May 30, 2024

Zhejiang CuraWay Medical Technology Co., Ltd.
Ruiran Song
Regulatory Affairs Officer
Building 1, No.600, 21st street, Qiantang New Area
Hangzhou, Zhejiang 310018
China

Re: K232505
Trade/Device Name: Endovenous Radiofrequency Generator, Endovenous Radiofrequency Catheter
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: NA
Received: April 30, 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.

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: 2024.05.30 17:54:33 -04'00'

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)*
K232505

Device Name
Endovenous Radiofrequency Generator
Endovenous Radiofrequency Catheter

Indications for Use *(Describe)*
The JM-S40 Endovenous Radiofrequency Generator is intended for use with CuraWay's Endovenous RF Catheter intended for vessel and tissue coagulation.
The Endovenous Radiofrequency Catheter is intended to be used with CuraWay's JM-S40 Endovenous RF Generator indicated for endovascular coagulation of blood vessels in patients with superficial vein reflux.

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

Company Name/Owner	Zhejiang CuraWay Medical Technology Co., Ltd.
Contact person/Author	Ruiran Song (Miss)
Date prepared	05/29/2024
Contact details Address	Room 106, Building 1,Room 293, Building 2, No. 600, 21st Avenue, Baiyang Sub-district, Qiantang New District, 310018, Hangzhou City, Zhejiang Province, China
Trade name	Endovenous Radiofrequency Generator (JM-S40) Endovenous Radiofrequency Catheter
Common name	Electrosurgical device
Classification name	Electrosurgical cutting and coagulation device and accessories
Review panel	General & Plastic Surgery (SU)
Regulation number	878.4400
Product code	GEI
Predicate device	VNUS Radiofrequency Generator (K040638) VNUS®Closure FAST™ Catheter(K061373)

Description

The JM-S40 Endovenous Radiofrequency Generator includes a host and a power cord. The JM-S40 Endovenous Radiofrequency Generator is intended to be used with the Endovenous Radiofrequency Catheter for vessel and tissue coagulation. The JM-S40 Endovenous Radiofrequency Generator outputs RF energy and the Endovenous Radiofrequency Catheter is the applied part. The JM-S40 Endovenous Radiofrequency Generator has simple operation and simple interface, and can accurately provide real-time monitoring of temperature, power and time during RF output.

The generator generates high frequency alternating current and transfers to the catheter. When the cable of the catheter or its connection is interrupted, the host will stop the power output and trigger alarm. When the temperature of catheter detected by the generator exceeds 130℃, the device will automatically cut off the power output and give a corresponding reminder. The power output can also be manually stopped.

Indications for use

The JM-S40 Endovenous Radiofrequency Generator is intended for use with CuraWay's Endovenous RF Catheter intended for vessel and tissue coagulation.

The Endovenous Radiofrequency Catheter is intended to be used with CuraWay's JM-S40 Endovenous RF Generator indicated for endovascular coagulation of blood vessels in patients with superficial vein reflux.

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 Endovenous Radiofrequency Catheter

Comparison Elements	Subject Device	Predicate Device	Comment
Classification Regulation	878.4400	878.4400	Identical
Product Code	GEI	GEI	Identical
510(k) Number	K232505	K061373	
Indications for use	The Endovenous Radiofrequency Catheter is intended to be used with CuraWay's JM-S40 Endovenous RF Generator indicated for endovascular coagulation of blood vessels in patients with superficial vein reflux.	The VNUS®Closure FAST™ Catheter is intended for endovascular coagulation of blood vessels in patients with superficial vein reflux.	Identical
Monopolar or bipolar	Bipolar	Bipolar	Identical
Catheter length(cm)	60, 100	60, 100	Identical
Heating element length(cm)	1, 2, 3, 5, 7	3, 7	Different. More available catheter dimensions are designed for different clinical application, it will not impact device safety and effectiveness.
Outer diameter of catheter(mm)	1.6, 2.0, 2.3	2.3	
Patient contact Materials	PET, FEP, PEEK	PET, FEP, PEEK	Identical
Connector type	8 pin	7 pin	Different. Connector type is dependent on design specifications. The difference

			will not impact device safety and effectiveness.
Disposable /Single-use Device	The RF catheters are disposable and are to be used within a single patient procedure only.	The RF catheters are disposable and are to be used within a single patient procedure only.	Identical
RF Catheter sterilization	EO	EO	Identical
Biological tests	Test for Cytotoxicity, irritation, sensitization,Acute system toxicity, Pyrogen, Hemocompatibility, Genotoxicity was performed according to ISO 10993-1 Fifth edition 2018-08 requirements	Not available	

Substantial equivalence Comparison table of Endovenous Radiofrequency Generator

The predicate device VNUS Radiofrequency Generator can worked with two types of catheters: Closure FAST™ Catheter and ClosureRFS Catheter, when working with different catheter, the parameters of the VNUS Radiofrequency Generator are slightly different. The subject device (Endovenous Radiofrequency Catheter) is equivalent to the Closure FAST™ Catheter (predicate device), so the comparison of the generator will only be applied to the following condition:

- Subject device: JM-S40 Endovenous Radiofrequency Generator working with the Endovenous Radiofrequency Catheter
- Predicate device: VNUS Radiofrequency Generator working with Closure FAST™ Catheter

The following is the detailed comparison table:

