July 18, 2022

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

Re: K212614
Trade/Device Name: Ultrasonic Scalpel System
Regulatory Class: Unclassified
Product Code: LFL
Dated: May 24, 2022
Received: June 15, 2022

Dear Ms. 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,

for

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)*
K212614

Device Name
Ultrasonic Scalpel System

Indications for Use *(Describe)*
The Ultrasonic Scalpel System is intended to be used to transect, dissect, and coagulate tissue. The instruments are indicated for use in open and endoscopic general surgical procedures where bleeding control and minimal thermal injury to tissue are desired. The instruments allow for the coagulation of vessels (veins and arteries) up to 5 mm in diameter while using the power level 1. Device have not been shown to be effective for sterilization procedures or tubal coagulation. Do not use these instruments for these 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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510(k) Summary

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

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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  QA&RA Director

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  Email: QARA@surgnova.com

- **Date Prepared: July 15, 2022**

3.2 Proposed Device Information

Trade/Proprietary Name: Ultrasonic Scalpel System

Common Name: Ultrasonic Scalpel System

Model: SC100E

Device Classification Names: Instrument, Ultrasonic Surgical

Regulations Number: Unclassified

Product Code: LFL

Device Class: Unclassified

Panel: General & Plastic Surgery

3.3 Predicate Device

510(k) Number	K141122	K132612

Device Name	Generator G11	HARMONICACE®+Shears with Advanced Hemostasis
Classification Name	Electrosurgical, Cutting & Coagulation & Accessories; Electrocautery, Gynecologic (and Accessories); Instrument, Ultrasonic Surgical.	Instrument, Ultrasonic Surgical
Product Code	GEI, HGI, LFL	LFL
Device Class	Class II	Unclassified
Panel	General & Plastic Surgery	General & Plastic Surgery
Manufacturer	ETHICONENDO-SURGERY,LLC	ETHICONENDO-SURGERY,LLC

3.4 Device Description

The Ultrasonic Scalpel System is an ultrasonic dissection and coagulation system composed of four components: the single use Ultrasonic Scalpel including four shaft lengths; a multiple use transducer; a generator and a foot switch, details see following table:

Table III-1: Ultrasonic Scalpel System

Name		**Model**
Ultrasonic Scalpel System	Ultrasonic Generator	SC100E
	Ultrasonic Transducer	SC100T
	Ultrasonic Scalpel	SC43C+, SC35C+, SC21C+, SC13C+
	Foot Switch	TG-A

The single-use Ultrasonic Scalpel with EO sterilization contains the waveguide, shaft, jaws, trigger and activation button. Trigger activation opens and closes the jaws against the distal tip of the waveguide where the tissue is clamped.

The Ultrasonic Generator provides AC electrical energy to drive the Ultrasonic Transducer. The Ultrasonic Transducer converts the electrical energy into mechanical vibrations, making the Ultrasonic Scalpel waveguide tip keep vibrating with amplitude between 50μm-100μm at frequency about 55.5kHz. When the vibrating Ultrasonic Scalpel waveguide tip contacts with soft tissues, the hydrogen bond in proteins of the soft tissues is broken apart. The proteins become viscous and coagulate so as to stop bleeding and reduce damage to soft tissues in cutting.

The single-use Ultrasonic Scalpel with EO sterilization, the Ultrasonic Generator and Ultrasonic Transducer are of non-sterile package, the transducer has to be sterilized by users before being used in surgery.

This device is intended to be used in the hospital environment, such as surgical operation room and imaging intervention room.

3.5 Comparison list of the technological characteristics

Table III-2 Comparison with predicate device (K141122)

