July 8, 2019

Surgnova Healthcare Technologies (Zhejiang) Co., Ltd.
Guofang Ma
Quality Director
No.1 XinXing Yilu Road, Emerging Industrial Cluster Area
Zonghan Subdistrict, Cixi City, Zhejiang, China 315300

Re: K183153
Trade/Device Name: Microwave Ablation System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: NEY
Dated: November 2, 2018
Received: November 14, 2018

Dear Guofang Ma:

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 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K183153

Device Name
Microwave Ablation System

Indications for Use *(Describe)*
The Microwave Ablation System is intended for coagulation (ablation) of soft tissue. It is not intended for use in cardiac procedures.

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."

Section III 510(k) Summary

This summary of 510(k) is being submitted in accordance with the requirements of 21 CFR 807.92.

There is no prior submission for the device.

3.1 Submitter Information

- **510(k) Submitter/Holder:**
  Surgnova Healthcare Technologies (Zhejiang) Co., Ltd.
  No.1 Xinxing Yilu Road, Emerging Industrial Cluster Area, Zonghan Subdistrict, Cixi City, Zhejiang, China
- **Contact**
  Guofang Ma
  Quality Director
  Telephone: +86-10-64116115
  Fax: +86-10-64113261
  Email: QARA@surgnova.com
- **Date Prepared: August 02, 2018**

3.2 Proposed Device Information

Device Common Name: Microwave ablation system and accessories
Device Trade/Proprietary Name: Microwave Ablation System
Model: M150E
Classification Name: Electrosurgical cutting and coagulation device and accessories
Regulation Number: 878.4400
Product Code: NEY
Class: II
Panel: General & Plastic Surgery

3.3 Predicate Device

510(k) Number: K133821
Common Name: Microwave ablation system and accessories
Device Trade/Proprietary Name: Emprint™ Ablation System
Classification Name: Electrosurgical cutting and coagulation device and accessories
Regulation Number: 878.4400
Product Code: NEY
Class: II
Panel: General & Plastic Surgery
Manufacturer: Covidien LLC

3.4 Device Description

The Microwave Ablation System M150E is microwave-based system intended to deliver energy through an antenna inserted into soft tissue for the purpose of coagulating (ablating) a defined volume of that tissue. The Microwave Ablation System utilizes a 2450MHz generator to deliver power to single microwave ablation antenna or double microwave ablation antennas. The Microwave Ablation Generator provides for user setting of ablation time and ablation power.

The proposed device consists of Microwave Ablation Generator, Microwave Ablation Electrode Kits, Temperature Probe and Foot Switch. Wherein, The Microwave Ablation Electrode Kits consists of Microwave Ablation Antenna, water pipe and Coax cable, to be used for puncturing the patient's lesion position during operation and also for outputting microwave energy to ablate the tumor tissue through connection with Microwave Ablation Generator. The Temperature Probe is applied to monitor the temperature of the target location and to protect important organs and tissues in the periphery of the lesion from unexpected damage by microwave energy.

It supports both power and temperature modes.

Power mode

Under the power mode, at the beginning, the system output microwave power according manually setting. When the tissue temperature reaches the target temperature, the system adjusts the duty cycle in real time according to the specific algorithm and load power to keep the tissue temperature on the target temperature. Two microwave ablation antennas can be used for microwave ablation.

Temperature mode

Under the temperature mode, at the beginning, the system output microwave power according manually setting. When the tissue temperature reaches the target temperature, the system adjusts the output of microwave power in real time according to the specific algorithm to keep the tissue temperature on the target temperature. Two microwave ablation antennas can be used for microwave ablation.

The Microwave Ablation Generator is non-sterile, while Microwave Ablation Electrode Kits and Temperature Probe are sterile.

The device is software-driven and the software validation is provided in Section of Software.

3.5 Comparison list of the technological characteristics

Based on the comparison of the clinical, technical and ablation antennas of the predicate device—Emprint™ ablation system, there are no significant differences between the two devices in the material, the key technology, the design characteristics, the applicable population, the site of action, etc. Confirming that both devices are equivalent in terms of clinical performance and safety. The specific results are as follows:

Comparison Elements		**Predicate Device (K133821)**	**Proposed Device**	**Comparison (Equivalent, Similar, Different)**
Product Name		Emprint™ Ablation System	Microwave Ablation System	/
Regulation No.		21 CFR 878.4400	21 CFR 878.4400	Equivalent
Classification		II	II	Equivalent
Classification Name		Electrosurgical cutting and coagulation device and accessories	Electrosurgical cutting and coagulation device and accessories	Equivalent
Product Code		NEY	NEY	Equivalent
Clinical	Indications for Use	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 Emprint™ Ablation System is not	The Microwave Ablation System is intended for the coagulation (ablation) of soft tissues. The Microwave Ablation System is not intended for use in cardiac procedures.	Equivalent

		intended for use in cardiac procedures.		
	Intended purpose	coagulation and ablation of tissue	coagulation and ablation of tissue	Equivalent
Comparison Statement		**The proposed device has the same indications for use and classification as the predicate device.**		
Technical	Design	Single channel	Double channels	Different
		cooling-water cycle, thermal ablation, the probe of TEMP, foot switch	cooling-water cycle, thermal ablation, the probe of TEMP, foot switch	Equivalent
	Comparison Statement	**Compared with the predicate device, the proposed device has double channel to output energy. The two channel not only can output energy at the same time but also can work respectively.**		
	Operating temperature	10℃-30℃	5℃-40℃	Similar
	Operating humidity	20%~80% non condensation	20%~80% non condensation	Equivalent
	Comparison Statement	**The proposed device operating environment temperature is wider than that of the equivalent product. We have confirmed through environmental tests that this temperature range does not affect the product's safety and performance.**		
	Output Parameters	2450MHz±50MHz, 0-100W	2450MHz±10MHz, 0-100W	Equivalent
	Output Impedance	50Ω nominal	50Ω nominal	Equivalent

