July 9, 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
China

Re: K201262
Trade/Device Name: Microwave Therapeutic System
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: 2021.07.09 08:54:29 -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)*
K201262

Device Name
Microwave Therapeutic System

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

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

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
E-mail:	weihong@njeco.com.cn
Tel:	+86- 025-58872663 Ext: 8020

2. Device Identification

Trade/Device Name:	Microwave Therapeutic System
Models:	SABERWAVE ECO-200G
Regulation Number:	21 CFR 878.4400
Device Common Name:	Microwave ablation system and accessories
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

The Microwave Therapeutic System is a host machine which will be used together with Disposable Microwave Ablation Needle for ablation of soft tissue. The Microwave Therapeutic System consists of microwave source, control system, display system and temperature measurement system. It is a software-controlled microwave generator that deliver the microwave energy at a working frequency of 2450 MHz.

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.

5. Indication for use

The Microwave Therapeutic System is indicated for the coagulation (ablation) of soft tissue. The Microwave Therapeutic System 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 K201262	Predicate device K183153	Comments
Manufacturer/K#	Nanjing ECO Microwave System Co., Ltd.	Surgnova Healthcare Technologies (Zhejiang) Co., Ltd.	--
Trade name	Microwave Therapeutic System Model: SABERWAVE ECO-200G	Microwave ablation system Model: M150E	--
Classification 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	Same

Indications for use	The Microwave Therapeutic System is indicated for the coagulation (ablation) of soft tissue. The Microwave Therapeutic System 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 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	Same
Operating principle	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.	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 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.	Equivalent. The microwave generator instrument and antenna of the predicate device are combined to submit 510k together, the subject device only include generator instrument, the principle of generator instrument is equivalent.
Design	Single channel	Double channels	Different, please refer to comment 1.
	cooling-water cycle, thermal ablation, the probe of TEMP, foot switch	cooling-water cycle, thermal ablation, the probe of TEMP, foot switch	Same
AC input Voltage	AC100-240V, 50/60Hz	100-240VAC 50-60 Hz	Same
Output Impedance	50Ω nominal	50Ω nominal	Same
Output parameters	2450MHz±20MHz,	2450MHz±10MHz,	Same

	0-100W	0-100W	
Device Temperature Monitoring	Temperature monitoring features used to ensure system safety	Temperature monitoring features used to ensure system safety	Same
Device cooling	Pumped, normal saline is used to cool the antenna.	Pumped, normal saline is used to cool the antenna.	Same
Operational mode	Three modes can be selected by the user.	Only one operational mode	Different, please refer to comment 2.

Comment 1: Different, predicate device support double channels and two ablation needles can be inserted at the same time for tissue ablation. Our product only supports single channel and only one ablation needle for tissue ablation, Double-needle ablation speeds up the time of a single ablation, but there are injury and risks due to multiple punctures to patient. Single-needle ablation can also achieve the intended use and reduce the injury and risk of multiple punctures to the patient. The subject device has performed the Thermal effects test, performance test according to IEC 60601-2-6, temperature measurement accuracy test, the test result prove that single needle ablation can also achieve the intended use, the performance meet the requirements of IEC 60601-2-6, the temperature measurement accuracy meet the requirements of intended use, the difference does not affect the product's safety and performance.

Comment 2: Different, predicate devices have only a single operation mode. We have designed three modes according to the expected usage scenarios, which are convenient for users to operate according to different tissue types and sizes. 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, these are just to give users more operating options, and do not change the intended use and function of the product, the subject device has been conducted software verification according to the FDA software guidance, the test result proves the functions in each operational mode can be achieved. This difference does not raise a new risk.

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

Microwave Therapeutic System and predicate device are substantially equivalent in design concepts, technologies, which have been designed and tested in accordance 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

Software validation:

- Software validation is in compliance with FDA guidance for the content of premarket submissions for software contained in Medical devices.

Shelf Life:

- Accelerated aging tests were conducted to confirm the validity of the 8 years shelf life for machine.

Thermal Effects test and Temperature monitoring test:

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

8. Conclusion

The proposed device is equivalent with respect to the basic system design and function to that of the predicate device. The proposed device isn't the implants and high-risk device. And it doesn't have new intended purposes, new medical, new target populations, and new users and so on. What's more. The differences between the predicate and proposed device do not raise new questions of safety or effectiveness.