June 25, 2019

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

Re: K190052
Trade/Device Name: Radio Frequency Ablation System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: December 31, 2018
Received: January 11, 2019

Dear Grace 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)*
K190052

Device Name
Radio Frequency Ablation System

Indications for Use *(Describe)*
The Radio Frequecy Ablation System is intended for coagulation and 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.

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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**
  Grace Ma
  Quality Director
  Telephone: +86-10-64116115
  Fax: +86-10-64113261
  Email: QARA@surgnova.com
- **Date Prepared: November 12, 2018**

3.2 Proposed Device Information

Device Common Name: Electrosurgical cutting and coagulation device and accessories
Device Trade/Proprietary Name: Radio Frequency Ablation System
Model: R150E
Classification Name: Electrosurgical cutting and coagulation device and accessories
Regulation Number: 878.4400
Product Code: GEI
Class: II
Panel: General & Plastic Surgery

3.3 Predicate Device

510(k) Number: K052796
Device Trade/Proprietary Name: Cool-tip™ RF Ablation System
Common/Classification Name: Electrosurgical cutting and coagulation device and accessories
Regulation Number: 878.4400
Product Code: GEI
Class: II
Panel: General & Plastic Surgery
Manufacturer: VALLEYLAB

3.4 Device Description

The proposed device consists of Radio Frequency Generator, Radio Frequency Electrode Kits, Temperature Probe and Foot Switch. Wherein, the radiofrequency generator integrated with cooling pump is capable of delivering up to 200W while monitoring tissue impedance, tissue temperature and electrode tip temperature during the delivery of the RF energy. The Radio Frequency Electrode Kits consists of Radio Frequency Electrode, introducer, inflow - outflow tubing sets and Return Pad to be used for puncturing the patient's lesion position during operation and also for outputting Radio Frequency energy to ablate the tumor tissue through connection with Radio Frequency 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 Radio Frequency energy.

The Radio Frequency generator supplies 470 kHz of radio frequency current, which enters into target tissue of patient, and builds a circuit loop with the Return Pad. The alternating current cause alternating motion of the positive and negative ions in the tumor region. Because of the different size, mass and charge of each ion, the moving speeds of the ions are different, resulting in collision friction and thermal energy. When the temperature is above 50 ℃, tumor tissue come into irreversible coagulation necrosis.

It supports three working modes: Auto Mode, POWER Mode and TEMP Mode.

Auto Mode

The Auto Mode allows the use of 1-3 RF ablation electrodes for ablation. When multiple RF Ablation electrodes are connected, the RF generator will switch between the electrodes for energy output. In Auto Mode, the system automatically adjusts the power output according to the built-in algorithm.

Power mode

In POWER Mode, the RF generator outputs according to the maximum power set by users. In this mode, only single RF electrode is allowed to be used. The RF Electrode is kept below 40°C by means of internal cooling with cooling-water delivers from a peristaltic pump.

Temperature mode

In TEMP Mode, the RF generator detects the temperature of the RF electrode automatically, and adjusts the power output according to the detected temperature. In this mode, "SET POWER(W)" is forbade to set. Single RF electrode is permitted to use. Once the temperature of RF electrode reaches 85℃, a beep sounds. Then users can pull the RF electrode out of patient at a rate of 1centimetre every 2 seconds.

The Radio Frequency Generator is non-sterile, the return pad is non-sterile and for single use, while Radio Frequency Electrode and Temperature Probe are sterile and for single

use.

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

3.5 Comparison list of the technological characteristics

Comparison Elements	**Predicate Device (K052796)**	**Proposed Device**
Product Name	Cool-tip™ RF Ablation System	Radio Frequency Ablation System
Regulation No.	21 CFR 878.4400	21 CFR 878.4400
Classification	Ⅱ	Ⅱ
Product Code	GEI	GEI
Indications for Use	The Valleylab Cool-tip RF System (generator and accessories) is intended for the use in percutaneous, laparoscopic, intraoperative coagulation and ablation of tissue, such as partial or complete ablation of non-resectable liver lesions and osteoid osteoma tumors within bone.	The Radiofrequency Ablation System is intended for coagulation and ablation of soft tissue. It is not intended for use in cardiac procedures.
Component	RF Generator, peristaltic pump, electrodes, inflow and outflow tubing for electrode cooling, and return pads	Radio Frequency Generator, Radio Frequency Electrode Kits, Temperature Probe and Foot Switch
Electrosurgical unit		
Output Parameters	480KHZ±2%	470KHZ±2%
Drive on time	Up to 30minutes	Up to 30minutes

Maximum power output	Up to 200 watts @50 ohm	Up to 200 watts @50 ohm
Voltage Supply	100-240VAC 50-60 Hz	100-240VAC 50-60 Hz
Active accessary		
Monopolar/Bipolar	Monopolar	Monopolar
Antenna Length (mm)	100, 150, 200, 250	70, 150, 200, 250
Exposure Length (mm)	7, 10, 20, 30	5, 7, 10, 15, 20, 30, 40
Outer Diameter (mm)	1.47	1.2, 1.47
Material	Stainless steel 304	Stainless steel 304
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.
Sterility	The accessories are sterilized with EO(SAL: 10^{-6})	The accessories are sterilized with EO(SAL: 10-6)
Biocompatibility	Patient-contacting materials are biocompatible.	Patient-contacting materials are biocompatible.
Device Temperature Monitoring	Temperature monitoring features used to ensure system safety	Temperature monitoring features used to ensure system safety
Neutral electrodes		
Conductive or Capacitive	Conductive	Conductive
Patient Contacted Material	Hydrogel	Hydrogel

3.6 Indications for use

The Radio Frequency Ablation System is intended for coagulation and ablation of soft tissue. It is not intended for use in cardiac procedures.

3.7 Testing

Non-Clinical Testing

The Radio Frequency Ablation System and Accessories and the predicate device are substantially equivalent in design concepts, technologies and materials. The Radiofrequency 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 60601-2-2:2009 Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories.

• 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 Radiofrequency 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 60601-2-2
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	High Frequency Leakage Current Test according to FDA Guidance Premarket Notification (510(K)) Submissions for Electrosurgical Devices for General Surgery
8	Shelf Life Test
9	Package Verification Test according to ISO 11607-1
10	Sterilization validation according to ISO 11135
11	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.