November 13, 2023

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

Re: K232241
Trade/Device Name: Disposable Microwave Ablation Needle (T-1408, T-1410, T-1608, T-1610, L-1815, L-1818, L-2015, L-2018)
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 11:07:30 -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)*
K232241

Device Name
Disposable Microwave Ablation Needle

Indications for Use *(Describe)*
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.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

I Submitter

Betters(Suzhou) Medical Co., Ltd
Room 101, 201, 501, Building 7, 52 Yingang Road, Taicang Port Economic and Technological Development Zone Suzhou, Jiangsu Province, China, 215412

Contact person:
Lei Liu
Position: Operation Manager
Tel.: +86-15261671606
E-mail: liulei@baidemed.com

Preparation date: July 28, 2023

II Proposed Device

Trade Name of Device:	Disposable Microwave Ablation Needle
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:	K201265
Trade/Device Name:	Disposable Microwave Therapeutic Antennas
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

Disposable Microwave Ablation Needle is a puncture needle with microwave energy transmission. It is inserted into the human body through puncture, and the tissue is ablated by the thermal energy transformed by the needle tip.

The Disposable Microwave Ablation Needle is composed of an inlet pipe, an outlet pipe, a handle, a needle rod, a medium tube, a radiation pole, and a coaxial transmission cable. It is a sterile disposable product. The coaxial transmission cable connect the Microwave Ablation System to transmit microwaves to the ablation needle (radiator), a handle is set at the connection between the microwave cable and the ablation needle to facilitate the operation of the operator.

The Disposable Microwave Ablation Needle is provided sterile, for single use.

The proposed Disposable Microwave Ablation Needle are available in different model is shown as Table 1.

Table 1 Models, specifications and dimensions

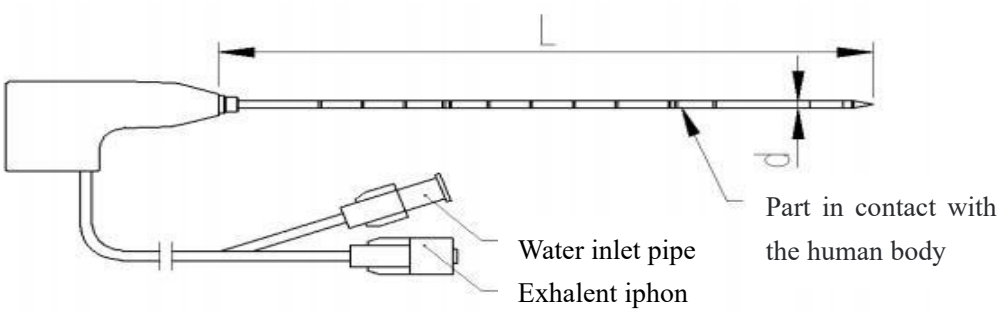

FIG. 1 Schematic diagram of the Curved handle

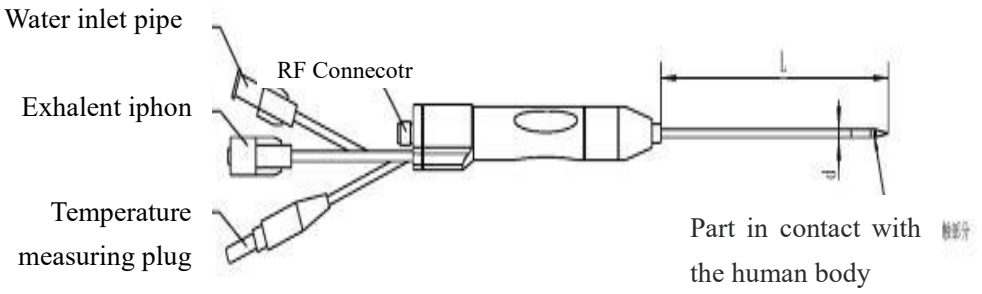

FIG. 2 Schematic diagram of the straight stalk structure

Serial number	Type	d±0.2 (mm)	L±5 (mm)	Frequency（MHz）	Type of handle
1	T-1408	1.4	80	2450	Straight handle
2	T-1410	1.4	100	2450	Straight handle
3	T-1608	1.6	80	2450	Straight handle
4	T-1610	1.6	100	2450	Straight handle
5	L-1815	1.8	150	2450	Curved handle
6	L-1818	1.8	180	2450	Curved handle
7	L-2015	2.0	150	2450	Curved handle
8	L-2018	2.0	180	2450	Curved handle

V Indication for 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.

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 Disposable Microwave Ablation Needle

Item	Proposed device	Predicate device (K201265)	Discussion
Device/Trade name	Disposable Microwave Ablation Needle	Disposable Microwave Therapeutic Antennas	--
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 Disposable Microwave Ablation Needle is used with the Microwave Ablation System, which is indicated for the coagulation (ablation) of soft tissue. The Disposable Microwave Ablation Needle 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
Intended purpose	Coagulation and ablation of tissue	Coagulation and ablation of tissue	Same
Operating principle	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	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	Equivalent[1]