Comparison Elements		**Predicate Device (K141122)**	**Proposed Device**
Generator			
Product Name		Generator G11	Ultrasonic Generator
Regulation No.		21 CFR 878.4400, 21 CFR 878.4120, Unclassified (LFL)	Unclassified (LFL)
Classification		II	Unclassified
Product Code		GEI, HGI, LFL	LFL
Indications for Use		The Generator G11 provides radiofrequency power to drive Enseal electrosurgical instruments that are used during open or laparoscopic general and gynecological surgery to cut and seal vessels and to cut, grasp, and dissect tissues. In addition, the generator provides power to drive Harmonic ultrasonic surgical instruments that are indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. Enseal and Harmonic instruments when used with the Generator G11 have not been shown to be effective for sterilization procedures or tubal coagulation. Do not use these instruments for these procedures.	The Ultrasonic Scalpel System is intended to be used to transect, dissect, and coagulate tissue. The instruments are indicated for use in open and endoscopic general surgical procedures where bleeding control and minimal thermal injury to tissue are desired. The instruments allow for the coagulation of vessels (veins and arteries) up to 5 mm in diameter while using the power level 1. Device have not been shown to be effective for sterilization procedures or tubal coagulation. Do not use these instruments for these procedures.
Technological characteristics	Working Principle	The generator outputs the AC energy at a resonating frequency of 55.5KHz to the ultrasonic transducer, which transforms it to mechanical vibrations to reach the clamped tissue at the blade tip of the ultrasonic scalpel's waveguide. Vibrating at high frequency, the blade tip denatures protein in the tissue to form a sticky coagulum, with the pressure exerted on tissue with the blade surface collapses blood vessels and allows the coagulum to form a hemostatic seal. The precision of cutting and coagulation is controlled by the surgeon's technique and adjusting the power level, blade edge, tissue traction and blade pressure.	
	Size: Width x Height x Depth	Generator: 35.0cm x 35.5cm x 13.6cm	Generator: 40.0cm x 40.0cm x 12.0cm
	Design	The generator is configured to resonate with the transducer and scalpel at a resonant frequency to drive the scalpel's distal tip to vibrate at a high frequency.	The generator is configured to resonate with the transducer and scalpel at a resonant frequency to drive the scalpel's distal tip to vibrate at a high frequency.
	Power supply:	100–240 V, 50/60 Hz, 500 VA	100-240V AC, 50/60Hz, 200 VA
	Voltage output	Inconstant voltage	Inconstant voltage
	Power Output	Maximum electric power: 60W	Maximum electric power: 45W

	Output frequency	55.5KHz	55.5KHz
	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.
Transducer			
Product Name		HARMONIC Hand Piece	Ultrasonic Transducer
Device Model		HP054	SC100T
Working Principle		The hand pieces which contain piezoelectric transducers that convert electronic energy into ultrasonic vibration to power HARMONIC® Devices.	The Ultrasonic Transducer which contains piezoelectric transducers that converts electronic energy into ultrasonic vibration to power Ultrasonic Scalpel.
Reusable /Single-use Device		Reusable device	Reusable device
Reusable times		95 times	99 times.
Supply		It supplied non-sterilize, sterilize prior to use.	It is supplied non-sterilize, sterilize prior to use.
Sterilization method		Gravity /Prevacuum	Pulsation vacuum/Low temperature plasma
Foot Switch			
Product Name		Foot Switch	Foot Switch
Device Model		FSW11	TG-A
Working Principle		It connected to the Generator G11, can be used to control the energy output of the generator by the users stepping down the pedal.	It is connected to the Ultrasonic Generator, can be used to control the energy output of the generator by the users stepping down the foot switch.
Design features		Press the left foot pedal of the footswitch is equivalent to press the hand control MIN button. Press the right foot pedal of the footswitch is equivalent to press the hand control MAX button.	Press the left foot pedal of the foot switch is equivalent to press the hand control MIN button. Press the right foot pedal of the foot switch is equivalent to press the hand control MAX button.
Reusable /Single-use Device		Reusable	Reusable
Sterility		Non-sterile	Non-sterile
Cleaning and disinfection		Cleaning and disinfection, if foot switch contaminated by blood or body fluid according to IFU.	Cleaning and disinfection, if foot switch contaminated by blood or body fluid according to IFU or the hospital regulations.

