October 28, 2026

Canyon Medical, Inc.
Huiqi Jiang
RA Manager
Bldg. 3, Phase 2 Accelerator, #11 Yaogu Ave., Jiangbei New Area, 210032
Nanjing, Jiangsu Province, People'S Republic Of China
Nanjing,
China

Re: K261636
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: September 29, 2026
Received: September 29, 2026

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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

Office of Industry and Consumer Education (OICE) to ask a question about a specific regulatory topic. See the OICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-office-industry-and-consumer-education-oice) for more information or contact OICE by email (AskOICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Colin K. Chen -S

Digitally signed by Colin K. Chen -S
Date: 2026.10.28 17:56:13 -04'00'

Colin Kejing 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K261636

Please provide the device trade name(s).

Microwave Ablation Antennas

Please provide your Indications for Use below.

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.

Please select the types of uses (select one or both, as applicable).

- [x] Prescription Use (21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

Please select the age group(s) for which the device(s) is to be used.

- [ ] Neonates/Newborns (Birth to < 29 days old)
- [ ] Infants (29 days old to < 2 years old)
- [ ] Children (2 years old to < 12 years old)
- [ ] Adolescents (12 years old to < 22 years old)
- [ ] Adults (22 years old and greater)

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: April 24th, 2026

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:	Canyon Medical Inc.
510(K) Number:	K241825
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

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 imaging 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. Technical Characteristics

The subject devices are substantially equivalent to the predicate devices in terms of intended use and technological characteristics. The differences between the subject devices and predicate devices do not affect the basic design principle, usage, effectiveness and safety of the subject device.

The technological characteristics of the subject devices are identical to those of predicate devices, with the exception of the following changes:

1) Add new models.

2) Change the shaft length of one existing model.

3) Change the material of bushing of part of models; and the bushing actually is used in other unchanged models cleared in K241825

Equivalence has been identified as follows:

Item	Subject Device-K261636	Predicate Device-K241825
Device	Microwave Ablation Antennas	Microwave Ablation 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.	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.
Operating Principle	During the surgery, the Microwave Ablation Antennas 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 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 imaging techniques.	During the surgery, the Microwave Ablation Antennas 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 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 imaging techniques.
Shaft length(mm)	70, 80, 100, 130, 150, 160, 180, 200, 250, 300, 1200mm	70, 80, 100, 130, 150, 180, 200, 250, 300, 1200mm
Antenna outer diameter(G)	13G, 14G, 15G, 16G, 17G, 18G, 19G, 20G	13G, 14G, 15G, 16G, 17G, 18G, 19G, 20G
Antenna active tip(mm)	3, 5, 11, 17, 25, 28, 31mm	3, 5, 11, 25, 28mm
Max tolerable power	Up to 150W	Up to 150W
Sterilization method	EO gas	EO gas
Single Use	Yes	Yes
Device Temperature Monitoring	Temperature monitoring features used to ensure	Temperature monitoring features used to ensure

Item	Subject Device	Predicate Device-K241825
Device	Microwave Ablation Antennas	Microwave Ablation Antennas
	safety	safety
Device Cooling	Pumped, coolant is used to cool the antenna.	Pumped, coolant is used to cool the antenna.
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 identical 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:

• Similar indications for use

• 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

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. Clinical Test

No. Use of microwave ablation therapy is proven technology and is well accepted by the medical community. Performance test is sufficient to demonstrate safety and effectiveness of the subject devices with the predicate devices.

11. Conclusion

The conclusions drawn from the comparison and analysis above demonstrate that the proposed subject devices are as safe, as effective, and performs as well as

the legally marketed predicate devices and raises no new questions of safety or effectiveness.

The differences between both devices are insignificant in terms of safety and effectiveness.