June 8, 2023

Zhejiang CuraWay Medical Technology Co., Ltd.
Xiaoyu Guan
Regulatory Affairs Manager
Building 1, No.600, 21st street, Qiantang New Area
Hangzhou, Zhejiang 310018
China

Re: K222001
Trade/Device Name: Irreversible Electroporation Ablation Generator, Irreversible Electroporation Probe
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: OAB
Dated: May 8, 2023
Received: May 8, 2023

Dear Xiaoyu Guan:

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: 2023.06.08 11:40:14 -04'00'

Mark Trumbore, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
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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)*

K222001

Device Name
Irreversible Electroporation Ablation Generator
Irreversible Electroporation Probe

Indications for Use *(Describe)*
The Irreversible Electroporation Ablation Generator is indicated for the surgical ablation of soft tissue.

The Irreversible Electroporation Probe is used in conjunction with Irreversible Electroporation Ablation Generator of CuraWay indicated for the surgical ablation of soft tissue.

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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K222001 510(K) Summary

Company Name/Owner	Zhejiang CuraWay Medical Technology Co., Ltd.
Contact person/Author	Xiaoyu Guan(Miss)
Date prepared	06/06/2023
Contact details Address	Room 106, Building 1, No. 600, 21st Avenue, Baiyang Sub-district, Qiantang New District, 310018, Hangzhou City, Zhejiang Province, China
Trade name	Irreversible Electroporation Ablation Generator Irreversible Electroporation Probe
Common name	Low energy direct current ablation device
Classification name	Low Energy Direct Current Thermal Ablation System
Review panel	General & Plastic Surgery (SU)
Regulation number	878.4400
Product code	OAB
Predicate device	Nanoknife system (K183385)
Reference device	The VIVA combo RF System (K163450)

Device Description

The Irreversible Electroporation Ablation Generator consists of a generator, foot switch and power cord. The generator will be used together with the Irreversible Electroporation Probe and Neutral Electrode.
The Irreversible Electroporation Probe has two types: monopolar probe and bipolar probe. Monopolar probe also has two types: Standard Probe and Activation Probe.

The Irreversible Electroporation Ablation Generator has three working modes:

- Mode 1: Monopolar steep pulse mode;
- Mode 2: Bipolar steep pulse mode;
- Mode 3: Needle Track Coagulation.

Mode 1 and Mode 2 are used for soft tissue ablation, the working principle is that the generator transfers non-thermal energy to electrodes which are placed at the target area, it will release high-voltage electrical pulses forming nano-scale permanent perforations on the soft tissues to disrupt the intracellular balance and induce cell apoptosis. The cells die and are removed by the human body's own lymphatic system.

The Mode 3 is used for the soft tissue coagulation during the process when the probe is pulled out. This module works at 480kHZ, the high frequency flows to the probe's tip and then is applied to the tissue. Frictional heat occurs and causes the ions to move between the negative pole and the positive pole 40,000 to 50,000 times per second. Heat generated from the tissue impedance induces tissue necrosis.

Subject device can work at ECG synchronization trigger mode. During this mode, an external R-wave detector must be connected. R-wave detector monitors the patient's cardiac rate and transfers it to R waves which will be detected by the generator and then a pulse will be triggered. Every time a R wave is detected, one pulse is triggered such that every time the heart beats, a pulse will be triggered, so that the electroporation pulses can be triggered and delivered in proper synchronization with the patient's cardiac rhythm.

Indications for use
The Irreversible Electroporation Ablation Generator is indicated for the surgical ablation of soft tissues.

The Irreversible Electroporation Probe is used in conjunction with Irreversible Electroporation Ablation Generator of CuraWay indicated for the surgical ablation of soft tissue.

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

Comparison Elements	Subject Device	Predicate Device	Reference Device	Comment
Classification Regulation	878.4400	878.4400	878.4400	Identical
Product Code	OAB, GEI	OAB	GEI	Identical
510(k) Number	-	K183385	K163450	
Indications for use	The Irreversible Electroporation Ablation Generator is indicated for the surgical ablation of soft tissues.	The NanoKnife System with six outputs is indicated for the surgical ablation of soft tissue.	The VIVA combo RF System is intended for use in percutaneous and intraoperative coagulation and ablation of tissue.	Identical
Principle	The Irreversible Electroporation Ablation Generator has three working modes: Monopolar steep pulse mode (Mode 1), Bipolar steep pulse mode (Mode 2) and Needle Track Coagulation (Mode 3). Mode 1 and Mode 2 are used	The Nanoknife System uses a series of microsecond electrical pulses to open “pores” in the cell membranes. The electrical pulses are delivered through several needle-like probes placed into or around the ablation zone under CT or ultrasound	The RF generator works at 500kHz. 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	Identical

