March 2, 2026

Nanjing Devin Medical Technology Co., Ltd.
℅ Jack Fang
Primary Correspondent
Aplus Healthcare Technology (Shanghai) Co., Ltd.
1201 Floor, Zhongzhi Bldg., #9299 Humin Rd.
Xuhui District
Shanghai,
China

Re: K253771
Trade/Device Name: Disposable Microwave Ablation Antenna (DW-XR-II1, DW-XR-II3, DW-XR-II4, DW-XR-II14, DW-XR-II5, DW-XR-II6, DW-XR-II7, DW-XR-II8, DW-XR-II9, DW-XR-II10, DW-XR-II18, DW-XR-II19, DW-XR-II20, DW-XR-II21, DW-DG-II6, DW-DG-II7, DW-DG-II9, DW-DG-II10, DW-DG-II13)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: NEY
Dated: January 22, 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 13485 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 17:03:34 -05'00'

Colin Kejing Chen, Ph.D.
Acting Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical and Infection Control 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)*
K253771

Device Name
Disposable Microwave Ablation Antenna

Indications for Use *(Describe)*
The Disposable Microwave Ablation Antenna, used in conjunction with the compatible Microwave Ablation Device, is intended for the coagulation (ablation) of soft tissue. The Disposable Microwave Ablation Antenna 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

I Submitter

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Preparation date: January 20, 2026

II Proposed Device

Trade Name of Device: Disposable Microwave Ablation Antenna

Models: DW-XR-II1, DW-XR-II3, DW-XR-II4, DW-XR-II14, DW-XR-II5, DW-XR-II6, DW-XR-II7, DW-XR-II8, DW-XR-II9, DW-XR-II10, DW-XR-II18, DW-XR-II19, DW-XR-II20, DW-XR-II21, DW-DG-II6, DW-DG-II7, DW-DG-II9, DW-DG-II10, DW-DG-II13

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: K232241

Trade/Device Name: Disposable Microwave Ablation Needle

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 Disposable Microwave Ablation Antenna is intended to be used together with Microwave Ablation Device (K252632) for soft tissue ablation. The Disposable Microwave Ablation Antenna consists of antenna, antenna shaft (temperature measurement component and cooling component), handle and coaxial cable.

Principles of Operation

When being used with the Microwave Ablation Device, 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 energy output by the Disposable Microwave Ablation Antenna is transmitted to the emitting end at the front of the ablation antenna through the radio frequency cable. The emitting end of the ablation antenna radiates the microwave energy into the tissue of the treatment target area, causing the target tissue to instantly generate high temperature and result in irreversible coagulative necrosis.

V Indications for use

The Disposable Microwave Ablation Antenna, used in conjunction with the compatible Microwave Ablation Device, is intended for the coagulation (ablation) of soft tissue. The Disposable Microwave Ablation Antenna 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 Disposable Microwave Ablation Antenna is shown in Table 1. Comparison between the Disposable Microwave Ablation Antenna 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	Disposable Microwave Ablation Antenna	Disposable Microwave Ablation Needle
510(k) number	K253771	K232241
Prescription or OTC	Prescription	Prescription
Product Code	NEY	NEY
Regulation Number	878.4400	878.4400
Indications for use	The Disposable Microwave Ablation Antenna, used in conjunction with the compatible Microwave Ablation Device, is intended for the coagulation (ablation) of soft tissue. The Disposable Microwave Ablation Antenna is not intended for cardiac use.	Disposable Microwave Ablation Needle is used with the Microwave Ablation System, which is indicated for the ablation of soft tissue during open procedures. The Disposable Microwave Ablation Needle is not intended for cardiac use.
Intended purpose	Coagulation and ablation of tissue	Coagulation and ablation of tissue
Operating principle	When being used with the Microwave Ablation Device, 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 energy output by the Disposable Microwave Ablation Antenna is transmitted to the emitting end at the front of the ablation antenna through the radio frequency cable. The emitting end of the ablation antenna radiates the microwave energy into the tissue of the treatment target area, causing the target tissue to instantly generate high temperature and result in irreversible coagulative necrosis.	Microwave energy is delivered to the lesion tissue by the Disposable Microwave Ablation Needle. The lesion tissue contains a large number of charged particles, water molecules, and protein molecules, and these polar molecules rotate with the frequency of the applied electric field. In the process of rotation, friction with neighboring molecules generates heat, which causes coagulation necrosis of the lesion tissue.
AC input Voltage	AC 100~240V 50/60Hz	AC 100~240V 50/60Hz
Output impedance	50Ω nominal	50Ω nominal
Output parameters	2450 MHz ± 50MHz	2450 MHz ± 25MHz
Applicator Patient Contacting Materials	Polytetrafluoroethylen (PTFE) Polyimide (PI) Copper	Tin Bronze Polytetrafluoroethylene SUS304
Applicators Length (mm)	100, 150, 180, 200, 250, 300, 900, 1200	80, 100, 150, 180
Applicators Outer Diameter (mm)	1.4, 1.6, 1.8, 2.0, 2.2	1.4, 1.6, 1.8, 2.0

Items	Proposed Device	Predicate Device
Radiation Pole (exposed length) (mm)	3, 5	3.5, 10
Maxpower (W)	50, 80	60, 70
Disposable/Single use Device	The device is provided sterile, for single use.	The device is provided sterile, for single use.
Sterility	The device is sterilized with EO (SAL:10^{-6})	The device is sterilized with EO (SAL:10^{-6})
Biocompatibility	Conforms to the requirements of ISO10993 series standards	Conforms to the requirements of ISO10993 series standards
Device Temperature Monitoring	Temperature monitoring features used to ensure system safety	Temperature monitoring features used to ensure system safety
Device cooling	Pumped, distilled water or saline is used to cool the Disposable Microwave Ablation Antenna.	Pumped, distilled water or saline is used to cool the ablation needle.

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

Thermal effects test and temperature monitoring test were conducted as per FDA Guidance “Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery”.

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

Shelf life

Shelf life of 4 years was validated by accelerated aging test.

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. Non clinical 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.