Table III-3 Comparison with predicate device (K132612)

Comparison Elements	**Predicate Device (K132612)**	**Proposed Device**
Product Name	HARMONIC ACE®+ Shears with Advanced Hemostasis	Ultrasonic Scalpel

Regulation No.		Unclassified	Unclassified
Classification		Unclassified	Unclassified
Product Code		LFL	LFL
Indications for Use		The HARMONIC ACE+7, 5 mm Diameter Shears with Advanced Hemostasis are indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instruments can be used as an adjunct to or substitute for electro-surgery, lasers and steel scalpels in general, plastic, pediatric, gynecologic, urologic, thoracic, exposure to orthopedic structures(such as spine and joint space)， sealing and transection of lymphatic vessels, and other open and endoscopic procedures. The instruments allow for the coagulation of vessels up to and including 7 mm in diameter, using the Advanced Hemostasis hand control button.	The Ultrasonic Scalpel System is intended to be used to transect, dissect, and coagulate tissue. The instruments are indicated for use in open and endoscopic general surgical procedures where bleeding control and minimal thermal injury to tissue are desired. The instruments allow for the coagulation of vessels (veins and arteries) up to 5 mm in diameter while using the power level 1. Device have not been shown to be effective for sterilization procedures or tubal coagulation. Do not use these instruments for these procedures.
Technological characteristics	Model Number	HARH23 HARH36 HARH45	SC43C+ SC35C+ SC21C+ SC13C+
	Shaft Length (cm)	HARH23: 23 cm HARH36: 36 cm HARH45: 45 cm	SC43C+: 43cm SC35C+: 35cm SC21C+: 21cm SC13C+: 13cm
	Working Principle	Utilize ultrasonic energy to enable hemostatic cutting and/or coagulation of soft tissue. All Blades are powered through a generator that outputs optimal power curves and communicates with the surgical instruments.	The Ultrasonic Transducer connects the Ultrasonic Generator and the Ultrasonic Scalpel together. It converts electrical energy from the generator into mechanical vibrations and transmits them to the waveguide of the scalpel. The scalpel transmits the vibrations from the Ultrasonic Transducer to the clamped soft tissues for dissection and coagulation
	Description of function	The HARMONIC ACE+7, 5 mm Diameter Shears (Product Codes HARH23 / HARH36 / HARH45) with Advanced Hemostasis are sterile, single patient use instruments consisting of an ergonomic grip housing assembly with hand control buttons (MIN for minimum power level, MAX for maximum power level, and Advanced Hemostasis for large vessel	Ultrasonic Scalpel is sterile, single patient use instruments consisting of an ergonomic grip housing assembly with hand control buttons (MIN for minimum power level, MAX for maximum power level, and power level 1 of MIN button for large vessel sealing).

		sealing).	
	Description of power level	The MAX button is typically used for smaller vessels where cutting speed is fastest. The MIN button is typically used in slightly larger vessels and has reduced cutting speed. It is indicated for vessels up to 5 mm in size. The Advanced Hemostasis button is designed for larger vessels and is indicated for vessels up to 7 mm in size. In this mode, cutting speed is further reduced and hemostasis is maximized.	The MAX button is typically used for smaller vessels where cutting speed is fastest. The MIN button at power level 1 is typically used in larger vessels and has reduced cutting speed. It is indicated for vessels up to 5 mm in diameter.
	Tissue self-adjustment technology	The instruments utilize Adaptive Tissue Technology. This provides the generator with the ability to identify and monitor the instrument during use, which enables the generator to modulate and adjust its power output as well as provide audible feedback to the user as appropriate.	Energy timely adjustment technology provides the generator with the ability to monitor the real-time impedance during use so that the generator auto adjusts the power output and delivers it to the ultrasonic scalpel, as well as provides audible feedback to the user.
	Outer Diameter (mm)	5.5 mm	5.5 mm
	Blade frequency	55.5KHz	55.5KHz
	Blade amplitude	50~100 μm	50~100 μm
	Blade design/geometry	Multi-purpose shears	Multi-purpose shears
	Handle type	Pistol Grip	Pistol Grip
	Energy activation method	Press Max/Min button	Press Max/Min button
	Indicated vessel type	Veins and arteries	Veins and arteries
	Energy buttons	Max/Min	Max/Min
	Design	The device utilizes ultrasonic energy to enable hemostatic cutting and/or coagulation of soft tissue.	The device utilizes ultrasonic energy to enable hemostatic cutting and/or coagulation of soft tissue.
	Human Tissue or Body Fluids in Contact with the Device	Tissue	Tissue

3.6 Indications for use

The Ultrasonic Scalpel System is intended to be used to transect, dissect, and coagulate tissue. The instruments are indicated for use in open and endoscopic general surgical procedures where bleeding control and minimal thermal injury to tissue are desired. The instruments allow for the coagulation of vessels (veins and arteries) up to 5 mm in diameter while using the power level 1. Device have not been shown to be effective for sterilization procedures or tubal coagulation. Do not use these instruments for these procedures.