Comparison Elements	Subject Device	Predicate Device	Reference Device	Comment
	for soft tissue ablation, the working principle is that the generator transfers non-thermal energy to electrodes which are placed at the target area, it will release high-voltage electrical pulses forming nano-scale permanent perforations on the soft tissues to disrupt the intracellular balance and induce cell apoptosis. The cells die and are removed by the human body's own lymphatic system. The Mode 3 is used for the soft tissue coagulation during the process when the probe is pulled out. This module works at 480kHZ, the high frequency flows to the probe's tip and then is applied to the tissue. Frictional heat occurs and	guidance. By applying enough high voltage energy, the open pores cause irreversible damage to the cells. The cells die and are removed by the human body's own lymphatic system.	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.	

Comparison Elements		Subject Device	Predicate Device	Reference Device	Comment
		causes the ions to move from the negative pole to the positive pole and from the positive pole to the negative pole 40,000 to 50,000 times per second. Tissue necrosis is the principle that occurs by using heat generated from the tissue impedance.			
Working mode		Mode 1: Monopolar steep pulse mode Mode 2: Bipolar steep pulse mode Mode 3: Needle track coagulation	Steep pulse mode	Coagulation	Identical
Prescription or OTC		Prescription	Prescription	Prescription	Identical
Component		Irreversible Electroporation Ablation Generator, electroporation probes, neutral electrode, foot switch	NanoKnife Generator, Electrode Probes, Foot Pedal	Electrosurgical unit, active electrode, grounding pad, peristaltic pump and foot pedal	
ESU	Bipolar or monopolar	Bipolar and Monopolar	Bipolar	Monopolar	Different. The subject device has

Comparison Elements			Subject Device	Predicate Device	Reference Device	Comment
						two configurations. It does not impact device safety and effectiveness
	Pulse Amplitude/Voltage output		500 ~ 3000V	500 ~ 3000V	N/A, no pulse mode	Identical
	Pulse amplitude precision		±5%	±5%	N/A, no pulse mode	Identical
	Maximum Output Current	Pulse mode	~50A	~50A	N/A, no pulse mode	Identical
		Needle Track Coagulation Mode	1A	N/A	2A	Different. The working current is less than that of the Reference device.
	Pulse width	monophasic pulse mode	20 ~ 120μs	20 ~ 100μs	N/A, no pulse mode	Different. The pulse width of monopolar mode is wider than that of predicate device. Animal test results provided to
		biphasic pulse mode	5 ~ 40μs	N/A, no biphasic configuration	N/A, no pulse mode	

Comparison Elements		Subject Device	Predicate Device	Reference Device	Comment
					demonstrate equivalence.
	Pulse width precision	±2μs or ±2%(whichever is larger)	±2μs or ±2% (whichever is larger)	N/A,no pulse mode	Identical
	Number of pulse(s)	1 ~ 200	10 ~ 100	N/A, no pulse mode	Different. The difference is between allowable adjustment range.
	Volts/cm	500 ~ 3000	500 ~ 3000	N/A, no pulse mode	Identical
	Maximum probes	6	6	N/A, no pulse mode	Identical
	Pulse frequency, Un-sync	30~ 240PPM/every 10 pulse	240PPM/every 10 pulse 90PPM/every 10 pulse	N/A, no pulse mode	Different. The highest pulse frequency of subject device is same as that of predicate device.

Comparison Elements			Subject Device	Predicate Device	Reference Device	Comment
	Pulse frequency, Sync		ECG, frequency varies depending on heart rate, <120PPM	ECG, frequency varies depending on heart rate	N/A, no pulse mode	Different. For subject device, frequency varies depending on heart rate below 120PPM
	ECG synchronization triggering		Yes	Yes	N/A, no pulse mode	Identical
	Temperature sensors		None	None	yes	Identical to Predicate.
	Impedance monitor		Yes	Yes	Yes	Identical
	Continuity monitor		Yes	Yes	Yes	Identical
	RF Output frequency		480kHZ± 10 %	N/A (refer to Pulse frequency)	480kHZ± 10 %	Identical to Reference
	Waveform	monophasic	Square wave with steep edge (one direction)	Square wave with steep edge (one direction)	Square wave with steep edge (one direction)	Different, both the predicate device and reference device have no biphasic waveform. Animal tissue ablation testing
		biphasic	Square wave with steep edge (alternative direction)	N/A, no bipolar configuration	N/A, no bipolar configuration	

