June 18, 2025

Shanghai Saints Sages Surgical Co., Ltd.
℅ Giselle Zhang
Lead QA&RA Consultant
Emergo Global Consulting, LLC
2500 Bee Cave Road
Building 1, Suite 300
Austin, Texas 78746

Re: K242894
Trade/Device Name: SanAgile™ Ultrasonic Surgery Advanced Portable Controller (SA10); SanAgile™ Ultrasonic Surgery Advanced Dissector (SASD14); SanAgile™ Ultrasonic Surgery Advanced Dissector (SASD23); SanAgile™ Ultrasonic Surgery Advanced Dissector (SASD36); SanAgile™ Ultrasonic Surgery Advanced Dissector (SASD45)
Regulatory Class: Unclassified
Product Code: LFL
Dated: May 16, 2025
Received: May 16, 2025

Dear Giselle Zhang:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

James H. Jang -S

Digitally signed by James H. Jang -S
Date: 2025.06.18 13:51:41 -04'00'

James Jang, Ph.D.
Acting 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K242894

Device Name
SanAgile™ Ultrasonic Surgery Advanced Portable Controller (SA10); SanAgile™ Ultrasonic Surgery Advanced Dissector (SASD14); SanAgile™ Ultrasonic Surgery Advanced Dissector (SASD23); SanAgile™ Ultrasonic Surgery Advanced Dissector (SASD36); SanAgile™ Ultrasonic Surgery Advanced Dissector (SASD45)

Indications for Use *(Describe)*
SA10 Portable Controller is intended to provide power to drive SanAgile™ Ultrasonic Surgery Advanced Dissectors that are indicated for vessel sealing and soft tissue incisions when bleeding control and minimal thermal injury are desired.
SanAgile™ Ultrasonic Surgery Advanced Dissectors are indicated for vessel sealing and soft tissue incisions when bleeding control and minimal thermal injury are desired in general, sealing and transection of lymphatic vessels, and other open or laparoscopic procedures.
The dissectors can be used to coagulate isolated vessels up to and including 5 mm in diameter, using the MIN button.

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.

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"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

Shanghai Saints Sages Surgical Co., Ltd.

1. Submission Sponsor

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Contact: Giselle.Zhang@ul.com
Title: Lead QA&RA Consultant

3. Date Prepared

06/18/2025

4. Device Identification

Trade/Proprietary Name:	SanAgile™ Ultrasonic Surgery Advanced Dissector and Portable Controller
Classification Name:	Instrument, Ultrasonic Surgical
Regulation Number(s):	Pre-Amendment
Product Code(s):	LFL
Class:	Unclassified
Classification Panel:	General & Plastic Surgery

5. Legally Marketed Predicate Device(s)

Device name:	HARMONIC ACE+ 7 Laparoscopic Shears with Advanced Hemostasis (23cm, 36cm, 45cm length)
510(k) number:	K1312612
Manufacturer:	ETHICON ENDO-SURGERY, LLC

Device name:	Ethicon Endo-Surgery Generator GIII
510(k) number:	K101990
Manufacturer:	ETHICON ENDO-SURGERY, LLC

6. Indication for Use Statement

SA10 Portable Controller is intended to provide power to drive SanAgile™ Ultrasonic Surgery Advanced Dissectors that are indicated for vessel sealing and soft tissue incisions when bleeding control and minimal thermal injury are desired.

SanAgile™ Ultrasonic Surgery Advanced Dissectors are indicated for vessel sealing and soft tissue incisions when bleeding control and minimal thermal injury are desired in general, sealing and transection of lymphatic vessels, and other open or laparoscopic procedures.

The dissectors can be used to coagulate isolated vessels up to and including 5 mm in diameter, using the MIN button.

7. Device Description

The SanAgile™ Ultrasonic Surgery Advanced Dissector and Portable Controller consists of two interdependent devices: portable controller (Cat. # SA10) and single patient use dissector (Cat. #s SASD14, SASD23, SASD36 and SASD45). The SA10 Portable Controller is a compact portable generator and provides power to drive the dissectors for dissection, coagulation, and cutting tissues in open or laparoscopic procedures.

The SanAgile™ Ultrasonic Surgery Advanced Dissector and Portable Controller is intended to be used by qualified medical professionals trained in the techniques and surgical procedures, such as surgeons and nurses, in hospital operation rooms. SA10 Portable Controller is also intended to be maintained by trained service or biomedical engineers and validated for cleaning and disinfection between surgeries. The Advanced Dissector is integrated with a transducer for single use; therefore, no dissector-transducer assembly is required prior to surgery.

8. Substantial Equivalence Discussion

The following table compares the SanAgile™ Ultrasonic Surgery Advanced Dissector and Portable Controller to the predicate device with respect to indications for use, principles of operation, technological characteristics, materials, and performance, and forms the basis for the determination of

substantial equivalence. The subject device does not raise any new questions of safety or effectiveness as compared to the predicate device.