	Voltage Supply	100-240VAC 50-60 Hz	100-240VAC 50-60 Hz	Equivalent
	Fuse Rating	6.3 A, 250V	6.3 A, 250V	Equivalent
	Physicochemical Properties	Not contain any medications, animal tissues or blood components, especially in contact with human tissue does not contain the above substances.	Not contain any medications, animal tissues or blood components, especially in contact with human tissue does not contain the above substances.	Equivalent
	Working 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 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.	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
Comparison Statement		**The proposed device and predicated device have the same working principle and similar technical parameter.**		
Disposable accessories-	Antenna Length (mm)	CA15L1: 150	SS-MWA-1526C: 150 SS-MWA-1531C: 150	Different

Ablation Antennas		CA20L1: 200 CA30L1: 300	SS-MWA-2026C: 200 SS-MWA-2031C: 200 SS-MWA-2526C: 250 SS-MWA-2531C: 250	
	Comparison Statement	**The ablation antenna 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.**		
	Emission area length (mm)	CA15L1: 28 CA20L1: 28 CA30L1: 28	SS-MWA-1526C: 26 SS-MWA-1531C: 31 SS-MWA-2026C: 26 SS-MWA-2031C: 31 SS-MWA-2526C: 26 SS-MWA-2531C: 31	Different
	Comparison Statement	**The range of microwave emission area of the proposed device is wider than that of the predicate device, We have proved through performance tests that this difference does not affect the product's safety and performance.**		
	OD(mm)	CA15L1: 2.40 CA20L1: 2.40 CA30L1: 2.40	SS-MWA-1526C: 2.08 SS-MWA-1531C: 2.08 SS-MWA-2026C: 2.08 SS-MWA-2031C: 2.08 SS-MWA-2526C: 2.08 SS-MWA-2531C: 2.08	Different
	Comparison Statement	**Based on not affecting the area of the ablation, the diameter of the microwave antenna is thinner, so that the trauma caused by the puncture is smaller.**		
	Material	fiberglass, resin, ceramics	304SS, polyethlene terephthalate, ceramics	Different

	Comparison Statement	**The 304 stainless steel usually has excellent corrosion resistance, good weldability and formability, good resistance to hydrogen embrittlement, in addition to high ductility and toughness. The material of the proposed device has passed the Bicompatibility test according to ISO 10993-1.**		
	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.	Equivalent
	Sterility	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.	Equivalent
	Device Temperature Monitoring	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 Emprint™ Antenna.	Pumped, normal saline is used to cool the antenna.	Equivalent
Comparison Statement		**The proposed device and predicated device have the similar disposable accessories-Ablation Antennas and same sterilization method.**		

3.6 Indications for 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.

3.7 Testing

Non-Clinical Testing

The Microwave Ablation System and Accessories and the predicate device are substantially equivalent in design concepts, technologies and materials. The Microwave Ablation System and Accessories has been designed and tested and will be manufactured in accordance with both mandatory and voluntary standards, including:

- IEC 60601-1: 2005/A1:2012 Medical Electrical Equipment-Part 1: General requirements for safety.

- IEC 60601-2-6:2012 Medical electrical equipment –Part 2-6: Particular requirements for the basic safety and essential performance of microwave therapy equipment.

- IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.

- ISO 11607-1:2016 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems.

- ISO 11135: 2014 Sterilization of health care products -- Ethylene oxide -- Requirements for the development, validation and routine control of a sterilization process for medical devices

The Software Validation is in compliance with FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.

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”.

The shelf life of Microwave Ablation Electrode Kits and Temperature Probe is 2 years.

The list of non-clinical test performed on the proposed device.

No.	Test Name
1	Electrical Safety Test According to IEC 60601-1
2	Electromagnetic Compatibility Test According to IEC 60601-1-2

3	Performance Test according to IEC 60601-2-6
4	System Performance Test
5	Thermal Effects test according to FDA Guidance Premarket Notification (510(K)) Submissions for Electrosurgical Devices for General Surgery
6	Temperature Monitoring test according to FDA Guidance Premarket Notification (510(K)) Submissions for Electrosurgical Devices for General Surgery
7	Shelf Life Test
8	Package Verification Test according to ISO 11607-1
9	Sterilization validation according to ISO 11135
10	Irritation, Sensitization, Cytotoxicity, Pyrogenicity, Acute Systemic Toxicity Test according to ISO 10993

Clinical Testing

Clinical studies were not required to demonstrate the substantial equivalence of the microwave ablation system and the predicated device.

3.8 Determination of substantial equivalence

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, it can't use the medicinal substances or animal tissues. So differences between the predicate and proposed device do not raise new questions of safety or effectiveness.