January 31, 2024

Hygea Medical Technology Co., Ltd.
Jinping Duan
RA Manager
Floor 6&7, West Area of Building No. 8, No.30 YuHua
Road, Shunyi
Beijing, Shunyi 101318
China

Re: K233140
Trade/Device Name: Microwave Ablation Device (Exceed S10U); Sterile Microwave Ablation Probe (Exact)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: NEY
Dated: September 27, 2023
Received: September 27, 2023

Dear Jinping Duan:

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,

Mark Trumbore -S

Digitally signed by Mark Trumbore -S
Date: 2024.01.31 10:25:27 -05'00'

Mark Trumbore, 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K233140

Device Name
Microwave Ablation Device
Sterile Microwave Ablation Probe

Indications for Use *(Describe)*
The microwave ablation system is indicated for soft tissue coagulation (ablation) by healthcare professionals in healthcare facilities. Microwave ablation system is not intended for cardiac use.
Sterile Microwave Ablation Probe is used with Microwave Ablation Device, which is indicated for soft tissue coagulation (ablation) by healthcare professionals in healthcare facilities. Sterile Microwave Ablation Probe 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.

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510(k) Summary

Microwave Ablation Device
Sterile Microwave Ablation Probe

1. Submission Sponsor

Hygea Medical Technology Co., Ltd.

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PEOPLE'S REPUBLIC OF CHINA

Jinping Duan

RA Manager

2. Submission Correspondent

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Title: Technical Consultant, QA/RA, China

3. Device Identification

Trade/Proprietary Name: Microwave Ablation Device

Sterile Microwave Ablation Probe

Classification Name: Electrosurgical cutting and coagulation device and accessories

Regulation Number(s): 21 CFR 878.4400

Product Code(s): NEY

Class: II

Classification Panel: General & Plastic Surgery

4. Legally Marketed Predicate Device(s):

Microwave Therapeutic System (K201262)

Disposable Microwave Therapeutic Antennas (K201265)

Manufacturer: Nanjing ECO Microwave System Co., Ltd.

5. Device Description

The Microwave Ablation Device with Sterile Microwave Ablation Probe is a device system which is intended for soft tissue coagulation. The Microwave Ablation Device consists of power supply, microwave power source, control system, temperature measurement system, cooling system, RF connection cable, foot switch, and temperature probe. The Sterile Microwave Ablation Probe is a single-use sterile product, consisting of a handle, RF connector, RF coaxial cable, needle bar, inner tube, pinhead, temperature sensor and coolant tube. The Microwave Ablation Device also contains a single use Sterile Temperature Probe.

6. Indication for Use Statement

The microwave ablation system is indicated for soft tissue coagulation (ablation) by healthcare professionals in healthcare facilities. Microwave ablation system is not intended for cardiac use.

Sterile Microwave Ablation Probe is used with Microwave Ablation Device, which is indicated for soft tissue coagulation (ablation) by healthcare professionals in healthcare facilities. Sterile Microwave Ablation Probe is not intended for cardiac use.

7. Substantial Equivalence Discussion

The following table compares the Microwave Ablation Device with Sterile Microwave Ablation Probe to the predicate devices with respect to indications for use, principles of operation, technological characteristics, materials, and performance, and forms the basis for the determination of substantial equivalence. The subject device does not raise any new questions of safety or effectiveness as compared to the predicate device.

Table 1 – Comparison of Characteristics for Microwave Ablation Generator and Microwave Therapeutic System

Feature	Microwave Ablation Device	Microwave Therapeutic System（K201262）	Discussion
Device Classification	Class II Electrosurgical cutting and coagulation device and accessories.	Class II Electrosurgical cutting and coagulation device and accessories.	Same
Product Code	NEY	NEY	Same
Regulation No.	21 CFR 878.4400	21 CFR 878.4400	Same
Manufacturer	Hygea Medical Technology Co., Ltd.	Nanjing ECO Microwave System Co., Ltd.	-
Trade Name	Microwave Ablation Device.	Microwave Therapeutic System.	-
Indications for Use	The microwave ablation system is indicated for soft tissue coagulation (ablation) by healthcare professionals in healthcare facilities. Microwave ablation system 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.	Same
Prescription or OTC	Prescription	Prescription	Same
Intended Purpose	Coagulation and ablation of tissue.	Coagulation and ablation of tissue.	Same
Design	Single channel.	Single channel.	Same
	The host of Microwave Ablation Device, RF connection cable, foot switch, and Sterile Temperature Probe.	cooling-water cycle, thermal ablation, the probe of TEMP, foot switch.	Equivalent. See Comment 1.
Operating Principle	Microwave energy is generated by Microwave Ablation Device and then delivers to the applicator tip through microwave cable to thermally heat the target tissue, resulting in coagulation and ablation. The Microwave Ablation Device refers to equipment for treating diseases with microwave	Microwave oscillating signals are generated by a microwave transistor and amplified by a microwave power amplifier. The generator delivers microwave energy to the applicator tip to thermally target tissue, resulting in coagulation and ablation. A microwave therapeutic system	Same