Comparison of Characteristics

Portable Controller			
Attribute	**Subject:** **SanAgileTM Ultrasonic Surgery Advanced Dissector and Portable Controller**	**Predicate:** **Ethicon Endo-Surgery Generator GIII K101990**	**Comparison Comments**
Device Classification	Same	Class II	N/A
Product Code	Same	LFL, GEI, HGI	N/A
Regulation Number	Same	N/A	N/A
Indications for Use	SA10 Portable Controller is intended to provide power to drive SanAgile™ Ultrasonic Surgery Advanced Dissectors that are indicated for vessel sealing and soft tissue incisions when bleeding control and minimal thermal injury are desired. SanAgile™ Ultrasonic Surgery Advanced Dissectors are indicated for vessel sealing and soft tissue incisions when bleeding control and minimal thermal injury are desired in general, sealing and transection of lymphatic vessels, and other open or laparoscopic procedures. The dissectors can be used to coagulate isolated vessels up to and including 5 mm in diameter, using the MIN button.	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 tissue. 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.	Different
Technology	Ultrasonic energy	Ultrasonic energy, Adaptive Tissue Technology	Different
Output (Maximum Electrical Power)	Same	35W	N/A
Power Setting	Two energy delivery buttons Minimum and maximum button. User cannot adjust	Three energy delivery buttons: • MAX Hand Control Button (both sides of instrument) • MIN Hand Control Button (both sides of instrument) • Advanced Hemostasis Hand Control Button	Different

Dissector			
Attribute	**Subject:** **SanAgile™ Ultrasonic Surgery Advanced Dissector and Portable Controller**	**Predicate:** **HARMONIC ACE+ 7 Laparoscopic Shears with Advanced Hemostasis (23cm, 36cm, 45cm length)** **K132612**	**Comparison Comments**
Device Classification	Same	Unclassified	N/A
Product Code	Same	LFL	N/A
Regulation Number	Same	N/A	N/A
Indications for Use	SA10 Portable Controller is intended to provide power to drive SanAgile™ Ultrasonic Surgery Advanced Dissectors that are indicated for vessel sealing and soft tissue incisions when bleeding control and minimal thermal injury are desired. SanAgile™ Ultrasonic Surgery Advanced Dissectors are indicated for vessel sealing and soft tissue incisions when bleeding control and minimal thermal injury are desired in general, sealing and transection of lymphatic vessels, and other open or laparoscopic procedures. The dissectors can be used to coagulate isolated vessels up to and including 5 mm in diameter, using the MIN button.	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 electrosurgery, 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.	Different
Technology	Ultrasonic energy	Ultrasonic energy, Adaptive Tissue Technology	Different
Sterility	Same	EO Sterilized	N/A
Output (Drive Frequency)	Same	55.5 kHz	N/A
Shaft Diameter	5mm	5 mm	Different
Jaw Aperture	11.23 mm	11.16 mm	N/A
Jaw Length	17 mm	14.56 mm	N/A
Clamping Force	Same	13.30N	N/A
Grasping Force	> 10N	11.50N	N/A
Blade Design / Geometry	Same	Curved	N/A

Shaft Lengths	14, 23, 36, 45 cm	23, 36, 45 cm	Different
Packaging	Same	ASTM D4196 ISO 11607-1	N/A
Energy Activation Method	Hand-switches	Hand-switches and footswitches	Different
Maximum Indicated Vessel Size	Same	7mm	N/A
Handle Type	Same	Pistol Grip	N/A
Electrical Safety	Same	IEC 60601-1	N/A
EMC	Same	IEC 60601-1-2	N/A
Biocompatibility	Same	Biocompatible	N/A

9. Non-Clinical Performance Data

To demonstrate safety and effectiveness of SanAgile™ Ultrasonic Surgery Advanced Dissector and Portable Controller and to show substantial equivalence to the predicate device, Saint Sages completed the following non-clinical tests. Results confirm that the design inputs and performance specifications for the device are met. The SanAgile™ Ultrasonic Surgery Advanced Dissector and Portable Controller passed the testing in accordance with internal requirements, national standards, and international standards shown below, supporting its safety and effectiveness, and its substantial equivalence to the predicate device:

- Cytotoxicity testing per ISO 10993-5 – Passed
- Sensitization testing per ISO 10993-10 – Passed
- Acute Systemic Toxicity Effects per ISO 10993-11 – Passed
- Intracutaneous Reactivity testing per ISO 10993-23 – Passed
- Pyrogen per USP <151> – Passed
- Electrical Safety testing per IEC 60601-1 – Passed
- Electromagnetic Disturbance testing per IEC 60601-1-2 – Passed
- Electromagnetic Immunity testing per IEC 60601-4-2
- Software verification and validation per IEC 62304/FDA Guidance – results /conclusion
- Dimensional verification – Met specifications
- Sterilization validation – demonstrates SAL of 10^{-6}
- Shelf-Life testing – Supports shelf life of 3 years
- Transportation testing per ASTM D4169 – Demonstrates package integrity maintained
- Ex Vivo Burst Pressure Study – Demonstrates the device can perform as intended
- Acute and Chronic Animal Study – Demonstrates the device can perform as intended in animal models

10. Clinical Performance Data

No clinical data was necessary to determine the substantial equivalence of this device.

11. Statement of Substantial Equivalence

The SanAgile™ Ultrasonic Surgery Advanced Dissector and Portable Controller has the same intended use as the predicate device and similar technological characteristics. The differences in technological characteristics do not raise new or different questions of safety and effectiveness. Based on the results of the risk assessment and all applicable testing, the SanAgile™ Ultrasonic Surgery Advanced Dissector and Portable Controller is determined to perform as intended during normal anticipated usage and is at least as safe, as effective, and performs as well as the legally marketed predicate device and therefore is substantially equivalent to the predicate device.