October 25, 2021

Surgnova Healthcare Technologies (Zhejiang) Co., Ltd.
Guofang Ma
QARA Director
No.1 XinXing Yilu Road, Emerging Industrial Cluster Area
Zonghan Subdistrict, Cixi, Zhejiang 315301
China

Re: K210488
Trade/Device Name: Ultrasonic Surgical & Electrosurgical Generator
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: September 10, 2021
Received: August 30, 2021

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210488

Device Name
Energy Generator

Indications for Use *(Describe)*
The Energy generator intended for use in the operating room for general procedures where ESU cutting and coagulation is required. The Energy generator is equipped with monopolar and bipolar outputs.

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.

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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**
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- **Date Prepared: October 22, 2021**

3.2 Proposed Device Information

Device Common Name: Electrosurgical cutting and coagulation device and accessories
Device Trade/Proprietary Name: Energy Generator
Model: ES300, ES200, ES100
Classification Name: Electrosurgical cutting and coagulation device and accessories
Regulation Number: 21 CFR 878.4400
Product Code: GEI
Class: II
Panel: General & Plastic Surgery

3.3 Predicate Device

510(k) Number: K944602
Device Trade/Proprietary Name: Valleylab Force Fx
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulation Number: 21 CFR 878.4400
Product Code: GEI
Regulatory Class: II
Panel: General & Plastic Surgery
Manufacturer: VALLEYLAB, INC.

3.4 Device Description

The Energy Generator is a microprocessor controlled, isolated output, high frequency generator designed for use in cutting and coagulation of tissue. The generator has the ability to perform both monopolar cutting and coagulation and bipolar coagulation of tissue in a wide range of surgical applications. The three models ES300, ES200 and ES100 have the same hardware. They have different software on the control board and has different electrosurgical power limit.

The device working mode is shown in the following table:

Table 1 Device working mode

Model	Working mode								
	Monopolar						Bipolar		
	Low pure cut	Pure cut	Blend	Desiccate	Fulgurate	Spray	Precise	Standard	Macro
ES300	√	√	√	√	√	√	√	√	√
ES200	N/A	√	√	N/A	√	√	N/A	√	√
ES100	N/A	N/A	√	N/A	N/A	√	N/A	N/A	√

Monopolar

- Low pure cut mode: applicable to cutting of fine tissues and endoscopic surgery
- Pure cut mode: applicable to fine non-invasive cutting
- Blend mode: providing good coagulant effect when cutting
- Desiccate mode: applicable to the coagulation of endoscopic surgery and other fine tissues
- Fulgurate mode: applicable to the superficial coagulation of most surgeries and laparoscopic surgeries
- Spray mode: applicable to large area of tissue bleeding, and only forming a scab in superficial tissue structure.

Bipolar

- Precise mode: applicable to neurosurgery, ophthalmology and other microsurgeries
- Standard mode: applicable to neurosurgery and general surgeries
- Macro mode: applicable to open and endoscopic surgeries

The monopolar Low pure cut mode, Pure cut mode, Blend mode, Desiccate mode, Fulgurate mode and Spray mode are designed for use with conventional hand switching or foot switching electrosurgical devices. The three bipolar output modes are designed for use with conventional hand switching or foot switching electrosurgical bipolar forceps. When using conventional electrosurgical devices, the user selects the mode and desired power using a touch screen display on the generator.

The monopolar mode requires use of neutral electrode. The Energy Generator can be compatible with neutral electrode based on their output rating with FDA clearance. For

example: FDA 510k cleared Electorsurgical pad: K130027 or other FDA cleared neutral electrode. Bipolar devices do not require neutral electrode.

