May 18, 2022

Nanjing ECO Microwave System Co., Ltd.
Hong Wei
RA Manager
Third & Fourth Floors, J5 Building, No. 15 Wanshou Road,
Pukou District
Nanjing, Jiangsu 211800
China

Re: K201265
Trade/Device Name: Disposable Microwave Therapeutic Antennas
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: NEY

Dear Hong Wei:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated July 23, 2021. Specifically, FDA is updating this SE Letter due to a typo in the IFU Statement as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Long Chen, Ph.D., OHT4: Office of Surgical and Infection Control Devices, 301-796-6389, long.chen@fda.hhs.gov.

Sincerely,

Long H. Chen -S

Digitally signed by Long H. Chen -S
Date: 2022.05.18 12:57:58 -04'00'

Long Chen, 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

July 23, 2021

Nanjing ECO Microwave System Co., Ltd.
Hong Wei
RA Manager
Third & Fourth Floors, J5 Building, No. 15 Wanshou Road,
Pukou District
Nanjing, Jiangsu 211800
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Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: NEY
Dated: July 1, 2021
Received: July 6, 2021

Dear Hong Wei:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Long H. Chen -S

Digitally signed by Long H. Chen -S
Date: 2021.07.23 14:07:05 -04'00'

Long Chen, 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K201265

Device Name
Disposable Microwave Therapeutic Antennas

Indications for Use *(Describe)*
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.

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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Food and Drug Administration
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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

Prepared in accordance with the requirements of 21 CFR Part 807.92

Prepared Date: July 8, 2021

1. Submitter's Information

The submitter of this pre-market notification is:

Name:	Nanjing ECO Microwave System Co., Ltd.
Address:	Third & Fourth Floors, J5 Building, NJUT Science & Technology Industrial Park, No.15 Wanshou Road, Pukou District, 211800, Nanjing, Jiangsu, P.R.China.
Contact person:	Hong Wei
Title:	RA Manager
E-mail:	weihong@njeco.com.cn
Tel:	+86- 025-58872663 Ext: 8020

2. Device Identification

Trade/Device Name:	Disposable Microwave Therapeutic Antennas
Models:	ECO-100AI1, ECO-100CL28C, ECO-100CL27C, ECO-100CL22C, ECO-100CL5, ECO-100CL5C, ECO-100AL23C, ECO-100AL13C, ECO-100CL11C, ECO-100CL10, ECO-100CL10C, ECO-100CL8, ECO-100CL8C, ECO-100AI26, ECO-100AI3, ECO-100AI18C, ECO-100AI25, ECO-100AI30, ECO-100CL29, ECO-100AL29, ECO-100CL31
Device Common Name:	Microwave ablation system and accessories
Regulation Number:	21 CFR 878.4400
Regulation Name:	Electrosurgical cutting and coagulation device and accessories
Regulation Class:	Class II
Product Code:	NEY

3. Predicate Device

Predicate device:	
510(K) number:	K183153
Device Common Name:	Microwave ablation system and accessories
Device Trade /Proprietary Name:	Microwave Ablation System
Model:	M150E
Manufacturer:	Surgnova Healthcare Technologies (Zhejiang) Co., Ltd.
Regulation Number:	21 CFR 878.4400
Regulation Name:	Electrosurgical cutting and coagulation device and accessories

Regulation Class:	Class II
Product Code:	NEY

Reference device:

510(K) number:	K133821
Device Name:	Emprint™ Ablation System
Manufacturer:	Covidien LLC
Regulation Number:	21 CFR 878.4400
Regulation Name:	Electrosurgical cutting and coagulation device and accessories
Regulation Class:	Class II
Product Code:	NEY

4. Device Description

Disposable Microwave Therapeutic Antennas 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.

Disposable Microwave Therapeutic Antennas is composed of radiator, handle, microwave cable with/without cooling tubes. The microwave 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 radiator is composed of a needle tip, a needle shaft, a cooling tube, and a coaxial cable. The metal parts are connected by a welding process, and the non-metal parts are connected by glue. The needle and needle shaft are made of medical stainless steel, and the shape of the needle is a triangular pyramid tip or pyramid type tip, which is mainly used for percutaneous puncture and microwave radiation; the handle is made of ABS material, the cooling tube is made of stainless steel to cool the needle bar all the way, the thermocouple is arranged in the handle to effectively monitor the temperature of the ablation needle not to exceed 45 degrees.

Disposable Microwave Therapeutic Antennas is provided sterile, for single use.

5. Indication for 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.

6. Comparison to Predicate Device

Comparison to the predicate devices, the subject device has same intended use, similar product design, same performance effectiveness, performance safety as the predicate device as summarized in the following table.

Feature	Subject device K201265	Predicate device K183153	Reference device K133821	Comments
Manufacturer	Nanjing ECO Microwave System Co., Ltd.	Surgnova Healthcare Technologies (Zhejiang) Co., Ltd.	Covidien LLC	--

Trade name	Disposable Microwave Therapeutic Antennas	Microwave ablation system Model: M150E	Emprint™ Ablation System	--
Classifications name and Regulation Name	Electrosurgical cutting and coagulation device and accessories Class : II Product code : NEY	Electrosurgical cutting and coagulation device and accessories Class : II Product code : NEY	Electrosurgical cutting and coagulation device and accessories Class : II Product code : NEY	Same
Indications for 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.	The Microwave Ablation System is intended for the coagulation (ablation) of soft tissues. The MW Ablation System is not intended for use in cardiac procedures.	The Emprint™ Ablation System is intended for use in percutaneous, laparoscopic, and intraoperative coagulation (ablation) of soft tissue, including partial or complete ablation of non-resectable liver tumors. The EmprintTM Ablation System is not intended for use in cardiac procedures.	The microwave generator instrument and antenna of the predicate device are combined to submit 510k together, the microwave generator instrument and antenna of subject device are submitted 510k separately. The intended use description is the same.
Intended purpose	coagulation and ablation of tissue	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 radiated out through the	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 radiated out through the	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 radiated out through the	Same