Feature	Microwave Ablation Device	Microwave Therapeutic System（K201262）	Discussion
	energy at a working frequency of 2450 MHz. The liquid in the silicone tube is driven by the rotation of the motor of pump to flow to the probe to realize the purpose of probe cooling.	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.	Same
Output Impedance	50 Ω	50Ω	Same
Output Parameters	2450MHz±50MHz 0-120W	2450MHz±20MHz 0-100W	Different. See comment 2.
Treatment time	30min max	30min max	Same
Device Temperature Monitoring	Temperature monitoring features used to ensure system safety.	Temperature monitoring features used to ensure system safety.	Same
Device cooling	Pumped, normal saline is used to cool the probe.	Pumped, normal saline is used to cool the antenna.	Same
Operational Mode	Four modes, Mode A, Mode B, foot switch mode and manual mode.	Three modes can be selected by the user. Timing method, foot switch control and manual control.	Different. See comment 3.

Comment 1: The foot pedal switch and Sterile Temperature Probe of the subject device are the same as the predicate device. The host of the subject product is equivalent to the predicate device's thermal ablation and cooling-water cycle. RF connection cable of the subject device is connected between the host and probe to transmit microwave energy.

Comment 2: The max power of the subject device is different than the predicate device, and the max power of 120W is only suitable when used with the HS-1425150U and HS-1425200U probes. The thermal effects test with ex vivo animal tissues demonstrates the subject device and does not raise new safety and performance risks.

Comment 3: The predicate device has three operation modes, including timing method, foot switch control and manual control. Timing method will countdown or forward timing during energy output based on user setup, foot switch control mode uses a foot switch to control device output and manual control mode is controlled by user with button click.

The subject device has four modes, which are Mode A, mode B, foot switch mode and manual mode. Mode A of the subject device is the same as timing method of the predicate devices, but with timer countdown only. Foot switch mode and manual mode are also same as the predicate device, which control device output continuous or intermittent by foot switch or user. Mode B of the subject device need to use with Sterile Temperature Probe. Tissue protection temperature need to setup in advance and the subject device will monitor tissue temperature using the Sterile Temperature Probe. After tissue temperature reach the setup protection value, Microwave Ablation Device will adjust microwave output to control the tissue temperature stable around the preset protection value with ±3% tolerance of the set temperature, the protection value range is 37.0 ℃～100.0 ℃. Mode B does not raise new safety and performance risks.

Table 2 – Comparison of Characteristics for Microwave Ablation Probe and Disposable Microwave Therapeutic Antennas

Feature	Sterile Microwave Ablation Probe	Disposable Microwave Therapeutic Antennas（K201265）	Discussion
Device Classification	Class II Electrosurgical cutting and coagulation device and accessories.	Class II Electrosurgical cutting and coagulation device and accessories.	Same
Product Code	NEY	NEY	Same
Regulation No.	21 CFR 878.4400	21 CFR 878.4400	Same
Manufacturer	Hygea Medical Technology Co., Ltd.	Nanjing ECO Microwave System Co., Ltd.	-
Trade Name	Sterile Microwave Ablation Probe	Disposable Microwave Therapeutic Antennas	-
Indications for Use	Sterile Microwave Ablation Probe is used with Microwave Ablation Device, which is indicated for soft tissue coagulation (ablation) by healthcare professionals in healthcare facilities. Sterile Microwave Ablation Probe 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.	Same
Prescription or OTC	Prescription	Prescription	Same
Intended Purpose	Coagulation and ablation of tissue.	Coagulation and ablation of tissue.	Same
Operating Principle	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	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	Same

