March 2, 2026

Nanjing DeWen Medical Technology Co., Ltd.
℅ Jack Fang
Official Correspondent
APlus Healthcare Technology (Shanghai) Co., Ltd.
1201 Floor, Zhongzhi Building, No.9299 Humin Road
Xuhui District
Shanghai,
China

Re: K252632
Trade/Device Name: Microwave Ablation Device
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: NEY
Dated: January 20, 2026
Received: January 22, 2026

Dear Jack Fang:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 21 CFR 820.70) and document changes and approvals in the Medical Device File (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 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 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,

Colin K. Chen -S

Digitally signed by Colin K. Chen -S
Date: 2026.03.02 17:10:45 -05'00'

Colin Kejing Chen, Ph.D.
Acting Assistant Director
DHT4A: Division of General Surgery Devices
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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)*
K252632

Device Name
Microwave Ablation Device

Indications for Use *(Describe)*
The Microwave Ablation Device is indicated for the coagulation (ablation) of soft tissue. The Microwave Ablation 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

I Submitter

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Preparation date: December 13, 2025

II Proposed Device

Trade Name of Device: Microwave Ablation Device

Models: DW-M5G

Regulation Number: 21 CFR 878.4400

Regulation Name: Electrosurgical cutting and coagulation device and accessories

Regulatory Class: Class II

Product codes: NEY

Regulation Medical Specialty: General & Plastic Surgery

III Predicate Device

510(k) Number: K232240

Trade /Device Name: Microwave Ablation System

Regulation Number: 21 CFR 878.4400

Regulation Name: Electrosurgical cutting and coagulation device and accessories

Regulatory Class: Class II

Product codes: NEY

Regulation Medical Specialty: General & Plastic Surgery

IV Device description

The Microwave Ablation Device is intended to be used together with disposable microwave ablation antenna and disposable temperature probe for soft tissue ablation. The Microwave Ablation Device consists of a generator, a disposable temperature probe and a foot switch. The Microwave Ablation Device also contains software that controls and delivers the microwave energy at a working frequency of 2450 MHz.

Principles of Operation

When being used with the disposable microwave ablation antenna, the Microwave Ablation Device generates and delivers microwave energy to the disposable microwave ablation antenna after inserting the disposable microwave ablation antenna into the diseased tissue. The microwave acts on the tissue through the disposable microwave ablation antenna, causing charged ions and water molecules in the diseased tissue to oscillate and generate intense heat (similar to a small magnetic needle rotating in a magnetic field). The localized tissue heats up, creating a temperature gradient that decreases from the center outward. When the temperature reaches above 45°C, the proteins within the cells undergo coagulative necrosis, resulting in the destruction of the diseased tissue.

V Indications for use

The Microwave Ablation Device is indicated for the coagulation (ablation) of soft tissue. The Microwave Ablation Device is not intended for cardiac use.

VI Comparison of technological characteristics with the predicate device

The comparison between the overall specifications of the predicate device and the Microwave Ablation Device is shown in Table 1. Comparison between the Microwave Ablation Device and the predicate device was conducted with respect to intended use, technological characteristics and principles of operations, providing more detailed information regarding the bases for the determination of substantial equivalence.

Table 1 Comparison with the predicate device

Items	Proposed Device	Predicate Device
Device name	Microwave Ablation Device	Microwave Ablation System
510(k) number	K252632	K232240
Prescription or OTC	Prescription	Prescription
Product Code	NEY	NEY
Regulation Number	878.4400	878.4400
Indications for use	The Microwave Ablation Device is indicated for the coagulation (ablation) of soft tissue. The	The Microwave Ablation System is indicated for the coagulation (ablation) of soft tissue. The