	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.	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.	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	AC100-240V, 50/60Hz	100-240VAC 50-60 Hz	100-240VAC 50-60 Hz	Same
Output Impedance	50Ω nominal	50Ω nominal	50Ω nominal	Same
Output parameters	2450MHz±20MHz, 0-100W	2450MHz±10MHz, 0-100W	2450MHz±50MHz, 0-100W	Equivalent
Applicator Patient Contacting Materials	1. Ceramics 2. SUS 304 with double teflon coating 3. US 304 with single teflon coating 4. Nylon 5. Polytetrafluoroethylene	304SS, polyethlene terephthalate, ceramics	fiberglass, resin, ceramics	Different, The main structure of the needle is composed of 304SS stainless steel and Ceramics. It is the same as the predicate device, except that the external insulator and coating are different, these differences do not affect the performance of product, but only affect the biocompatibility of the material. The material used in the ablation needle has been performed biocompatibility test according to the ISO 10993-1, the results shows that the material is biocompatibility, the difference of material does not raise the new safety and effective risk.
Applicators Length (mm)	ECO-100AI1:100 ECO-100AI26:100	SS-MWA-1526C: 150	CA15L1: 150	Different, The ablation antenna

	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 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	SS-MWA-1531C: 150 SS-MWA-2026C: 200 SS-MWA-2031C: 200 SS-MWA-2526C: 250 SS-MWA-2531C: 250 (mm)	CA20L1: 200 CA30L1: 300	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 tumor to be ablated and does not affect the product's safety and performance.
Applicators Outer Diameter (18G=1.3mm 17G=1.4mm 16G=1.6mm 15G=1.8mm 14G=2.0mm 8G=3.2mm)	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 ECO-100CL31:11G ECO-100AI30:14G	OD(mm):2.08	OD(mm):2.4	Different, According to different human tissues and Expected ablation volume, the applicators diameter range is wider than that of predicate devices. The only effect of different OD is that the trauma caused by puncture is smaller or bigger, based on the affecting the area of the ablation, the different applicator length does not raise new safety and performance risks.
Emission area length (exposed length) (mm)	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	SS-MWA-1526C: 26 SS-MWA-1531C: 31 SS-MWA-2026C: 26 SS-MWA-2031C: 31 SS-MWA-2526C: 26 SS-MWA-2531C: 31	CA15L1: 28 CA20L1: 28 CA30L1: 28	Different, The internal design details difference will affect the microwave emission area, resulting in a different ablation range and microwave radiation area. Our product has conduct ablation studies of in vitro tissues in accordance with FDA guidelines, and the study results support the intended use of our products, it does not raise new safety issues.

	ECO-100CL31:6 ECO-100AI30:6			
Max power (W)	ECO-100AI1:30 ECO-100AI26:30 ECO-100AI3:40 ECO-100AI18C:100 ECO-100CL8C:80 ECO-100CL8:80 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	100	100	Different, the max power of subject devices was less than or equal to the predicate device's, the difference of Max power will affect the microwave emission area, resulting in a different ablation range and microwave radiation area. Our product has conduct ablation studies of in vitro tissues in accordance with FDA guidelines, and the study results support the intended use of our products, it does not raise new safety issues.
Disposable /Single use Device	The antennas are disposable and are to be used within a single patient procedure only.	The antennas are disposable and are to be used within a single patient procedure only.	The antennas are disposable and are to be used within a single patient procedure only.	Same
Sterility	The accessories are sterilized with EO(SAL: 10^{-6})	The accessories are sterilized with EO(SAL: 10^{-6})	The accessories are sterilized with EO(SAL: 10^{-6})	Equivalent
Biocompatibility	Patient-contacting materials are biocompatible.	Patient-contacting materials are biocompatible.	Patient-contacting materials are biocompatible.	Equivalent
Device Temperature Monitoring	Temperature monitoring features used to ensure system safety	Temperature monitoring features used to ensure system safety	Temperature monitoring features used to ensure system safety	Equivalent
Device cooling	Pumped, normal saline is used to cool the antenna.	Pumped, normal saline is used to cool the antenna.	Pumped, normal saline is used to cool the antenna.	Equivalent

All the differences don't affect the safety and effectiveness which is concluded after all the required testing, so no safety and effectiveness issues relating to the system come into conclusion.

7. Performance Data

Clinical test:

Clinical testing is not required.

Non-clinical data

Disposable Microwave Therapeutic Antennas comply with:

Electrical Safety:

- ES60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)

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

Shelf Life:

- Accelerated aging tests were conducted to confirm the validity of the 2 years shelf life for Disposable Microwave Therapeutic Antennas.

Thermal Effects 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, “Biological Evaluation of Medical Devices”.

8. SE Conclusion

The proposed device is equivalent with respect to the basic design and function to that of the predicate device. It doesn’t have new intended purposed, new medical, new target populations, and new users. The differences between the predicate, reference device and proposed device do not raise new questions of safety or effectiveness. The proposed device is substantial equivalence to predicate device (K183153).