Feature	Sterile Microwave Ablation Probe	Disposable Microwave Therapeutic Antennas（K201265）	Discussion
	radiated out through the microwave antenna and absorbed by water molecules in the tumor tissue. The microwave energy transforms into heat, and the temperature rises rapidly result in tumor tissue losing bioactivity.	coaxial cable, and then it is radiated out through the microwave antenna and absorbed by water molecules in the tumor tissue. The microwave energy transforms into heat, and the temperature rises rapidly result in tumor tissue losing bioactivity.	
AC Input Voltage	A.C.100-240V, 50/60Hz.	AC100-240V, 50/60Hz.	Same
Output Impedance	50 Ω	50Ω	Same
Output Parameters	2450MHz±50MHz 0-120W	2450MHz±20MHz 0-100W	Different. See Comment 2
Temperature Monitoring	Temperature monitoring features used to ensure system safety.	Temperature monitoring features used to ensure system safety.	Same
Device Cooling	Pumped, sterile disposable saline solution to cool the probes.	Pumped, normal saline is used to cool the antenna.	Same

Feature	Sterile Microwave Ablation Probe	Disposable Microwave Therapeutic Antennas (K201265)	Discussion
Applicators Length (mm)	HP-1805080U:80 HP-1605100U:100 HP-1507200U:200 HP-1512200U:200 HC-1814100U:100 HC-1814150U:150 HC-1814200U:200 HC-1614150U:150 HC-1614200U:200 HC-1514150U:150 HC-1514200U:200 HC-1414250U:250 HS-1425150U:150 HS-1425200U:200 HT-1414200U:200	ECO-100AI26:100 ECO-100AI3:100 ECO-100AI1:100 ECO-100AL29:1000 ECO-100AI3O:1200 ECO-100CL29:1000 ECO-100CL31:1000 ECO-100CL8C:150 ECO-100CL10:200 ECO-100AI25:200 ECO-100CL27C:150 ECO-100CL28C:200 ECO-100CL5C:150 ECO-100CL5:150 ECO-100CL22C:200 ECO-100CL8C:150 ECO-100CL1OC:200 ECO-100AI18C:150 ECO-100CL11C:250 ECO-100AL13C:150 ECO-100AL23C:200	Different. See Comment 4.

Feature	Sterile Microwave Ablation Probe	Disposable Microwave Therapeutic Antennas（K201265）	Discussion
Applicators Outer Diameter (18G=1.3mm 17G=1.4mm 16G=1.6mm 15G=1.8mm 14G=2.0mm 8G=3.2mm)	HP-1805080U:18G HP-1605100U:16G HP-1507200U:15G HP-1512200U: 15G HC-1814100U:18G HC-1814150U:18G HC-1814200U:18G HC-1614150U:16G HC-1614200U:16G HC-1514150U:15G HC-1514200U:15G HC-1414250U:14G HS-1425150U:14G HS-1425200U:14G HT-1414200U:14G	ECO-100AI26:18G ECO-100AI1:17G ECO-100AI3:16G ECO-100CL29:14G ECO-100AL29:14G ECO-100CL31:11G ECO-100AI3O:14G ECO-100CL8:14G ECO-100CL10:14G ECO-100AI25:8G ECO-100CL27C:18G ECO-100CL28C:18G ECO-100CL5C:16G ECO-100CL5:16G ECO-100CL22C:16G ECO-100CL8C:14G ECO-100CL10C:14G ECO-100CL11C:14G ECO-100AI18C:8G ECO-100AL13C:15G ECO-100AL23C:15G	Different See Comment 4.

Feature	Sterile Microwave Ablation Probe	Disposable Microwave Therapeutic Antennas（K201265）	Discussion
Emission Area Length (exposed length) (mm)	HP-1805080U:5 HP-1605100U:5 HP-1507200U:7 HP-1512200U:12 HC-1814100U:14 HC-1814150U:14 HC-1814200U:14 HC-1614150U:14 HC-1614200U:14 HC-1514150U:14 HC-1514200U:14 HC-1414250U:14 HS-1425150U:25 HS-1425200U:25 HT-1414200U:14	ECO-100AI26:3.5 ECO-100AI1:3.5 ECO-100AI3:3.5 ECO-100CL29:6 ECO-100AL29:6 ECO-100CL31:6 ECO-100AI30:6 ECO-100CL8:11 ECO-100CL10:11 ECO-100AI25:11 ECO-100CL27C:12 ECO-100CL28C:12 ECO-100CL5C:12 ECO-100CL5:12 ECO-100CL22C:12 ECO-100CL8C:12 ECO-100CL10C:12 ECO-100CL11C:12 ECO-100AI18C:12 ECO-100AL13C:18 ECO-100AL23C:18	Different. See Comment 4.
Max power (W)	HP-1805080U:40 HP-1605100U:50 HP-1507200U:80 HP-1512200U:80 HC-1814100U:50 HC-1814150U:50 HC-1814200U:50 HC-1614150U:80 HC-1614200U:80 HC-1514150U:100	ECO-100AI26:30 ECO-100AI1:30 ECO-100AI3:40 ECO-100CL29:50 ECO-100AL29:50 ECO-100CL31:50 ECO-100AI30:60 ECO-100CL8:80 ECO-100CL10:80 ECO-100AI25:100	Different. See Comment 2.

