November 13, 2023

Betters (Suzhou)Medical Co., Ltd.
℅ Ada Wang
Operation Manager
APlus Healthcare Technology (Shanghai) Co., Ltd
Room 223, Building 17, JY-WISDOMBAY
Huqing Road 158, Baoshan District
Shanghai, Shanghai
China

Re: K232240
Trade/Device Name: Microwave Ablation System (BD-GT)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: NEY
Dated: July 28, 2023
Received: October 16, 2023

Dear Ada Wang:

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: 2023.11.13 11:12:52 -05'00'

Mark Trumbore, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
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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)*
K232240

Device Name
Microwave Ablation System

Indications for Use *(Describe)*
The Microwave Ablation System is indicated for the coagulation (ablation) of soft tissue. The Microwave Ablation System 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: July 28, 2023

II Proposed Device

Trade Name of Device:	Microwave Ablation System
Regulation Name:	Electrosurgical Cutting and Coagulation Device and Accessories
Regulation Number:	21 CFR 878.4400
Regulatory Class:	Class II
Product code:	NEY
Review Panel	General & Plastic Surgery

III Predicate Devices

510(k) Number:	K201262
Trade name:	Microwave Therapeutic System
Regulation Name:	Electrosurgical Cutting and Coagulation Device and Accessories
Classification:	Class II
Product code:	NEY
Manufacturer	Nanjing ECO Microwave System Co., Ltd

IV Device Description

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.

The Disposable Thermometer Needle and Foot Switch are accessories for the proposed device. And the proposed device is used in conjunction with the Disposable Microwave Ablation Needle made by our company.

The supported models and specifications of the Disposable Microwave Ablation Needle and Disposable Thermometer Needle are shown in Table 1.

Table 1 Specifications of Disposable Thermometer Needle and Supported Disposable Microwave Ablation Needle

Model	Name	Diameter(mm)	Length(mm)	Maximum output power	Type of handle
T-1408	Disposable Microwave Ablation Needle	1.4	80	60W	Straight handle
T-1410		1.4	100	60W	
T-1608		1.6	80	60W	
T-1610		1.6	100	60W	
L-1815		1.8	150	70W	Curved handle
L-1818		1.8	180	70W	
L-2015		2.0	150	70W	
L-2018		2.0	180	70W	
CWZ-1620	Disposable Thermometer Needle	1.6	200	-	-
CWZ-1615		1.6	150	-	-

V Indication for use

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

VI Comparison of technological characteristics with the predicate devices

The comparison and discussion between the proposed device and the predicate device are listed in Table 2.

Table 2 General Comparison of Microwave Ablation System

Item	Proposed device	Predicate device (K201262)	Discussion

Device/Trade name	Microwave Ablation System	Microwave Therapeutic System	--
Manufacturer	Betters(Suzhou) Medical Co., Ltd	Nanjing ECO Microwave System Co., Ltd	--
Product Code	NEY	NEY	Same
Regulation No.	21 CFR 878.4400	21 CFR 878.4400	Same
Class	II	II	Same
Indication for use	The Microwave Ablation System is indicated for the coagulation (ablation) of soft tissue. The 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
Intended purpose	Coagulation and ablation of tissue	Coagulation and ablation of tissue	Same
Operating principle	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.	Microwave oscillating signals are generated by a microwave transistor and amplified by a microwave power amplifier. Generator delivers microwave energy to the applicator tip to thermally target tissue, resulting in coagulation and ablation. A microwave therapeutic system 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.	Equivalent[1]
Design	One-way ring	Single channel	Same

	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.	cooling-water cycle, thermal ablation, the probe of TEMP, foot switch.	
Main Function	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.	The generator of the microwave therapeutic system is composed of a casing, a power module, a control feedback unit, a display module, a microwave transmitting module, a water circulation module, and a temperature measurement module.	Similar[2]
AC input Voltage	100-240V～，50/60Hz	AC100-240V, 50/60Hz	Same
Output Impedance	50Ω nominal	50Ω nominal	Same
Output parameters	2450MHz±25 MHz	2450MHz±20MHz	Same
Device Temperature Monitoring	Temperature monitoring features used to ensure system safety	Temperature monitoring features used to ensure system safety	Same
Device cooling	Pumped, distilled water or saline is used to cool the ablation needle	Pumped, normal saline is used to cool the antenna	Same
Operational mode	Three modes: continuous mode, pulse mode, foot mode	Three modes can be selected by the user	Different[3]

[1] The operating principle description of the proposed device is different from the predicate device. However, the proposed device and the predicate device have the same working frequency, deliver microwave energy to the target tissue for coagulation and ablation, and have a device temperature monitor and cooling component. The operating principle of the devices are equivalent.

[2] The main function description of the proposed device is different from the predicate device. However, the performance test of proposed device has been conducted as same as the predicate device. The general control system of the proposed device has the same function as the power module, control feedback unit and microwave transmitting module of the predicate device; the peristaltic pump and the control system of the proposed device have the same function as the water circulation module of the predicate device. Therefore, the difference does not affect substantially equivalence.

[3] The operational mode of the proposed device is different from the predicate device. The predicate device has three modes, and the main difference between these three modes is that timing method is countdown or forward timing, foot switch control or manual control, output is continuous or intermittent. The proposed device has three modes: continuous mode, pulse mode and foot mode. The different operational modes are designed to give users more operating options, and do not change the intended use and function of the device. Software verification has been conducted on the proposed device according to the FDA software guidance, and the test result proves the functions in each operational mode can be achieved. The difference does not raise a new risk.

VII Non-Clinical Testing

The proposed device and the predicate device are substantially equivalent in design concepts, technologies, which have been designed and tested in accordance with:

Electrical Safety:

- IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

Electromagnetic Compatibility:

- EN 60601-1-2: 2015+A1: 2021/ IEC 60601-1-2: 2014+AMD1:2020 Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbance - Requirements and tests

Performance:

- IEC 60601-2-6: 2012, AMD1:2016 for use in conjunction with for use with IEC 60601-1:2005 and with IEC 60601-1:2005, COR1:2006, COR2:2007, AMD1:2012 Medical electrical equipment - Part 2-6: Particular requirements for the basic safety and essential performance of microwave therapy equipment

Software life-cycle:

-ANSI AAMI IEC 62304:2006/A1:2016 Medical device software - Software life cycle processes [Including Amendment 1 (2016)]

- FDA Guidance: Content of Premarket Submissions for Device Software Functions.

Thermal Effects test and Temperature monitoring test:

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

VIII Clinical Testing

No clinical study is included in this submission.

IX Conclusion

The proposed device is equivalent with respect to the basic system design and function of the predicate device. The proposed device isn't the implants and high-risk device. And it doesn't have new intended purpose, new medical indication, new target population, or new intended user. The differences between the predicate device and proposed device do not raise new questions of safety or effectiveness. Based on the comparison and analysis above, the proposed device is determined to be substantially equivalent to the predicate device.