December 11, 2024

Zhejiang CuraWay Medical Technology Co., Ltd.
Ruiran Song
International Registration Engineer
Room 106, Building 1,Room 293, Building 2, No. 600, 21st
Avenue, Baiyang Sub-district, Qiantang New District
Hangzhou, Zhejiang 310000
China

Re: K240758
Trade/Device Name: Radiofrequency Generator, Cura RF Electrode
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: November 14, 2024
Received: November 14, 2024

Dear Ruiran Song:

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,

Long H. Chen -S

Digitally signed by Long H. Chen -S
Date: 2024.12.11 10:39:49 -05'00'

Long Chen, 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)*
K240758

Device Name
Radiofrequency Generator System
Cura RF Electrode

Indications for Use *(Describe)*
Radiofrequency Generator System is used in conjunction with Cura RF Electrode for coagulation and ablation of tissue during percutaneous, laparoscopic, and intraoperative surgical procedures.
The Cura RF Electrode is to be used with Radiofrequency Generator System intended for coagulation and ablation of tissue during percutaneous, laparoscopic, and intraoperative surgical procedures.

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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K240758

510(k) Summary

1 SUBMITTER

Company Name: Zhejiang CuraWay Medical Technology Co., Ltd.
Contact details Address: Room 106, Building 1, No. 600, 21st Avenue, Baiyang Sub-district, Qiantang New District, 310018 Hangzhou City, Zhejiang Province, China
Phone: +86-057187016876
Contact person: Ruiran Song (Miss)
Date prepared: 12/11/2024

2 SUBJECT DEVICE

Trade name: Radiofrequency Generator System

Cura RF Electrode

Common name: Electrosurgical cutting and coagulation device and accessories

Classification name: Electrosurgical cutting & coagulation device & accessories

Review panel: General & Plastic Surgery (SU)

Regulation number: 878.4400

Product code: GEI

3 PREDICATE DEVICES

Primary predicate device: The VIVA combo RF System (K163450)

Secondary predicate device: Star RF Electrode, VIVA RF Electrode (K172012)

4 DESCRIPTION

Radiofrequency Generator System consists of a generator, a peristaltic pump for electrode cooling, a foot switch and a respiratory locator. This Radiofrequency Generator System is used in conjunction with the Cura RF electrode for coagulation and ablation of tissue during percutaneous, laparoscopic, and intraoperative surgical procedures.

The Radiofrequency Generator System is capable of delivering up to 250 W of RF power and the available power is limited through software control, and the power, impedance, current and temperature are monitored by software. The temperature of the electrode's tip is monitored for charring.

The generator generates high frequency alternating current and transferred to the RF electrode. When the connection of the electrode and generator is interrupted, the generator will stop the power output and trigger reminder. When the temperature of RF electrode detected by the generator exceeds 99℃, or the temperature of the neutral electrode reaches the setting temperature, the device will automatically cut off the power output and give a corresponding reminder. The power output can also be manually stopped.

5 INDICATIONS FOR USE

Radiofrequency Generator System is used in conjunction with Cura RF Electrode for coagulation and ablation of tissue during percutaneous, laparoscopic, and intraoperative surgical procedures.

The Cura RF Electrode is to be used with Radiofrequency Generator System intended for coagulation and ablation of tissue during percutaneous, laparoscopic, and intraoperative surgical procedures.

6 SUBSTANTIAL EQUIVALENCE COMPARISON WITH PREDICATE DEVICE

Detailed substantial comparison was made between subject device and predicate device. Please refer to below tables for details.

Substantial equivalence Comparison table of Cura RF Electrode

Comparison Elements	Subject Device	Predicate Device
Classification Regulation	878.4400	878.4400
Product Code	GEI	GEI
510(k) Number	K240758	K172012
Indications for use	The Cura RF Electrode is to be used with Radiofrequency Generator System intended for coagulation and ablation of tissue during percutaneous, laparoscopic, and intraoperative surgical procedures.	star/VIVA RF Electrode is intended for use in percutaneous and intraoperative coagulation and ablation of tissue.
Type of use	Prescription use	Prescription use
Monopolar or bipolar	Monopolar and Bipolar	Monopolar
Model	Cura RF Electrode has three models: - Cura RF Electrode Fixed - Cura RF Electrode Adjustable - Cura RF Electrode Double	star/VIVA RF Electrode has two models: - star RF Electrode_Fixed - VIVA RF Electrode (which is adjustable)

Electrode length (mm)		Monopolar: 70, 100, 150, 200, 250 Bipolar: 43, 103, 143			Monopolar: 70, 150, 200	
Active part length (mm)		Cura RF Electrode Fixed: 5, 7, 10, 15, 20, 25, 30, 40	Cura RF Electrode Adjustable: 5 to 40, and adjustable step is continuously.	Cura RF Electrode Double: 15, 20	star RF Electrode_Fixed: 5, 7, 10, 20, 30	VIVA RF Electrode (Adjustable): 5 to 30, and adjustable step is 5.
Diameter (Gauge)		Monopolar: 15,17,18 Bipolar: 15, 16, 17			Monopolar: 15, 17, 18	
Patient contacting materials	**Electrode Materials**	Stainless steel SUS 304			Stainless steel 304	
	Insulation film Materials	Polyester, Polyimide			Polyester, Polyimide	