3.7 Performance data

Bench testing and laboratory evaluations in an animal model including acute and 21-day chronic studies were conducted to demonstrate that the Ultrasonic Scalpel System SC100E performs as intended.

Sterilization

The ultrasonic scalpel, which was single -use, was sterilized via ethylene oxide. The Ethylene oxide sterilization process is validated as per ISO 11135. The method used for ethylene oxide sterilization validation was overkill (half-cycle approach) method in a fixed chamber. Ethylene oxide residuals were tested and met ISO 10993-7 requirements.

Biocompatibility Testing

The proposed scalpel is in direct contact with body tissue, with contact duration of less than 24 hours. Biocompatibility testing was conducted on the scalpel in question on 5 tests of *in vitro* cytotoxicity, intracutaneous reactivity, skin sensitization, acute systemic toxicity and pyrogen as per FDA guidance *Use of international Standard ISO 10993-1*, which indicated that the device was not toxic, irritating or sensitizing, and was free of acute systemic toxicity and pyrogen.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the proposed device. The system was shown to comply with IEC 60601-1-2:2014 for electromagnetic compatibility and IEC 60601-1:2005/A1:2012 for electrical safety.

Performance testing

Performance test and functional tests were conducted on the proposed device in accordance with product design specifications and *IEC 61847:1998 Ultrasonics - Surgical systems - Measurement and declaration of the basic output characteristics*. Data generated from the test met the predetermined acceptance criteria.

Animal testing

The animal study was conducted on porcine model with test articles (SC43C+, SC35C+, SC21C+ and SC13C+) and control article (predicate device HARH36). It consisted of three experiments,

in vitro burst pressure, acute animal experiment and 21-day chronic animals experiment. The experiments results show that the safety and efficacy of the tested articles are similar to those of the control articles.

- *Burst pressure testing*

The test results demonstrated that either there was no statistical difference of burst pressure between test group and control group or the average burst pressure of test group was higher than that of the control group where there was statistical difference. There was no error or note observed during the *in vitro* burst experiment. Therefore, the results were deemed as acceptable.

- *Acute animal study*

The test results demonstrated the times and thermal damage range of test article of each vessel diameter range did not have statistical difference compared with those of control article. There was no failure of sealing identified during all sealings after first activation and after challenge.

- *Chronic Animal Testing*

Postoperative observation showed no abnormal phenomena in respiration, muscle movement, spasm, reflex, eye symptoms, salivation, hair standing, pain loss, muscle state, gastrointestinal condition, and skin condition in all animals. The gross examination of each animal demonstrated that there was no hematoma, bleeding or any other adverse condition of the sealed site. Few tissues showed moderate inflammatory cell infiltration, while most tissues showed a small number of inflammatory cells. There was wide fibrosis and mild tissue necrosis at the test site.

Packaging & Shelf life

The packaging and shelf life study was also conducted to ensure package integrity throughout the shelf life, including primary packaging validation as per ISO 11607 and shelf life validation as per ASTM F1980-16.

Software Verification and Validation

The Software verification and validation is in compliance with FDA Guidance-*Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*.

Clinical Study

Clinical studies were not required to demonstrate the substantial equivalence of the Ultrasonic Scalpel System and the predicated device.

3.8 Conclusion

The proposed device is similar to the predicate device; although the intended vessel sealing diameter is up to 5mm for the proposed device while 7mm for the predicate device, however, the substantial equivalence with the predicate is supported by the results of the bench testing and laboratory evaluations in an animal model, which demonstrates that the proposed device is as safe and effective, and performs as well as the predicate device under 5mm intended condition.