September 26, 2024

Canyon Medical Inc.
Huiqi Jiang
RA Manager
Building 3, Phase 2 Accelerator, No. 11 Yaogu Avenue
Jiangbei New Area
Nanjing, Jiangsu Province 210032
China

Re: K241827
Trade/Device Name: Microwave Ablation Generator (KY-2000A, KY-2100A)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: NEY
Dated: August 29, 2024
Received: August 30, 2024

Dear Huiqi Jiang:

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: 2024.09.26 15:18:55 -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)*
K241827

Device Name
Microwave Ablation Generator (KY-2000A, KY-2100A)

Indications for Use *(Describe)*
Microwave Ablation Generator is indicated for the coagulation (ablation) of soft tissue.
The device is not intended for cardiac use.

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.

1. 510(k) Owner

Canyon Medical Inc.

2. Submission Correspondent

Submitter Name: Canyon Medical Inc.

Address: Building 3, Phase 2 Accelerator, No. 11 Yaogu Avenue, Jiangbei New Area, 210032, Nanjing, Jiangsu Province, People's Republic of China

Official Correspondent: Ms. Huiqi Jiang

Position: RA Manager

E-mail: jhq@canyonmedical.com.cn

Telephone: +86-13241196637

3. Date of Preparation: September 25, 2024

4. Subject Device(s) Information

Common Name:	Microwave Ablation Generator
Trade Name:	Microwave Ablation Generator (KY-2000A, KY-2100A)
Review Panel:	General & Plastic Surgery
Regulation Number:	21 CFR 878.4400
Regulation Description:	Electrosurgical cutting and coagulation device and accessories
Classification Name:	System, Ablation, Microwave and Accessories
Device Class:	II
Product Code:	NEY

5. Predicate Device(s) Information

Manufacturer:	Nanjing ECO Microwave System Co., Ltd.
510(K) Number:	K201262
Trade Name:	Microwave Therapeutic System
Review Panel:	General & Plastic Surgery
Regulation Number:	21 CFR 878.4400
Regulation Description:	Electrosurgical cutting and coagulation device and accessories
Classification Name:	System, Ablation, Microwave and Accessories
Device Class:	II
Product Code:	NEY

6. Device Description

Microwave ablation is a kind of thermal ablation technology used in the treatment of soft tissue, utilizing electromagnetic waves in the microwave energy spectrum (300 MHz to 300 GHz) to produce tissue-heating effects. The oscillation of polar molecules produces frictional heating, ultimately generating tissue necrosis.

Microwave Ablation Generator consists of microwave source, pump, foot pedal etc. It is a software-controlled microwave generator that delivers the microwave energy at a working frequency of 2450 MHz and can meet various clinical needs of soft tissue ablation therapy. Microwave Ablation Generator delivers microwave energy to Microwave Ablation Antennas into the target tissue through Microwave Ablation Cable(sterile or non-sterile cable). When reaching the target temperature, the soft tissue will be damaged, leading to irreversible necrosis. The Microwave Ablation Temperature Probe is applied to monitor the temperature of the target location and to protect important organs and tissues in the periphery of the lesion from unexpected damage by microwave energy. Coagulated zones are monitored during treatment using appropriate imaging techniques.

7. Indications for Use

Microwave Ablation Generator is indicated for the coagulation (ablation) of soft tissue.

The device is not intended for cardiac use.

8. Summary and Comparison of Technological Characteristics

Equivalence comparison has been identified with following summary of technical characteristics:

Item	Subject Device - K241827		Predicate Device - K201262
Device	**Microwave Ablation Generator Model: KY-2000A**	**Microwave Ablation Generator Model: KY-2100A**	**Microwave Therapeutic System Model: SABERWAVE ECO-200G**
Classification	Class II	Class II	Class II
Product Code	NEY	NEY	NEY
Regulation Number	21 CFR 878.4400	21 CFR 878.4400	21 CFR 878.4400
Indications for Use	Microwave Ablation Generator is indicated for the coagulation (ablation) of soft tissue. The device is not intended for cardiac use.	Microwave Ablation Generator is indicated for the coagulation (ablation) of soft tissue. The device is not intended for cardiac use.	The Microwave Therapeutic System is indicated for the coagulation (ablation) of soft tissue. The Microwave Therapeutic System is not intended for cardiac use.
Operating Principle	Microwave Ablation Generator with frequency of 2450MHz delivers microwave energy to Microwave Ablation Antennas into the target tissue through Microwave Ablation Cable(sterile or non-sterile cable). When reaching the target temperature, the soft tissue will be damaged, leading to irreversible necrosis.	Microwave Ablation Generator with frequency of 2450MHz delivers microwave energy to Microwave Ablation Antennas into the target tissue through Microwave Ablation Cable(sterile or non-sterile cable). When reaching the target temperature, the soft tissue will be damaged, leading to irreversible necrosis.	Microwave oscillating signals are generated by a microwave transistor and amplified by a microwave power amplifier. Generator delivers microwave energy to the applicator tip to thermally target tissue, resulting in coagulation and ablation. A microwave therapeutic system refers to equipment for treating diseases with microwave energy at a working frequency of 2450 MHz. The liquid in the silicone tube is driven by the rotation of the motor to flow through the radiator to realize the purpose of radiator cooling.
AC input Voltage	AC100-240V, 50/60Hz	AC100-240V, 50/60Hz	AC100-240V, 50/60Hz
Frequency	2450MHz	2450MHz	2450MHz

Item	Subject Device - K241827		Predicate Device - K201262
Device	**Microwave Ablation Generator Model: KY-2000A**	**Microwave Ablation Generator Model: KY-2100A**	**Microwave Therapeutic System Model: SABERWAVE ECO-200G**
Output Impedance	50Ω	50Ω	50Ω
Output power parameter	Up to 100W	Up to 150W	Up to 100W
Device Temperature Monitoring	Temperature monitoring features used to ensure safety	Temperature monitoring features used to ensure safety	Temperature monitoring features used to ensure safety
Device Cooling	Pumped, coolant is used to cool the antenna.	Pumped, coolant is used to cool the antenna.	Pumped, normal saline is used to cool the antenna.
Operational Mode	Three modes: continuous mode, pulse mode, foot pedal mode	Three modes: continuous mode, pulse mode, foot pedal mode	Three modes: continuous mode, pulse mode, foot pedal mode
Electricity safety	Meet requirements of IEC 60601-1	Meet requirements of IEC 60601-1	Meet requirements of IEC 60601-1
Electromagnetic compatibility	Meet requirements of IEC 60601-1-2	Meet requirements of IEC 60601-1-2	Meet requirements of IEC 60601-1-2
Software	Embedded software which meets requirements of IEC 62304	Embedded software which meets requirements of IEC 62304	Embedded software which meets requirements of IEC 62304
Particular requirement for microwave therapy safety	Meet requirements of IEC 60601-2-6	Meet requirements of IEC 60601-2-6	Meet requirements of IEC 60601-2-6

The technological characteristics of the subject device are identical to those of predicate devices. The subject devices have the same basic design as the predicate device. The comparison between the subject and predicate devices is based on the following:

- Same indications for use
- Same fundamental technology

There is no significant risk raised by the difference.

9. Non-Clinical Test Summary

Non-clinical performance data is provided in support of the substantial equivalence determination:

1) Electrical Safety as per IEC 60601-1

2) Electromagnetic Compatibility as per IEC 60601-1-2

3) Specific Performance as per IEC 60601-2-6

4) Software validation as per IEC 62304 and FDA Guidance: Content of Premarket Submissions for Device Software Functions.

5) Thermal Effects Test and Temperature Monitoring Test

FDA Guidance: Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery

10. Conclusion

The conclusions drawn from the comparison, analysis, and nonclinical testing above demonstrate that the proposed subject devices raise no new questions of safety or effectiveness, and are as safe, as effective, and performs as well as the legally marketed predicate devices for proposed indications for use.