Connector type		4 pin	4 pin
Neutral electrode	**Conductive or capacitive**	Conductive	Conductive
	Material (Conductive area)	Hydrogel	Hydrogel
Single use		Single use	Single use
Electrode sterilization		EO	EO

Substantial equivalence Comparison table of Radiofrequency Generator System

Comparison Elements	Subject Device	Predicate Device
Classification Regulation	878.4400	878.4400
Product Code	GEI	GEI
510(k) Number	K240758	K163450
Indications for use	Radiofrequency Generator System is used in conjunction with Cura RF Electrode for coagulation and ablation of tissue during percutaneous, laparoscopic, and intraoperative surgical procedures.	The VIVA combo RF System is intended for use in percutaneous and intraoperative coagulation and ablation of tissue.
Principle	The working frequency of the Radiofrequency Generator System is 480kHz±10%. When the radio frequency current flows through the human tissue, the rapid change of the electromagnetic field causes the positive and negative ions in the cell to move rapidly, so the friction between them, also between them and other molecules and ions causes the lesion to heat up, causing the water inside and outside the cell to evaporate, dry, shrink and fall off, resulting in aseptic necrosis, thereby achieving the purpose of treatment.	The RF generator works at 480kHz±10%. The frequency flows to the electrode's tip and then is applied to the tissue. Frictional heat occurs and causes the ions to move from the negative pole to the positive pole and from the positive pole to the negative pole forty to fifty thousand times per second. Tissue necrosis is the principle that occurs by using heat generated from the tissue impedance.

Type of use		Prescription	Prescription
Energy Used		Radiofrequency	Radiofrequency
Component		Radiofrequency Generator System consists of a generator, a peristaltic pump for electrode cooling, a foot switch and a respiratory locator.	The VIVA combo RF System consists of RF generator, active electrode, grounding pad and peristaltic pump for electrode cooling.
Bipolar or monopolar		Bipolar and Monopolar	Monopolar
Temperature Monitoring		Available	Available
Impedance monitor		Available	Available
Voltage Supply		100-240VAC 50/60 Hz	100-240VAC 50/60 Hz
Continuity monitor		Yes	Yes
Output frequency		480kHZ± 10 %	480kHZ± 10 %
Maximum Power Output		Up to 250 watts at 50 ohm	Up to 200 watts at 50 ohm
Drive on time		Up to 15 minutes	Up to 30 minutes
Crest factor		1.4	1.4
Physical dimension		360(L) x 334(W) x 185(H) mm	260mm (W) x 348mm (L) x 115 mm (H)
Foot	Function	Control the starting and stopping of the energy	Control the starting and stopping of the energy

switch		output.	output.
	Performance specification	Single trigger, IPX 8	Single trigger, IPX 8
Peristaltic pump	Pump type	Peristaltic pump	Peristaltic pump
	Flow rate	With load : 80ml or higher (no load: 120 ml or higher)	With load: 90ml or higher (no load: 120 ml or higher)
Electrical tests		Complied with IEC 60601-1, IEC 60601-2-2 and IEC60601-2-18	Complied with IEC 60601-1 and IEC 60601-2-2
EMC		Complied with IEC 60601-1-2	Complied with IEC 60601-1-2

7 SUMMARY OF NON-CLINICAL DATA

The following performance data were provided in support of the substantial equivalence determination.

Software testing

The software system of Radiofrequency Generator System is embedded software. The power, time, impedance and temperature are monitored by embedded software. Software verification and validation testing were conducted as recommended by IEC 62304:2015 and FDA guidance "Content of Premarket Submissions for Device Software Functions" to support enhanced level.

Ex-vivo tissue testing

The test on thermal effects was performed to evaluate the width and depth of thermally damaged zone in relation to the active part length, gauge, working mode and power setting. The test was performed on liver, kidney, and muscle tissue according to the FDA Guidance 'Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery'.

The test results demonstrated that the proposed device complies with the following standards:

- 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)]
- IEC60601-1-2 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
- IEC/TR 60601-4-2 Edition 1.0 2016-05 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 60601-2-2 Edition 6.0 2017-03 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
- IEC 60601-2-18: Edition 3.0 2009-08 Medical electrical equipment - Part 2-18:Particular requirements for the basic safety and essential performance of endoscopic equipment
- IEC 60601-1-6 Edition 3.1 2013-10 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

- ISO 10993-5 Third edition 2009-06-01 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10 Third Edition 2010-08-01 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
- ISO 10993-11 Third edition 2017-09 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
- ISO 10993-11 Third edition 2017-09 Biological evaluation of medical devices-Part 11: Test for systemic toxicity--Pyrogen test
- ISO 10993-7:2008 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals [Including: Technical Corrigendum 1 (2009)]- EO residual test
- ISO 11135 Second edition 2014-07-15 Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices [Including: Amendment 1 (2018)]
- ISO 11137-2 Third edition 2013-06 [Including AMD1:2022] Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose [Including Amendment 1 (2022)]
- ASTM F1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

8 CONCLUSION

The subject device is substantially equivalent to the currently marketed and predicate devices in terms of design features, fundamental scientific technology, indications for use, and safety and effectiveness.The standards testing and nonclinical performance testing demonstrates the subject device technological characteristics are equivalent to the predicate device for coagulation and ablation of tissue during percutaneous, laparoscopic, and intraoperative. In conclusion, the subject device is substantially equivalent to the predicate device.