June 18, 2024

Hunan Handlike Minimally Invasive Surgery Co., Ltd.
% Lee Cassie
Official Correspondent
Share Info (Guangzhou) Medical Consultant Ltd.
No. 1919-1920, Building D3, Minjie Plaza, Shuixi Road,
Huangpu District
Guangzhou, Guangdong 510700
China

Re: K233036
Trade/Device Name: Ultrasonic Surgical System
Regulatory Class: Unclassified
Product Code: LFL
Dated: May 17, 2024
Received: May 17, 2024

Dear Lee Cassie:

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.

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,

Mark Trumbore -S

Digitally signed by Mark Trumbore -S
Date: 2024.06.18 14:02:02 -04'00'

Mark Trumbore, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
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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)*
K233036

Device Name
Ultrasonic Surgical System

Indications for Use *(Describe)*
The Ultrasonic Surgical 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 3 mm in diameter.

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 for K233036

Prepared on: 2024-06-13

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 801.92.

1. Submitter's Information

510(k) Owner's Name: Hunan Handlike Minimally Invasive Surgery Co., Ltd.
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2. Subject Device Information

Type of 510(k): Traditional
Trade Name: Ultrasonic Surgical System
Model: HD-CSXT-001
Common Name: Ultrasonic Shears
Classification name: Instrument, Ultrasonic Surgical
Product Code: LFL
Regulation Number: Unclassified

3. Predicate Device Information

Predicate Device 1:
Sponsor: Surgnova Healthcare Technologies (Zhejiang) Co., Ltd.
Trade Name: Ultrasonic Scalpel System
510(K) Number: K212614
Classification name: Instrument, Ultrasonic Surgical
Product Code: LFL

Review Panel: General & Plastic Surgery
Regulation Class: Unclassified

Predicate Device 2:
Sponsor: Ethicon Endo-Surgery, LLC
Trade Name: HARMONIC Hook
510(K) Number: K151136
Classification name: Instrument, Ultrasonic Surgical
Product Code: LFL
Review Panel: General & Plastic Surgery
Regulation Class: Unclassified

4. Device Description

Ultrasonic Surgical System is an ultrasonic dissection and coagulation system composed of four components: Ultrasonic Generator (HD-CSD01), Hand Piece (HD-CSH01), a disposable Ultrasonic Shears includes 4 shaft lengths (HD-CS-DJ45, HD-CS-DJ36, HD-CS-DJ22, HD-CS-DJ14) and foot switch (HRF-M52).

A disposable Ultrasonic Shears is a sterile component that has undergone EO sterilization, including an ultrasonic horn, jaws, main shaft, axis rotation, handle, operating handle, and control switch. The operating handle is used to open and close the jaws that grip the tissue.

The Ultrasonic Surgical System can simultaneously cut and coagulate tissues by setting different output power levels. The high-power range allows for faster tissue cutting, while the low-power range allows for better tissue closure. The ultrasonic frequency current in the ultrasonic generator is transmitted to the hand piece, which converts electrical energy into mechanical energy for forward and backward vibration. Through the transmission and release of the blade, the end of the blade vibrates at a certain frequency. The heat generated by friction causes water vaporization in the tissue cells that come into contact with the blade, protein hydrogen bonds break, cells collapse and re fuse, and the tissue is cut open after solidification; When cutting blood vessels, the knife head contacts with Histone and generates heat through mechanical vibration, leading to the destruction of the collagen structure in the tissue, causing the protein to coagulate, and then sealing the blood vessels to stop bleeding.

The disposable ultrasonic shears are EO sterilized, but the other parts are non-sterilized packaging, and the hand piece must be cleaned and sterilized by the user before being used for surgery.

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

5. Intended Use / Indications for Use

The Ultrasonic Surgical 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 3 mm in diameter.