Comparison Elements	Subject Device	Predicate Device	Comment

Classification Regulation	878.4400	878.4400	Identical
Product Code	GEI	GEI	Identical
510(k) Number	K232505	K040638	
Indications for use	TheJM-S40 Endovenous Radiofrequency Generator is intended for use with CuraWay's Endovenous RF Catheter intended for vessel and tissue coagulation.	The VNUS Radiofrequency Generator is intended for use with VNUS radiofrequency devices intended for vessel and tissue coagulation.	Identical
Principle	The Endovenous Radiofrequency Generator JM-S40 will be worked together with the Endovenous Radiofrequency Catheter. The generator generates and transfers the RF current to the catheter and control the current output via software algorithm to heat the vein wall continuously. The high temperature makes the vascular endothelial degeneration, collagen contraction, tube wall thickening, rapid mechanical and fibrosis to achieve the clinical purpose.	The VNUS Radiofrequency Generator (RFGPLUS) is a product of VNUS Medical Technologies, Inc. It is designed to provide controlled delivery of radiofrequency (RF) energy to RF Devices (e.g., catheters). The generator generates and transfers the RF current to the catheter and control the current output via software algorithm so as to heat the vein wall continuously. The high temperature makes the vascular endothelial degeneration, collagen contraction, tube wall thickening, rapid mechanical and fibrosis to achieve the clinical purpose.	Identical
Working mode	Coagulation	Coagulation	Identical

Prescription or OTC	Prescription	Prescription	Identical
Energy Used	Radiofrequency	Radiofrequency	Identical
EUS			
Component	JM-S40 Endovenous Radiofrequency Generator consists of generator and power cord.	VNUS Radiofrequency Generator consists of generator and power cord.	
Bipolar or monopolar	Bipolar	Bipolar	Identical
Temperature Monitoring	Available	Available	Identical
Temperature control range	95~120℃	95~120℃	Identical
Impedance monitor	Available	Available	Identical
Voltage Supply	100-240VAC 50/60 Hz	100-240VAC 50/60 Hz	Identical
Continuity monitor	Yes	Yes	Identical
Output frequency	480kHZ	460 kHz	Different. The Output Frequency of the device have difference with the equivalent device,this difference is small and does not affect thermal efficiency. Animal testing results provided to demonstrate equivalence.
Maximum Power Output	Endovenous Radiofrequency Catheter 7cm: 40W (@200Ω), Endovenous Radiofrequency	ClosureFAST 7cm: 40W (@200Ω), ClosureFAST 3cm: 18W (@200Ω),	Different. There are more length specifications available for subject device than that of predicate

	Catheter 5cm: 30W (@200Ω), Endovenous Radiofrequency Catheter 3cm: 18W (@200Ω), Endovenous Radiofrequency Catheter 2 cm: 12W (@200Ω), Endovenous Radiofrequency Catheter 1cm: 6W (@200Ω),		device, different catheter length has different max. Power output. The longest catheter is 7cm for both predicate device and subject device, their max. Power output is the same. Other shorter lengths catheter have lower power output, which will not raise any safety risks, and the effectiveness of the shorter lengths catheters are demonstrated by the ex-vivo animal testing.
Drive on time	10 to 40s	10 to 40s	Identical
Crest factor	1.4	1.7	Different.The electrical safety test has been performed on the proposed device. The test result show that the device can operate normally and comply with related standard requirement. The difference

			will not affect the safety and effectiveness.
Physical dimension	320mm(L)×270mm(W)×145mm(H)	38 cm x 38 cm x 19 cm (15 in. x 15 in. x 7.5 in.)	Different. Size difference will not impact device safety and effectiveness.
Electrical tests	Complied with IEC 60601-1 and IEC 60601-2-2	Not available	
EMC	Complied with IEC 60601-1-2	Not available	

Software description

The software system of JM-S40 Endovenous Radiofrequency Generator is embedded software, which is written in C language and is developed on the Atollic TrueSTUDIO integrated development compilation software. The power, time, impedance, and temperature are monitored by embedded software. IEC 62304:2015 and FDA Guidance Content of Premarket Submissions for Device Software Functions were used as reference documents during software design verification/validation.

Non-Clinical Performance Testing

Non-clinical tests were conducted to verify that the subject devices met all design specifications.

Ex-vivo tissue thermal spread testing using bovine liver tissue was performed. The result showed the ablation effect and ablation zones of the subject device is substantial equivalent to the predicate device and the reference device.

In-vivo animal (goat) testing was conducted to compare the subject device group and predicate device group in following aspects: general observe, blood routine, blood biochemistry,Ultrasound Monitoring, Histopathological examination, intravascular blood coagulation, vascular wall thermal damage and vascular wall inflammation.

Safety Standards Testing

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

- ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)
- IEC60601-1-2:2014 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 60601-1-6 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 10993-4 Third edition 2017-04 Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood
- ISO 10993-3 Third edition Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
- Chinese Pharmacopoeia (2020 version) Bacteria Endotoxins 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

Conclusion

The indications for use of subject device are equivalent to the predicate device. The standards testing and nonclinical performance testing demonstrates the subject device technological characteristics are equivalent to the predicate device for endovascular coagulation of blood vessels in patients with superficial vein reflux.In conclusion, the subject device is substantially equivalent to and as safe and effective as the predicate.