passed the biocompatibility test and meet the ISO 10993 Cytotoxicity, Sensitization, Irritation or Intracutaneous reactivity Acute systemic toxicity and pyrogenicity. It can prove the safety of the product. So, this difference does not affect the effectiveness and safety of our device. Specific documents reference to: W62-0001-BVO, W62-0002-BVO, W62-0003-BVO, W62-0004-BVO, W62-0005-BAR.

So this difference does not affect the effectiveness and safety of our device.

10. Non-Clinical Performance Data

Biocompatibility Tests

The Steep Pulse Ablation Instrument (including Disposable Sterile Steep Pulse Probe) has been evaluated in accordance with Part 10993 of the International Standard Organization (ISO). Standard tests administered include:

- ISO 10993-5: 2009 Biological Evaluation of Medical Devices - Part 5: Tests for in vitro cytotoxicity.
- ISO 10993-10: 2021 Biological evaluation of medical devices - Part 10: Tests for skin sensitization
- ISO 10993-11:2017 Biological Evaluation of Medical Devices - Part 11: Tests for Systemic Toxicity
- ISO 10993-23:2021 Biological evaluation of medical devices - Part 23: Tests for irritation

Performance Tests

- IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020
- IEC 60601-1-6:2010, IEC 60601-1-6:2010/AMD1:2013, IEC 60601-1-6:2010/AMD2:2020

- IEC 62366-1:2015/AMD1:2020
- IEC 60601-1-2:2014/AMD1:2020
- IEC TR 60601-4-2:2016

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "major" level of concern, since a failure or latent flaw in the software could directly result in serious injury or death to the patient or operator.

Animal Study

Animal study was conducted. A total of 54 Yorkshire pigs were included in this animal study: all 54 animals were used for chronic experiments (27 in the experimental group and 27 in the control group). Among them, six animals will also be used in acute animal studies (only for the experimental group), three for cardiac safety distance studies, and three for thermal damage studies.

Based on result of chronic experiments, the ablation volume in the experimental group was comparable to the control group three days after ablation.

Based on the results of the cardiac safety distance test using clinically representative settings, the animal study demonstrates safe use when the distance from the heart is greater than 1.6 cm. The actual safe distance in human clinical use shall be determined based on the clinician's evaluation to ensure patient safety.

Conclusion: The Steep Pulse Ablation Instrument (including Disposable Sterile Steep Pulse Probe) have demonstrated the product has same intended use and similar technological characteristics as that of the predicate device. Performance testing showed it performs in a manner that is substantially equivalent to the legally marketed predicate device.

11. Substantial Equivalent Conclusions

Steep Pulse Ablation Instrument (including Disposable Sterile Steep Pulse Probe) has

the same intended use, similar technological characteristics as the predicate device. Moreover, non-clinical testing and animal test contained in this submission demonstrated that any difference in their technological characteristics does not raise any new issues of safety and effectiveness.

In conclusion, Steep Pulse Ablation Instrument (including Disposable Sterile Steep Pulse Probe) is substantial equivalent to the predicate device.