6. Comparison to predicate device

6.1 Comparison table for Ultrasonic Generator, transducer and pedal

Elements of Comparison	Subject Device	Predicate Device 1
Manufacturer	Hunan Handlike Minimally Invasive Surgery Co., Ltd.	Surgnova Healthcare Technologies (Zhejiang) Co., Ltd.
Trade Name	Ultrasonic Surgical System	Ultrasonic Scalpel System
510(k) Number	K233036	K212614
Classification Name	Instrument, Ultrasonic Surgical	Instrument, Ultrasonic Surgical
Classification Product Code	LFL	LFL
Indications for Use	The Ultrasonic Surgical 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 3 mm in diameter.	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.
Working Principle	The Ultrasonic Generator outputs the AC energy at a resonating frequency of	The generator outputs the AC energy at a resonating frequency of 55.5KHz to the

Elements of Comparison	Subject Device	Predicate Device 1
	55.5KHz to the hand piece, which transforms it to mechanical vibrations to reach the clamped tissue at the blade tip of the ultrasonic shears' 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.	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)	Ultrasonic Generator: 37.0cm x 39.0cm x 16.3cm	Generator: 40.0cm x 40.0cm x 12.0cm
Design	The ultrasonic generator is configured to resonate with the Hand Piece 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 Source	110-240V AC, 50/60Hz, 500 VA	100-240V AC, 50/60Hz, 200 VA
Output Frequency	55.5KHz	55.5KHz
Environment of Use	Hospital environment	Hospital environment
Patient Population	For use in all patients	For use in all patients
Users	Healthcare professionals	Healthcare professionals
Transducer		
Product Name	Hand Piece	Ultrasonic Transducer
Model	HD-CSH01	SC100T

Elements of Comparison	Subject Device	Predicate Device 1
Working Principle	The Hand Piece which contains piezoelectric Hand Pieces that converts electronic energy into ultrasonic vibration to power ultrasonic Shears.	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 is supplied non-sterilize, sterilize prior to use.	It is supplied non-sterilize, sterilize prior to use.
Sterilization method	Low temperature plasma	Pulsation vacuum/Low temperature plasma
Foot Switch		
Product Name	Foot Switch	Foot Switch
Model	HRF-M52	TG-A
Working Principle	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.	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	The left foot switch is used to control the cutting mode; The right foot switch is used to control the coagulation mode	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 or the hospital regulations.	Cleaning and disinfection, if foot switch contaminated by blood or body fluid according to IFU or the hospital regulations.

6.2 Comparison table for Ultrasonic Scalpel

Elements of Comparison	Subject Device	Predicate Device 1	Predicate Device 2
Manufacturer	Hunan Handlike Minimally Invasive Surgery Co., Ltd.	Surgnova Healthcare Technologies (Zhejiang) Co., Ltd.	Ethicon Endo-Surgery, LLC
Trade Name	Ultrasonic Surgical System	Ultrasonic Scalpel System	HARMONIC Hook
510(k) Number	Applying	K212614	K151136
Classification Name	Instrument, Ultrasonic Surgical	Instrument, Ultrasonic Surgical	Instrument, Ultrasonic Surgical
Classification Product Code	LFL	LFL	LFL
Indications for Use	The Ultrasonic Surgical 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 3 mm in diameter.	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.	The HARMONIC Hook instrument is indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instrument can be used as an adjunct to or substitute for electrosurgery, lasers, and steel scalpels in general, plastic, gynecologic, exposure to orthopedic structures (such as spine and joint space), and thoracic surgery, including mobilization of the Internal Mammary Artery (IMA).
Product Name	Ultrasonic Shears	Ultrasonic Scalpel	HARMONIC Hook
Model	HD-CS-DJ14	SC43C+	--

