January 18, 2024

Jiangsu Rong Fu Kang Medical Instruments Co., Ltd.
Mr. Steve Livneh
CEO/President
3rd floor, Building D6, 6 Dongsheng Road West
Jiangyin, Jiangsu 214400
China

Re: K231405
Trade/Device Name: Sterile Single Use Electrosurgical Pencil with Non-Coated and Non-Stick Electrode

Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: July 17, 2023
Received: December 21, 2023

Dear Mr. Livneh:

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,

Mark Trumbore -S
Digitally signed by Mark Trumbore -S
Date: 2024.01.18 10:07:00 -05'00'

Mark Trumbore, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical and Infection Control 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)*
K231405

Device Name
Sterile Single Use Electrosurgical Pencil with Non-coated and Non-stick Electrodes

Indications for Use *(Describe)*
The devices are used to cut and coagulate soft tissue by means of high frequency electrical current during an electrosurgical procedure.

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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Tel: 01186(0510) 86911838

510(K) SUMMARY- K231405

1. 510(k) Owner:

Name: Jiangsu Rong Fu Kang Medical Instruments Co., Ltd
Address: 3rd floor, Building D6, 6 Dongsheng Road West, Jiangyin, Jiangsu, China 214400
Prepared on: January 17, 2024

2. 510(k) Contact Information:

Please Contact:
Mr. Steve Livneh, CEO/President (1)-720-277-6060
Email: info@rfkinetics.com
Address: 1589 Roseanna Drive, Northglenn Colorado 80234 USA

3. Device:

Trade Name: Sterile Single Use Electrosurgical Pencil with Non-coated and Non-stick Electrodes
Common Name: RFK Disposable Electrosurgical Pencil with Standard and Non-Stick Tip Electrodes

Device Models:
For the pencil: EP-100-3, EP-100-5
For the electrodes:

1. Non coated electrode AE-EBD
2. Non-stick electrode: AE-EBDN

Classification Name: 878.4400: Electrosurgical Cutting and Coagulation Device and Accessories
Class: II
Product Code: GEI

4. Predicate and Reference Devices:

Predicate Device: K192542 Single Use Electrosurgical pencil with non-coated and non-stick electrode (Nonsterile and sterile)
Reference Device: K170369 Disposable Electrosurgical Pencils, CP1001 Series

made by Cathay Manufacturing Corp.

5. Product Description:

The Jiangsu Rong Fu Kang Medical Instruments Co. Ltd (here and after RFK) Electrosurgical Pencils and Electrodes are handheld instruments that are used for cutting and coagulation of soft tissue. They consist of a plastic handle, a connecting cable and plug, control buttons, internal PCB, and either a stainless steel uncoated or non-stick electrode tip. The Electrosurgical Pencils and electrodes are disposable and are supplied sterile.

The connecting cable is plugged into an Electro-Surgical Generator Unit (ESU) which provides the high-frequency energy to be deployed in the surgical procedure. The plastic handle has two buttons: cutting and coagulation. The cutting button activates the CUT mode of the ESU and the coagulation button activates the COAG mode of the ESU.

The electrode tip makes contact with the target tissue and delivers high frequency energy from the ESU to the target organs for the purposes of cutting and coagulation. This energy then passes through the body tissues and returns to the ESU via a return electrode (ground pad).

6. Indications for Use:

The devices are used to cut and coagulate soft tissue by means of high frequency electrical current during an electrosurgical procedure.

7. Technological Characteristics:

The proposed devices have substantially equivalent construction and performance as the predicate devices.

8. Substantial Equivalence:

The technological characteristics and performance testing of the subject and predicate devices are substantially equivalent. The following table shows the comparisons in more detail information among the subject device and the predicate devices.