3.5 Comparison list of the technological characteristics

Based on the components of the Energy Generator, the subject device is compared with Valleylab Force Fx (K944602). The technological characteristics, features, specifications and intended use of Energy Generator is substantially equivalent to the predicated devices quoted above. The specific results are as follows:

Table 2 Comparison between Energy Generator and Valleylab Force Fx (K944602)

Comparison Elements	**Subject Device**	**Predicated device (K944602)**
Product Name	Energy Generator	Valleylab Force Fx
Regulation No.	21 CFR 878.4400	21 CFR 878.4400
Classification	II	II
Classification Name	Electrosurgical cutting and coagulation device and accessories	Electrosurgical cutting and coagulation device and accessories
Indications for Use	The Energy generator intended for use in the operating room for general procedures where ESU cutting and coagulation is required. The ESU generator is equipped with monopolar and bipolar outputs.	The Valleylab Force Fx is an isolated, microprocessor based ESU generator intended for use in the operating room for general procedures where ESU cutting and coagulation is required. The generator is equipped with monopolar and bipolar outputs.
Working principle	Monopolar: ESU generator connects its accessories and split ESU neutral electrode (adhered to patient skin) to form a cyclic circuit, the HF current generated	Monopolar: ESU generator connects its accessories of a ESU pencil and a split ESU pad (adhered to patient skin) to form a cyclic circuit, the HF current

			from the generator and through the ESU accessories (such as electrosurgical pencil and laparoscopic electrode) to achieve CUT or COAG, then return to generator by the ESU neutral electrode. Bipolar: HF current generated from the generator and the cyclic circuit formed between the two tips of the bipolar forceps, the HF power through the two tips to work on patient obtaining COAG, no need extra ESU neutral electrode.	generated from the generator and through the ESU pencil to achieve CUT or COAG, then return to generator by the ESU pad. Bipolar: HF current generated from the generator and the cyclic circuit formed between the two tips of the bipolar forceps, the HF power through the two tips to work on patient obtaining COAG, no need extra ESU pad.
Energy			HF energy	HF energy
Input power			100V -240V AC	100-120V/220-240V, 60Hz/50Hz
Performance Specifications	**Waveform**	Monopolar CUT	Low Pure Cut Mode Pure Cut Mode Blend Mode	Low Pure Cut Mode Pure Cut Mode Blend Mode
		Monopolar COAG	Desiccate Mode Fulgurate Mode Spray Mode	Desiccate Mode Fulgurate Mode Spray Mode
		Bipolar	Precise Mode Standard Mode Macro Mode	Precise Mode Standard Mode Macro Mode
	Operation mode		Intermittent use 10s on, 30s off	Under maximum power settings and rated load conditions (pure cut 300W, 300ohm load) the generator is suitable for activation times of 10s on, 30s off for 1 hour.

Special function	**CQMS**	The Neutral Electrode Contact Quality Monitor will measure the resistance, if the resistance was beyond the range of defined by an upper and lower limit, the alarm system will be activated.	Force FX (REM): The Return Electrode Contact Quality Monitor will measure the resistance, if the resistance was beyond the range of defined by an upper and lower limit, the alarm system will be activated.
	Memory	The previous power setting digits presented when restart	Recall the last activated previous setting when Power On next time by pressing RECALL
	Power ON self diagnostics	The generator starts self diagnosis after power on, if the self diagnosis fail, an alarm sounds and an Error Code is displayed on the display panel.	Force Fx: When the generator senses a system alarm conditions, an alarm sounds and an alarm number is displayed on the front panel. A system alarm condition deactivates the generator.
	Operating	Only one output device to be activated at any given time	Only one output device to be activated at any given time

3.6 Indications for Use

The Eenergy generator intended for use in the operating room for general procedures where ESU cutting and coagulation is required. The ESU generator is equipped with monopolar and bipolar outputs.

3.7 Testing

Non-Clinical Testing

The Energy Generator and the predicate device are substantially equivalent in design concepts and technologies. The Energy Generator 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 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.

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

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

Clinical Testing

Clinical studies were not required to demonstrate the substantial equivalence of the Energy Generator and the predicated device.

3.8 Determination of substantial equivalence

The subject device is equivalent with respect to the basic system design and function to that of the predicate device. The subject 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. So the proposed device is determined to be substantially equivalent to the predicate device.