Elements of Comparison	Subject Device	Predicate Device 1	Predicate Device 2
	HD-CS-DJ22 HD-CS-DJ36 HD-CS-DJ45	SC35C+ SC21C+ SC13C+	
Shaft Length (cm)	HD-CS-DJ14: 14cm ±10% HD-CS-DJ22: 23cm ±10% HD-CS-DJ36: 36 cm ±10% HD-CS-DJ45:45 cm ±10%	SC43C+: 43cm SC35C+: 35cm SC21C+: 21cm SC13C+: 13cm	32 cm
Working Principle	The Hand Piece connects the Ultrasonic Generator and the Disposable Ultrasonic Shears together. It converts electrical energy from the ultrasonic Generator into mechanical vibrations and transmits them to the waveguide of the scalpel. The scalpel transmits the vibrations from the Ultrasonic Hand Piece to the clamped soft tissues for dissection and coagulation	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	The HPBLUE handpiece connects the HARMONIC Hook device to the Generator G11, and converts electrical energy into mechanical motion (ultrasonic energy). The high-frequency mechanical vibration at 55.5 kHz of the HARMONIC Hook blade transects, dissects, and coagulates tissue, sealing vessels up to 2 mm
Description of function	Ultrasonic Shears is sterile, single patient use instruments consisting of an ergonomic grip housing assembly with hand control buttons.	Ultrasonic Scalpel is sterile, single patient use instruments consisting of an ergonomic grip housing assembly with hand control buttons.	Not public

Elements of Comparison	Subject Device	Predicate Device 1	Predicate Device 2
Description of power level	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 3 mm in diameter.	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.	The instrument allows for the cutting of soft tissue and coagulation of vessels up to and including 2 mm in diameter.
Tissue self-adjustment technology	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 Shears, as well as provides audible feedback to the user.	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.	Not public
Outer Diameter (mm)	5.5 mm	5.5 mm	Not public
Blade frequency	55.5KHz	55.5KHz	55.5KHz
Blade amplitude	(50-70) ±15μm	50~100 μm	Not public
Blade design/geometry	Multi-purpose shears	Multi-purpose shears	Not public
Handle type	Pistol Grip	Pistol Grip	Not public
Energy activation method	Press Max/Min button	Press Max/Min button	Not public
Indicated vessel type	Veins and arteries	Veins and arteries	Not public
Energy buttons	Max/Min	Max/Min	Not public
Design	The device utilizes ultrasonic energy to	The device utilizes ultrasonic energy to	The device utilizes ultrasonic energy to

Elements of Comparison	Subject Device	Predicate Device 1	Predicate Device 2
	enable hemostatic cutting and/or coagulation of soft tissue	enable hemostatic cutting and/or coagulation of soft tissue	enable hemostatic cutting and/or coagulation of soft tissue
Human Tissue or Body Fluids in Contact with the Device	Tissue	Tissue	Tissue

7. Test Summary

7.1 Summary of Non-Clinical Tests

Ultrasonic Surgical System has been evaluated the safety and performance by lab bench testing as following:

- Sterilization

The Ultrasonic Shears, 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 Ultrasonic Shears is in direct contact with body tissue, with contact duration of less than 24 hours. Biocompatibility testing was conducted on the shear 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 60601-1-2:2020 for electromagnetic compatibility, IEC 60601-1:2020 and IEC 60601-2-18 for electrical safety.

- Performance testing

Performance test and functional tests were conducted on the proposed device in accordance with product design specifications. Data generated from the test met the predetermined acceptance criteria.

- Animal testing

The animal study was conducted on porcine model with test articles (Ultrasonic Surgical System) and control article (predicate device Ethicon G11). It consisted of three experiments, in vitro burst pressure, acute animal experiment and 21-day chronic animal's 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.

- 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.

- Cleaning, Disinfection and Sterilization effectiveness

The methods for cleaning, disinfection, and sterilization of Hand Piece have been validated as per ISO 17664-1.

- Cybersecurity

The subject device does not have any external interfaces, according to FDA guidance “Content of Premarket Submissions for Management of Cybersecurity in Medical Devices”, no need cybersecurity evaluation.

8. Final Conclusion:

The subject device Ultrasonic Surgical System has technological characteristics similar to the predicate device. Performance testing demonstrated that the differences do not affect the safety and effectiveness of the subject device. Thus, the subject device is substantially

equivalent to the predicate devices K212614 and K151136 in terms of safety and effectiveness for requested indications for use.