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FIGURE 5-1: SUMMARY OF TECHNOLOGICAL CHARACTERISTICS AND PERFORMANCE TESTING

	Subject Device: K231405	**Predicate Device:** K192542
Intended Use	The devices are used to cut and coagulate soft tissue by means of high frequency electrical current during an electrosurgical procedure.	The devices are used to cut and coagulate soft tissue by means of high frequency electrical current during an electrosurgical procedure.
Device Description	This device is intended to be used as a hand-switching monopolar accessory in conjunction with a compatible electrosurgical generator for tissue cutting and coagulation. The distal end of the pencil has a 3/32" (2.36mm) collet that will accept a variety of electrosurgical electrodes with 3/32" (2.38mm) diameter shafts.	This device is intended to be used as a hand-switching monopolar accessory in conjunction with a compatible electrosurgical generator for tissue cutting and coagulation. The distal end of the pencil has a 3/32" (2.36mm) collet that will accept a variety of electrosurgical electrodes with 3/32" (2.38mm) diameter shafts.
Classification	878.4400	878.4400
Product Code	GEI	GEI
OTC or Prescription	Prescription	Prescription
Energy Type	High-Frequency Monopolar	High-Frequency Monopolar
Sterile?	Yes	Yes
Sterilization Type	EO Sterilization	EO Sterilization
Single Use?	Yes	Yes
Electrode Type	Monopolar	Monopolar
Electrode Material	Stainless Steel	Stainless Steel
Electrode non-stick coating	Silicon oxide	Teflon
Electrode Insulation Material	ABS	ABS
Electrode Dimensions	Standard Blade Electrode 2.38 mm x 70 mm	Standard Blade Electrode 2.38 mm x 70 mm
Insulating collar Materials	ABS	ABS
Handle Length	145 mm	165 mm
Effective Electrode Length	45 mm	45 mm
Total Device Length	190 mm	210 mm
Cable Material	Blue PVC Cable	Blue PVC Cable
Standards Applied	IEC 60601-1, IEC 60601-2-2, ISO 11135, ISO 11607	IEC 60601-1, IEC 60601-2-2, ISO 11135, ISO 11607
Biocompatibility	Conforms to ISO 10993	Conforms to ISO 10993
Labeling	Conforms to 21 CFR Part 801,	Conforms to 21 CFR Part 801,

Performance	Conforms to IEC 60601-1, and IEC 60601-2-10, Part 2 particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories. Performance conforms to the requirements specified in "Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery	Conforms to IEC 60601-1, and IEC 60601-2-10, Part 2 particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories. Performance conforms to the requirements specified in "Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery
Stability and Shelf Life	3 Years	3 Years

9. Non-Clinical Bench Testing:

Thermal Effects on Tissue

In accordance with the nonbinding FDA guidance on "Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery", part XI-E, the thermal effects on animal tissue of our device was compared with the predicate device K192542

Ex-vivo kidney, liver, and muscle tissues were used and the thermal damage zone sizes were compared for length, width, and depth.

These tests showed that the thermal effects of our electrode are virtually identical to those shown in the predicate device.

The non-stick performance of our non-stick electrode was found to be similar to the predicate device but without occurring holes and craters as in the predicate device's non-stick coating.

Third party electrical testing:

The device K231405 successfully passed the following electrical tests:

- Conducted Emmisions (150kHz-30MHz)
- Radiated Emissions (30MHz-1GHz)
- Radiated Emissions (1GHz-18GHz)
- Electrostatic Discharge (ESD)
- Radio frequency electromagnetic field radiation immunity
- Power frequency magnetic field

All other EMC tests are not applicable to our device.

The testing was conducted by:

Organization Name: Suzhou Yipin Quality Technical Service Co., Ltd.

Institutional Address: No. 558, Fenhu Avenue, Lili Town, Wujiang District,

Suzhou City, Jiangsu Province
Test Location Name: Suzhou Yipin Quality Technical Service Co., Ltd. Industrial Park Branch
Test Location Address: South side of Building B, No. 5 Minsheng Road, Suzhou Industrial Park 215028
www.epintek.com Tel: 0512-67997780

Third party biocompatibility testing was performed by:
Sanitation & Environment Technology Institute, Soochow University No.199 Ren'ai Road, Suzhou Industrial Park, China
Postcode 215123, www.sudatest.com.
Tel: Direct: +86 512 65880038, Free: 4001078828, Email: med@sudatest.com

Subject device package integrity and functional performance tests were performed in-house in our Jiangsu facilities after aging and real-time stability tests to confirm the proposed shelf life.

10.Conclusion:

The device has been shown to be substantially equivalent to the predicate device in terms of performance and physical and technological characteristics. The devices passed all tests both in-house and by third party qualified labs. It has been deemed safe and conforms to the standards discussed above.