Asensus Surgical
Madhuvanthi Soundirarajan
Senior Regulatory Affairs Specialist
1 Tw Alexander Dr., Suite 160
Durham, North Carolina 27701

May 12, 2026

Re: K254192
Trade/Device Name: Senhance Ultrasonic System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: NAY
Dated: April 10, 2026
Received: April 13, 2026

Dear Madhuvanthi Soundirarajan:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

Colin K. Chen -S

Digitally signed by Colin K. Chen -S
Date: 2026.05.12 17:06:31 -04'00'

Colin Kejing Chen, 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K254192

Please provide the device trade name(s).

Senhance Ultrasonic System

Please provide your Indications for Use below.

The Senhance Ultrasonic System and accessories are indicated for soft tissue surgical incisions when bleeding control and minimal thermal injury are important. The instruments are indicated for the sealing of vessels up to and including 5 mm in diameter. The Senhance Ultrasonic System and accessories are indicated for use with the Senhance Surgical System.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary
Senhance Ultrasonic System
[In accordance with 21 CFR 807.92]

Submitter Information

Submitter:	Asensus Surgical, Inc. 1 TW Alexander Drive, Suite 160 Durham, NC 27703
Contact:	Madhuvanthi Soundirarajan Sr. Regulatory Affairs Specialist Email: msoundirarajan@asensus.com Ph.no: 3524339130

Date Summary Prepared:	May 11, 2026

Subject Device Information

Proprietary (Trade) Name:	Senhance® Ultrasonic System
Common Name:	System, Surgical, Computer Controlled Instrument
Classification:	Class II
Classification Advisory Committee:	General and Plastic Surgery
Regulation Number:	21 CFR 876.1500, Endoscope and Accessories
Product Codes:	NAY (System, Surgical, Computer Controlled Instrument)

Predicate Device Information

Primary Predicate Device:	HARMONIC ACE® Shears + Adaptive Tissue Technology (K120729)
Reference Device:	Senhance Ultrasonic System (K182421)

Device Description:

The Senhance Ultrasonic System is an energized instrument system which delivers ultrasonic energy for soft tissue incisions and sealing of vessels up to and including 5 mm in diameter. It is designed to be used with the Senhance Surgical System, which precisely manipulates laparoscopically based instruments in surgery.

The Senhance Ultrasonic System is composed of five components:

1. The Dissector which interfaces with the tissue of interest
2. The Transducer which converts electrical energy into ultrasonic energy
3. The Senhance Adapter which physically attaches the instrument to the Senhance Surgical System manipulator arm
4. The Ultrasonic Generator which controls the energy settings to be delivered to the tissue
5. The Footswitch which attaches to the generator for the activation of ultrasonic energy by the surgeon's foot

The system components are presented in Figure 1 below:

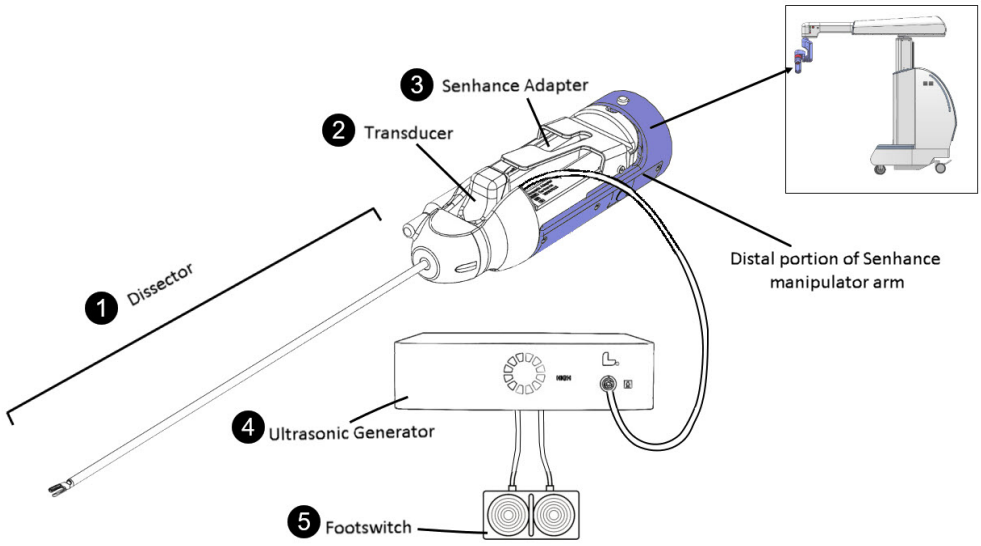

Figure 1: The Senhance Ultrasonic System Components

Intended Use/ Indications for Use:

The Senhance Ultrasonic System is intended to be used to incise soft tissues and seal vessels during laparoscopically based surgery using robotic control of the instrument provided by the Senhance Surgical System. The proposed indications for use statement is as follows:

The Senhance Ultrasonic System and accessories are indicated for soft tissue surgical incisions when bleeding control and minimal thermal injury are important. The instruments are indicated for the sealing of vessels up to and including 5 mm in diameter. The Senhance Ultrasonic System and accessories are indicated for use with the Senhance Surgical System.

The change to the indication statement is the addition of the underlined text.

Summary of Technological Characteristics:

The Senhance Ultrasonic System has the same technological characteristics as the reference Senhance Ultrasonic System cleared under K182421. No changes to the technology have been made since the prior

clearance. The indications for use of Senhance Ultrasonic System and HARMONIC ACE® Shears + Adaptive Tissue Technology are the same.