Items	Proposed Device	Predicate Device
	Microwave Ablation Device is not intended for cardiac use.	Microwave Ablation System is not intended for cardiac use.
Intended purpose	Coagulation and ablation of tissue	Coagulation and ablation of tissue
Operating principle	The generator of the Microwave Ablation Device generates microwave oscillating signal and amplifies the microwave oscillating signal with a microwave power amplifier. Then the microwave energy is delivered to the applicator tip to thermally target tissue at a working frequency of 2450 MHz, resulting in coagulation and ablation. The peristaltic pump drives liquid to flow through the radiator to realize the purpose of radiator cooling.	The Microwave Ablation System is a microwave power (energy) source that can meet the needs of clinical soft tissue microwave thermal ablation therapy. The microwave energy is transmitted to the disposable microwave ablation needle through coaxial transmission cable, and the disposable microwave ablation needle is directly inserted into the targeted soft tissue, and the electromagnetic wave (microwave) is radiated from the front end of the disposable microwave ablation needle to cause the soft tissue to produce heat and rise. When it reaches the temperature of tissue coagulation and necrosis, in-situ inactivation is formed, that is, the purpose of microwave ablation therapy is achieved.
Design	Single channel	One-way ring
	Cooling-water cycle, thermal ablation, disposable temperature probe, built-in peristaltic pump, footswitch	The device is mainly composed of the microwave ablation instrument with its built-in peristaltic pump and external foot switch, as well as coaxial transmission cable, disposable thermometer needle and water cooling system.
Main Function	The Microwave Ablation Device consists of solid state microwave source, control system, display system and temperature measurement system, LCD touch screen, foot switch, peristaltic pump.	The host is mainly composed of solid state source and power supply, general control system, temperature control system, display system and LCD touch screen, foot switch, peristaltic pump and control system, etc.
Maxpower	50W, 80W	60W, 70W
AC input Voltage	AC100-240V, 50/60Hz	AC100-240V, 50/60Hz
Output impedance	50Ω nominal	50Ω nominal
Output parameters	2450MHz ± 50MHz	2450MHz ± 25MHz
Device	The device is equipped with	The temperature range of the

Items	Proposed Device	Predicate Device
Temperature Monitoring	temperature measurement function, with a measuring range of 35℃ to 90℃. The device features tissue over-temperature protection. The over-temperature protection range is adjustable from 35℃ to 90℃ and the alarm temperature can be set by the user. The device features rod temperature over-temperature protection. The alarm temperature is fixed at 45°C which is non-adjustable.	temperature control can be set arbitrarily between 45℃ and 75℃. The over temperature protection range can be set arbitrarily between 50℃ and 80℃. The temperature range of the rod temperature measurement is within 45℃, and the alarm temperature is a fixed value of 45℃, which is non-adjustable.
Device cooling	Pumped, normal saline or distilled water as coolant is used cool the antenna	Pumped, normal saline or distilled water as coolant is used cool the ablation needle
Output mode	Continuous	Continuous, pulse mode or foot mode
Control	Manual or footswitch	Manual or footswitch

VII Performance Data

The following performance data were provided in support of the substantial equivalence determination.

Electrical Safety

IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020

Electromagnetic Compatibility

IEC 60601-1-2:2014+AMD1: 2020/EN 60601-1-2: 2015+A1:2021

Performance

IEC 60601-2-6:2012, IEC 60601-2-6:2012 / AMD1:2016, IEC 60601-2-6:2012 / AMD2:2022

Thermal Effects test and Temperature monitoring test

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

Software Verification and Validation

Software verification and validation testing were conducted and documentation was provided as recommended by FDA’s Guidance for Industry and FDA Staff, “Content of Premarket Submissions for Device Software Functions.” The software for this device required enhanced level documentation, since a failure a failure or flaw of device software function(s) could present a hazardous situation with a probable risk

of death or serious injury to a patient in the environment of use.

Biocompatibility

The biocompatibility evaluation for the proposed device was conducted in accordance with ISO 10993-1:2018 and FDA Biocompatibility Guidance. Below testing were conducted:

- Cytotoxicity
- Skin Sensitization
- Irritation
- Acute Systemic Toxicity
- Pyrogenicity

Service life

Service life of 8 years was validated by simulated use.

VIII Clinical Testing

No clinical study is included in this submission.

IX Conclusion

The proposed device has the same indications for use and has similar design features and technological characteristic as the predicate device. The differences between the predicate device and the proposed device do not raise new questions of safety or effectiveness. Performance testing data demonstrates that the proposed device is safety and effectiveness as the predicated device. Accordingly, the proposed device is substantially equivalent to the predicate device.