	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.	microwave ablation antenna through the coaxial cable, and then it is radiated out through the microwave antenna and absorbed by water molecules in the tumor tissue. The microwave energy transform into heat, and the temperature rises rapidly result in tumor tissue losing bioactivity.	
AC input Voltage	100-240V～，50/60Hz	AC100-240V, 50/60Hz	Same
Output Impedance	50Ω nominal	50Ω nominal	Same
Output parameters	2450MHz±25MHz	2450MHz±20MHz	Same
Applicator Patient Contacting Materials	Tin Bronze Polytetrafluoroethylene SUS 304	1. Ceramics 2. SUS 304 with double teflon coating 3. US 304 with single teflon coating 4. Nylon 5. Polytetrafluoroethylene	Different[2]
Applicators Length (mm)	T-1408: 80 T-1410: 100 T-1608: 80 T-1610: 100 L-1815: 150 L-1818: 180 L-2015: 150 L-2018: 180	ECO-100AI1:100 ECO-100AI26:100 ECO-100AI3:100 ECO-100AI18C:150 ECO-100CL8C:150 ECO-100CL8:150 ECO-100AL13C:150 ECO-100CL5C:150 ECO-100CL5:150 ECO-100CL27C:150 ECO-100CL28C:200	Different[3]

		ECO-100CL22C:200 ECO-100AL23C:200 ECO-100CL10:200 ECO-100CL10C:200 ECO-100AI25:200 ECO-100CL11C:250 ECO-100CL29:1000 ECO-100AL29:1000 ECO-100CL31:1000 ECO-100AI30:1200	
Applicators Outer Diameter (mm) (18G=1.3mm 17G=1.4mm 16G=1.6mm 15G=1.8mm 14G=2.0mm 8G=3.2mm)	T-1408: 1.4 T-1410: 1.4 T-1608: 1.6 T-1610: 1.6 L-1815: 1.8 L-1818: 1.8 L-2015: 2.0 L-2018: 2.0	ECO-100AI1:17G ECO-100AI26:18G ECO-100AI3:16G ECO-100AI18C:8G ECO-100CL8C:14G ECO-100CL8:14G ECO-100AL13C:15G ECO-100CL5C:16G ECO-100CL5:16G ECO-100CL27C:18G ECO-100CL28C:18G ECO-100CL22C:16G ECO-100AL23C:15G ECO-100CL10:14G ECO-100CL10C:14G ECO-100AI25:8G ECO-100CL11C:14G ECO-100CL29:14G ECO-100AL29:14G	Different[4]

		ECO-100CL31:11G ECO-100AI30:14G	
Radiation Pole (exposed length) (mm)	T-1408: 3.5 T-1410: 3.5 T-1608: 3.5 T-1610: 3.5 L-1815: 10 L-1818: 10 L-2015: 10 L-2018: 10	ECO-100AI1:3.5 ECO-100AI26:3.5 ECO-100AI3:3.5 ECO-100AI18C:12 ECO-100CL8C:12 ECO-100CL8:11 ECO-100AL13C:18 ECO-100CL5C:12 ECO-100CL5:12 ECO-100CL27C:12 ECO-100CL28C:12 ECO-100CL22C:12 ECO-100AL23C:18 ECO-100CL10:11 ECO-100CL10C:12 ECO-100AI25:11 ECO-100CL11C:12 ECO-100CL29:6 ECO-100AL29:6 ECO-100CL31:6 ECO-100AI30:6	Different[5]
Max power (W)	T-1408: 60W T-1410: 60W T-1608: 60W T-1610: 60W L-1815: 70W L-1818: 70W	ECO-100AI1:30 ECO-100AI26:30 ECO-100AI3:40 ECO-100AI18C:100 ECO-100CL8C:80 ECO-100CL8:80	Different[6]

	L-2015: 70W L-2018: 70W	ECO-100AL13C:60 ECO-100CL5C:60 ECO-100CL5:50 ECO-100CL27C:50 ECO-100CL28C:50 ECO-100CL22C:60 ECO-100AL23C:60 ECO-100CL10:80 ECO-100CL10C:100 ECO-100AI25:100 ECO-100CL11C:100 ECO-100CL29:50 ECO-100AL29:50 ECO-100CL31:50 ECO-100AI30:60	
Disposable /Single use Device	The device is provided sterile, for single use.	The antennas are disposable and are to be used within a single patient procedure only.	Same
Sterility	The device is sterilized with EO (SAL: 10^{-6})	The accessories are sterilized with EO (SAL: 10^{-6})	Same
Biocompatibility	Conforms to the requirements of ISO 10993 series standards	Conforms to the requirements of ISO 10993 series standards	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

[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 function, which is to transmit the microwave energy generated by the microwave generator through the coaxial cable to the microwave ablation needle or antenna, and then the microwave energy is radiated out through the ablation needle or

antenna and absorbed by water molecules in the target tissue. The operating principle of the devices are equivalent.

[2] There are some differences for the materials in direct contact with patient. The differences do not affect the performance of device, but only affect the biocompatibility of the material. Biocompatibility evaluation has been performed according to ISO 10993-1 on the material used in the proposed device, and the result shows that the material is biocompatibility, the difference of material does not raise new safety and effective risk.

[3] The applicator length of the proposed device is different from that of the predicate device, but this difference is only reflected in the depth of the position of the target tissue to be ablated and does not affect the device's safety and performance.

[4] The applicators outer diameter options are less than that of predicate device. The only effect of different OD is that the target tissue caused by puncture is smaller or bigger, based on the affecting area of the ablation. This difference does not raise new safety and performance risk.

[5] The internal design difference will affect the microwave radiation field, resulting in a different ablation range. The proposed device has conducted ablation studies of in vitro tissues in accordance with FDA guidance, and the study results support the intended use of the proposed device. This difference does not raise new safety issue.

[6] The difference of max power will affect the microwave emission area, resulting in a different ablation range and microwave radiation area. The proposed device has conducted ablation studies of in vitro tissues in accordance with FDA guidance, and the study results support the intended use of the proposed device. This difference does not raise new safety issue.

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 validation:

- 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.

Shelf Life:

- ASTM F 1980 Standard Guide for Accelerated Aging of Sterile Barrier Systems and Medical Devices machine.

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.