The subject Senhance Ultrasonic system characteristics are outlined in the table below alongside the predicate and reference device system characteristics.

Characteristics	**Subject Device Senhance Ultrasonic System**	**Predicate Device (K120729) HARMONIC ACE® Shears**	**Reference Device (K182421) Senhance Ultrasonic System**
Manipulation Method	Robotic	Manual	Robotic
Method of Activation	Footswitch – not integrated to robotic system	Foot or Hand Switch	Footswitch – not integrated to robotic system
End Effector Design	12 mm Curved Shear	Curved Shear	12 mm Curved Shear
End Effector packaging and Sterility	Single Use Disposable (EO Sterilization) SAL 10^{-6}	Single Use Disposable (EO Sterilization) SAL 10^{-6}	Single Use Disposable (EO Sterilization) SAL 10^{-6}
End Effector Dimensions	Shaft Diameter: 5.5 mm Shaft Length: 349 mm	Shaft Diameter: 5 mm Shaft Length: 360 mm	Shaft Diameter: 5.5 mm Shaft Length: 349 mm
Ultrasonic Mode	Torsional	Linear	Torsional
Ultrasonic Wavelength	35 to 37 kHz	Not Available	35 to 37 kHz
Generator	Rebranded Lotus Series 4 generator	Generator G 11	Rebranded Lotus Series 4 generator
Maximum Vessel Diameter for Vessel Sealing Indication	5mm	5mm	No vessel sealing indication claim

Performance Data:

Bench and pre-clinical animal testing were conducted to demonstrate that the subject device is safe and effective for the expanded indications for use. This included the following tests:

- Bench Pressure Testing: A sufficient quantity of explanted porcine arteries and veins ranging from 1.5-5.0 mm were sealed and divided using both Senhance Ultrasonic devices and the predicate device. The acceptance criteria of the 90 percent lower tolerance bound burst pressure for arteries up to 5 mm in diameter is ≥ 240 mmHg, and the acceptance criteria of the 90 percent

lower tolerance bound burst pressure for veins up to 5 mm in diameter is ≥ 50 mmHg were satisfied. The burst pressure performance of the Senhance Ultrasonic System was not statistically inferior to the burst pressure performance of the predicate device.

- Acute Animal Study: To ensure there is no excessive tissue damage to the regions surrounding a sealed vessel when sealing a vessel using the Senhance Ultrasonic System, thermal spread testing via histological analysis was performed. The thermal spread test was conducted with the subject device and predicate device in a Good Lab Practices (GLP) environment using live porcine models. Each laparoscopic procedure was performed by a surgeon, during which both veins and arteries up to 5 mm in diameter were sealed using either Senhance Ultrasonic devices or control devices. The vessels were evaluated for cell viability and thermal spread by a board-certified pathologist via a histological analysis in order to identify any differences in performance between the two systems. The thermal spread with the use of the Senhance Ultrasonic System was noted to be comparable to the predicate, satisfying the primary objective of the acute study.

- Chronic Animal Study: Asensus Surgical performed a chronic animal study of a duration of a minimum of 3 weeks post-procedure in at least 5 animals to demonstrate that the Senhance Ultrasonic System can function properly to withstand normal body parameters for a variety of vessel types covering the entire range of sizes (0.1-5.0 mm diameter) for both veins and arteries. This study demonstrated that Senhance Ultrasonic System was able to safely seal appropriately sized abdominal cavity vessels while obtaining hemostasis and without structural changes at the treatment sites or in downstream tissues based on lack of procedural or in-life adverse events.

No change to any material or manufacturing process has been made since the clearance of the reference device, Senhance Ultrasonic System (K182421), and no change is being requested in this submission. All patient-contacting components remain biocompatible as demonstrated in K182421.

No changes to the reprocessing/cleaning and disinfection instructions are made as part of this submission. The shelf life of the dissector is labeled as 24 months, which was increased from 6 months as included in the K182421. This change is due to the completion of a new packaging validation study data showing sterility, package integrity, and device performance were maintained after 2 years' accelerated and real-time aging.

Software and Cybersecurity:

The software for the Senhance Ultrasonic System is found within the Senhance Ultrasonic generator. No changes to the Senhance Ultrasonic System software have been made since the latest clearance on January 11, 2019, through K182421. Software verification and validation testing documentation, as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices", was provided in K182421 and remains applicable to the subject device.

The documentation level for the software of this device was determined to be basic level, since no failure of any device software function could lead to a hazardous situation with a probable risk of death or serious injury to the patient, user of the device, or others in the environment of use, prior to the implementation of risk control measures. The generator software was assessed per the FDA guidance "Cybersecurity in Medical Device: Quality System Considerations and Content of Premarket Submissions" to identify any issues related to cybersecurity. Because the system is neither intended nor able to be connected to any private intranet or the public Internet, the risks attendant to networked devices are eliminated, and the risk of cyberattack is greatly reduced.

Conclusion:

The subject device, the Senhance Ultrasonic System, has the same intended use as the predicate, and its expanded indications for use do not affect the safety or effectiveness of the device. In addition, Senhance Ultrasonic System has the same technological characteristics as the reference Senhance Ultrasonic System cleared under K182421.

The bench testing and both the acute and chronic animal studies conducted in the GLP environment demonstrated that the subject device is safe and effective for sealing vessels up to and including 5 mm in diameter.

Thus, the subject Senhance Ultrasonic System is substantially equivalent to predicate devices.