January 23, 2025

Shanghai SAMedical & Plastic Instruments Co., Ltd.
Louis Li
Level 1-4 & Room 501,506,510, Building No.12, No.2755
Sanlu Highway, Minhang District
Shanghai, 201100
China

Re: K241367
Trade/Device Name: RF Cannula
Regulation Number: 21 CFR 882.4725
Regulation Name: Radiofrequency Lesion Probe
Regulatory Class: Class II
Product Code: GXI
Dated: December 23, 2024
Received: December 23, 2024

Dear Louis Li:

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,

Adam D. Pierce -S

Digitally signed by Adam D. Pierce -S
Date: 2025.01.23 15:24:17 -05'00'

Adam D. Pierce, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical, Neurointerventional, and Neurodiagnostic Devices
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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.

Submission Number *(if known)*

K241367

Device Name

RF Cannula

Indications for Use *(Describe)*

The RF cannula is intended for use in RF heat lesion procedures for the relief of pain.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Submitter: Shanghai SA Medical & Plastic Instruments Co., Ltd.
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Device Trade Name: RF Cannula

Device Class: Class II

Regulation Number: 21 CFR 882.4725

Regulation name: Radiofrequency Lesion Probe

Product code: GXI

Predicate Device: K112231

Date Prepared: January 23, 2024

Device Description

The RF Cannula is indicated for RF heat lesion procedures for the relief of pain.

The RF Cannula is composed of Cannula, Cannula hub, Stylet, Stylet hub, Insulating layer, Depth stop and Protection tube.

Materials being used include SUS 304 stainless steel, K-Resin, polyethylene, polyethylene terephthalate.

RF Cannula is supplied sterile and is only for single-use. It is used in conjunction with a RF Generator and RF Electrode and other accessories to create Radiofrequency (RF) Lesions of nerve tissue or for use in percutaneous nerve blocks. During the RF heat lesion procedure, the RF cannula bare tip is placed into the target tissue; preloaded stylet is withdrawn and replaced by the RF Electrode. The radio frequency is produced by the RF Generator and released by the cannula bare tip.

A) Indications for Use:

The RF cannula is intended for use in RF heat lesion procedures for the relief of pain.

B) Comparison of Technological Characteristics with the Predicate Device

The RF Cannula is substantially equivalent in indication for use, principles of operation and fundamental technological characteristics to the legally marketed predicate LCCS Insulated Spinal Needle (RF Cannula)(K112231). The following table summarizes the similarities and differences in design, materials and dimensions between the subject and predicate device.

Table 5-1 Comparison of RF Cannula with predicate device

Feature	**Subject Device** **RF Cannula** **(K241367)**	**Predicate Device** **LCCS Insulated Spinal Needle (RF Cannula)** **(K112231)**	**Discussion of Differences**
Intended/ Indications for use	The RF cannula is intended for use in RF heat lesion procedures for the relief of pain.	LCCS Insulated Spinal Needle (RF Cannula) is indicated for use in RF heat lesion procedures for the relief of pain.	Similar
Basic Design	The RF Cannula is supplied sterile and is for single-use only. and mainly consists of a Stylet hub, Stylet, Cannula hub, Cannula, Depth Stop, Protection Tube and Insulating layer.	This RF Cannula is provided as a sterile, single use, and consists of a Protection sleeve, Needle tube, Insulating layer, Needle hub, Stylet, Stylet hub.	Similar
Performance Characteristics	Puncture in RF lesion of peripheral nerve, treatment of pain	In RF heat lesion procedures for the relief of pain	Identical

Material type	Stainless Steel	Stainless Steel	Similar
Cannula gauge	18G, 20G, 22G	18G, 20G, 21G, 22G	Similar
Cannula length	50mm 100mm 150mm	50mm 100mm 150mm 200mm	Similar
Active tip length	2mm, 5mm, 10mm	Not available	
Structure	Straight bevel tip Curved bevel tip Curved blunt tip	Straight sharp tip Curved sharp tip Curved blunt tip	Identical
Mechanics of Operation	Manual instrument	Manual instrument	Identical
Method of Sterilization	Single use, Ethylene Oxide sterilization	Single use, Ethylene Oxide sterilization	Identical

The technological characteristics of the subject device are similar to those of predicate device. The subject device has the same basic design as the predicate device. The comparison between the proposed and predicate devices is based on the following:
- Indication for use
- Performance characteristics
- Sterilization method
- Basic design

C) Performance Testing

Characteristic	Test Method	Result
Risk Management	ISO 14971:2019 Medical devices—Application of risk management to medical devices	Pass
Biocompatibility	ISO 10993-1:2018 Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process	Pass

	ISO 10993-5:2009 Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity	Pass
	ISO 10993-10:2021 Biological evaluation of medical devices — Part 10: Tests for skin sensitization	Pass
	ISO 10993-11:2017 Biological evaluation of medical devices — Tests for acute systemic toxicity	Pass
	ISO 10993-11:2017 Biological evaluation of medical devices—Test for material-mediated pyrogenicity	Pass
	10993-23:2021 Biological evaluation of medical devices – Part 23: Tests for irritation	Pass
Ethylene Oxide Sterilization Residuals	ISO 10993-7:2008 Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals	Pass
Sterilization	ISO 11135:2014 Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices	Pass
Sterilization	ISO 11138-1:2017 Sterilization of health care products—Biological indicators—Part 1: General requirements	Pass
Sterilization	ISO 11737-1:2018 Sterilization of health care products—Microbiological methods—Part 1: Determination of a population of microorganisms on products	Pass
Package Stability	ASTM F 1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices[1]	Pass
Packaging	ISO 11607 Packaging for terminally sterilized medical devices	Pass

—Device Shelf-life

The proposed devices in their packaging were subjected to accelerated aging to simulate a 5-year shelf life (Treatment: 60±2℃, 194 days, RH70±5%). The aged proposed devices were tested for seal Strength, Dye Penetration, Vacuum Leak and Packaging resistance Bacterial performance.

—Performance testing

The performance of the subject device was compared to the performance of the predicate device for the following tests:

Characteristic	Test Method	Result
Performance	ISO 9626:2016 Stainless steel needle tubing for the manufacture of medical devices— Requirements and test methods	Pass
	ISO 80369-7:2021 Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications	Pass

Electrical safety	IEC 60601-1:2005+A1:2012 Medical electrical equipment—Part 1: General requirements for basic safety and essential performance	Pass
	IEC 60601-2-2:2017 Medical electrical equipment—Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories	Pass
Surface Finish and Visual Appearance	ISO 7864:2016 Sterile hypodermic needles for single use — Requirements and test methods	Pass
Bonding Strength Test	ISO 7864:2016 Sterile hypodermic needles for single use - Requirements and test methods	Pass
Stiffness Test	ISO 9626:2016 Stainless steel needle tubing for the manufacture of medical devices - Requirements and test methods	Pass
Resistance to Breakage Test	ISO 9626:2016 Stainless steel needle tubing for the manufacture of medical devices - Requirements and test methods	Pass
Dimension Test	ISO 9626:2016 Stainless steel needle tubing for the manufacture of medical devices - Requirements and test methods	Pass
Luer Lock Connector Test	ISO 80369-7:2021 Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular for hypodermic applications	Pass

D) Conclusion

Based on the similarities of the indications for use, device design, principles of operation, technological characteristics and the results of the non-clinical performance testing, the subject device, RF Cannula, is substantially equivalent to the legally marketed predicate device LCCS Insulated Spinal Needle (RF Cannula) (K112231).