September 20, 2024

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

Re: K241825
Trade/Device Name: Microwave Ablation Antennas
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: NEY
Dated: June 21, 2024
Received: June 24, 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: 2024.09.20 06:10:53 -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)*
K241825

Device Name
Microwave Ablation Antennas

Indications for Use *(Describe)*
Microwave Ablation Antennas, in conjunction with the compatible Microwave Ablation Generator, is intended for coagulation (ablation) of soft tissue.
This 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

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 19, 2024

4. Subject Device(s) Information

Common Name:	Microwave Ablation Antennas
Trade Name:	Microwave Ablation Antennas
Regulation Number:	21 CFR 878.4400
Classification Name:	System, Ablation, Microwave and Accessories
Device Class:	II
Product Code:	NEY
Review Panel:	General & Plastic Surgery

5. Predicate Device(s) Information

Manufacturer:	Nanjing ECO Microwave System Co., Ltd.
510(K) Number:	K201265
Trade Name:	Disposable Microwave Therapeutic Antennas
Regulation Number:	21 CFR 878.4400
Classification Name:	System, Ablation, Microwave and Accessories
Device Class:	II
Product Code:	NEY
Review Panel:	General & Plastic Surgery

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 Antennas generally consist of the Microwave Ablation Antennas, Microwave Ablation Cable. This device is single-use and sterilized by EO.

During ablation, Microwave Ablation Antennas will be punctured into the target tissue of the patients. In order to achieve the intended use, Microwave Ablation Antennas shall be connected with Microwave Ablation Generator which deliver microwave energy to Microwave Ablation Antennas through Microwave Ablation Cable (sterile or non-sterile cable). When reaching the target temperature, the soft tissue will be damaged leading to irreversible necrosis. Coagulated zones are monitored during treatment using appropriate monitoring techniques.

7. Indications for Use

Microwave Ablation Antennas, in conjunction with the compatible Microwave Ablation Generator, is intended for coagulation (ablation) of soft tissue.

This 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-**K241825	**Predicate Device-K201265**
Device	**Microwave Ablation Antennas**	**Disposable Microwave Therapeutic Antennas**
Classification	Class II	Class II
Product Code	NEY	NEY
Regulation Number	21 CFR 878.4400	21 CFR 878.4400
Indications for Use	Microwave Ablation Antennas, in conjunction with the compatible Microwave Ablation Generator, is intended for coagulation (ablation) of soft tissue. This device is not intended for cardiac use.	Disposable Microwave Therapeutic Antennas is used with the Microwave Therapeutic System, which is indicated for the coagulation (ablation) of soft tissue. The Disposable Microwave Therapeutic Antennas is not intended for cardiac use.
Operating Principle	During the surgery, the Microwave Ablation Antennas is accurately placed in the target area by imaging techniques (such as CT, US, etc.). The microwave energy generated by the microwave generator transmits to the Microwave Ablation Antennas through Microwave Ablation Cable. When reaching the target temperature, the soft tissue will be damaged leading to irreversible necrosis. Coagulated zones are monitored during treatment using appropriate monitoring techniques.	During the surgery, the microwave ablation antenna is accurately placed in the tumor target area by imaging techniques (such as CT, US, etc.). The microwave energy generated by the microwave generator transmits to the microwave ablation antenna through the coaxial cable, and then it is radiated out through the microwave antenna and absorbed by water molecules in the tumor tissue. The microwave energy transform into heat, and the temperature rises rapidly result in tumor tissue losing bioactivity.
Shaft length (mm)	70, 80, 100, 130, 150, 180, 200, 250, 300, 1200mm	100, 150, 200, 250, 1000, 1200mm
Antenna outer diameter(G)	13G, 14G, 15G, 16G, 17G, 18G, 19G, 20G	8G, 11G, 14G, 15G, 16G, 17G, 18G
Antenna active tip(mm)	3, 5, 11, 25, 28mm	3.5, 6, 8, 11, 12, 18mm
Max tolerable power	Up to 150W	Up to 100W
Sterilization method	EO gas	EO gas
Single Use	Yes	Yes
Device Temperature Monitoring	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.

Item	**Subject Device-**K241825	**Predicate Device-K201265**
Device	**Microwave Ablation Antennas**	**Disposable Microwave Therapeutic Antennas**
Patient-contacting information	Externally communicating device, in contact with the patient for a limited duration (no more than 24 hours)	Externally communicating device, in contact with the patient for a limited duration (no more than 24 hours)
Biocompatibility	Biocompatible according to ISO 10993 applicable parts	Biocompatible according to ISO 10993 applicable parts

The technological characteristics of the subject device are similar to those of predicate device. The subject device has 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 technological characteristics

• Same material types that meet ISO 10993 biocompatibility requirements

• Same sterilization methods

• Same fundamental technology

There is no significant risk raised by the difference.

9. Non-Clinical Test Summary

Non-clinical performance data is performed to evaluate the performance and functionality of the subject device against requirement specification. The subject device has been subjected to compliance testing according to, by FDA, recognized consensus standards IEC 60601-1, IEC 60601-1-2, IEC 60601-2-6, ISO 10993 series standards, ISO 11607-1, ISO 11607-2, ASTM F 1980, and specific FDA guidance etc. Results from testing performed confirm the design requirements.

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) Thermal Effects Test and Temperature Monitoring Test:

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

5) Biocompatibility

The subject devices are externally communicating medical devices with tissue less than 24h which means limited duration. Relevant tests are conducted as per ISO 10993 series standards.

6) Package Validation

Primary package of the proposed device is intended to maintain the sterility of the product during its claimed shelf life. The integrity performance as per ISO 11607-1 and ISO 11607-2 is carried out.

7) Transport

Subject devices are processed by compression, first vibration, shock and second vibration, and then check. The result indicates that packaging is not damaged.

8) Shelf Life

Accelerated aging was used to simulate the storage of 3 years and the test results demonstrate that the aged samples complied with the pre-determined acceptance criteria.

9) EO/ECH Residual

Examination of the EO and ECH residuals have been conducted in accordance with ISO 10993-7 to evaluate whether the sterilized proposed device comply with the above selected allowable limits, and the results meet the requirements.

10. Conclusion

The conclusions drawn from the comparison, analysis, 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.