Comparison Elements		Subject Device	Predicate Device	Reference Device	Comment
					demonstrate safety and effectiveness
	Maximum Energy per Pulse (normal)	Up to 40 watts at 50Ω (18J)	15J	Up to 200 watts at 50 ohm	Different. The maximum power output is almost the same with the predicate device.
	Drive on time	It will stop working when the impedance is up to 800Ω	N/A, no needle track coagulation	Up to 30 minutes, and will stop working when the impedance is up to 800Ω	Identical to the reference device
	Crest factor	1.414	1.414	1.414	Identical
	Physical dimension	460mm(L)×410mm (W) ×200mm (H)	680mm(L) x 560 mm(W) x 1490 mm(H)	193mm (W) x 60mm(H) x 135 mm(D)	Different. Size difference does not impact safety and effectiveness.
Active Accessory	Monopolar or bipolar	Monopolar and Bipolar	Monopolar	Monopolar	Different. The subject device has two configurations, it

Comparison Elements		Subject Device	Predicate Device	Reference Device	Comment
					does not impact safety and effectiveness
	Physical dimension	The following lengths of Monopolar Probe are available: 13cm, 15cm, 18cm, 25cm. Working length is adjustable in 0.5 cm increments from 0 – 4 cm via the thumbslide. Probe needle size: 19G Bipolar Probe lengths: 15cm, 25cm. Working length is 1cm, 2cm, 3cm and 4cm. Probe needle size: 18G, 15G.	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.	Monopolar length: 15 cm, 20cm, working length 0.5cm, 1cm, 1.5cm, 2cm, 2.5cm and 3cm. Probe needle size: 15G and 17G. Bipolar: not available.	Different. More available probe dimensions are designed for different clinical application. No impact safety and effectiveness.
	Connector type	6 pin	6 pin	1 pin	Different. Connector type is dependent on design specifications. The difference does not impact safety and effectiveness.

Comparison Elements			Subject Device	Predicate Device	Reference Device	Comment
	Patient contact Materials	monopolar	Stainless steel, PI	Stainless steel, PI	Stainless steel, PI	Different. All materials meet ISO 10993-1 biocompatibility requirement.
		bipolar	Stainless steel, PI,PTFE	N/A, no bipolar configuration	N/A,no bipolar configuration	
Neutral electrodes	Conductive or capacitive	Conductive		N/A, no neutral electrodes	Conductive	Identical to Reference
	Materials	Hydrogel			Hydrogel	
Foot Switch	Functions	Control the starting and stopping of the energy output.		Control the starting and stopping of the energy output.	Control the starting and stopping of the energy output.	Identical
	Performance specification	Single trigger, IPX 8		Double trigger, IPX 8	Single trigger, IPX 8	Different. The difference does not impact safety and effectiveness.

Software description

The software is a built-in(embedded) software. The main function of it is to support Irreversible Electroporation Ablation Generator to achieve its intended use. It comprises of 11 submodules including user interface, IRE process control, coagulation process control, sensor measurement, button control, warning judgement, data storage, power output calibration, preoperative plan, postoperative analysis, and ECG synchronization. IEC62304:2015 and Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (Issued on May 11,2005) were used as reference documents during software design verification/validation.

Non-Clinical Tests

Non-clinical tests were conducted to verify that the subject devices met all design specifications and is substantially equivalent to the predicate.

Ex-vivo tissue testing using swine muscle tissue, liver tissue and kidney 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.

ECG trigger mode testing was conducted to compare ECG synchronization trigger mode of subject to that of the predicate device.

In-vivo animal (swine) testing was conducted to compare the subject device group and predicate device group in following aspects: blood routine, blood biochemistry, myocardial enzymes and the diameter of ablation. The long ablation diameter and short ablation diameter of subject device group was compared to those of predicate device.

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
- Chinese Pharmacopoeia (2020 version) Bacteria Endotoxins Test
- ISO 10993-7:2008 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
- 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
- ISO 11137-2:2019 Sterilization of health care products - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
- ASTM F1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

Clinical data

No clinical data was provided.

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 general soft tissue electroporation. In conclusion, the subject device is substantially equivalent to the predicate device.