Feature	Sterile Microwave Ablation Probe	Disposable Microwave Therapeutic Antennas（K201265）	Discussion
	HC-1514200U:100 HC-1414250U:100 HS-1425150U:120 HS-1425200U:120 HT-1414200U:100	ECO-100CL27C:50 ECO-100CL28C:50 ECO-100CL5C:60 ECO-100CL5:50 ECO-100CL22C:60 ECO-100CL8C:80 ECO-100CL10C:100 ECO-100CL11C:100 ECO-100AI18C:100 ECO-100AL13C:60 ECO-100AL23C:60	
Disposable /Single use Device	The Sterile Microwave Ablation Probes are disposable and are to be used with in a single patient procedure only.	The antennas are disposable and are to be used within a single patient procedure only.	Same
Sterility	EO (SAL: 10^{-6}).	EO (SAL: 10^{-6}).	Same
Biocompatibility	Patient-contacting materials are biocompatible.	Patient-contacting materials are biocompatible.	Same
Patient Contacting Materials	1. Ceramics. 2. SUS 304 with double Teflon coating. 3. Polytetrafluoroethylene.	1. Ceramics. 2. SUS 304 with double Teflon coating. 3. US 304 with single Teflon coating. 4. Nylon. 5.Polytetrafluoroethylene.	Equivalent. See Comment 5.

Comment 4: The subject device has slightly different specifications including length, diameter and emission area length. The thermal effects test with ex vivo animal tissues demonstrates the subject device and does not raise new safety and performance risks.
Comment 5: The subject device uses SUS 304 with double Teflon coating ceramics and Polytetrafluoroethylene, the materials are also used by the predicate device and does not raise new safety and performance risks.

8. Non-Clinical Performance Data

Hygea completed the following non-clinical tests. The Microwave Ablation Device with Sterile Microwave Ablation Probe passed the testing in accordance with internal requirements, national standards, and international standards shown below. The test results support the device substantial equivalence to the predicate device:

Electrical Safety:

- ES60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.

Electromagnetic Compatibility:

- IEC 60601-1-2 Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance -- Collateral Standard: Electromagnetic disturbances -- Requirements and tests.

Performance:

- IEC 60601-2-6 Medical electrical equipment - Part 2-6: Particular requirements for the basic safety and essential performance of microwave therapy equipment.

Software validation:

- Software validation is in compliance with FDA guidance for the content of premarket submissions for software contained in Medical devices.

Shelf Life:

- Accelerated aging and package tests were conducted to confirm the validity of the 3 year shelf life claim for the Sterile Microwave Ablation Probe.

Thermal Effects test and Temperature monitoring test:

- FDA Guidance Premarket Notification (510(K)) Submissions for Electrosurgical Devices for General Surgery.

Package Verification:

- ISO 11607-1:2016 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems.

Sterilization validation:

- ISO 11135-1: 2014 Sterilization of health care products -- Ethylene oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices.

Biocompatibility:

- The compatibility of the skin-contact component material in the finished product meets the requirement of Biocompatibility. The Biological Evaluation Tests are in compliance with the standards of ISO 10993-1 and its applicable parts, “Biological Evaluation of Medical Devices”.

Additional Bench Performance Tests:

- Sterile Microwave Ablation Probe Stability Tests with maximum output power and extended treatment duration
- Temperature Sensor Measurement Accuracy Verification Tests

9. Clinical Performance Data

No clinical data was necessary to determine the substantial equivalence of this device.

10. Statement of Substantial Equivalence and Conclusion

The Microwave Ablation Device with Sterile Microwave Ablation Probe has the same intended use as the Microwave

Therapeutic System and Disposable Microwave Therapeutic Antennas and similar technological characteristics. The differences in technological characteristics do not raise new or different questions of safety and effectiveness. Performance testing has demonstrated the Microwave Ablation Device with Sterile Microwave Ablation Probe is as safe and effective as the predicate devices. Therefore, the Microwave Ablation Device with Sterile Microwave Ablation Probe is substantially equivalent to the predicate devices.