Asensus Surgical, Inc.
Ravi Kommineni
Head of Global Quality and Regulatory
1 TW Alexander Drive, Suite 160
Durham, North Carolina 27703

Re: K212054
Trade/Device Name: Senhance Surgical System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: NAY
Dated: June 30, 2021
Received: June 30, 2021

Dear Ravi Kommineni:

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,

Mark Trumbore, Ph.D.
Acting Assistant Director
THT4A1: Robotically-Assisted Surgical Devices Team
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)*

K212054

Device Name
Senhance® Surgical System

Indications for Use *(Describe)*

The Senhance® Surgical System is intended to assist in the accurate control of laparoscopic instruments for visualization and endoscopic manipulation of tissue including grasping, cutting, blunt and sharp dissection, approximation, ligation, electrocautery, suturing, mobilization and retraction. The Senhance Surgical System is intended for use in general laparoscopic surgical procedures and laparoscopic gynecological surgery. The system is indicated for adult use. It is intended for use by trained physicians in an operating room environment in accordance with the Instructions for Use.

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

[In accordance with 21 CFR 807.92]

1. Submitter

510(k) Sponsor:	Asensus Surgical, Inc.
Address:	1 TW Alexander Drive, Suite 160 Durham, NC 27703 USA
Contact Person:	Ravi Kommineni Global Head of Quality and Regulatory
Contact Information:	Email: rkommineni@asensus.com Phone: +1 763.227.5896 Facsimile: +1 919.765.8459
Date Summary Prepared:	08/19/2021

2. Device

Proprietary (Trade) Name:	Senhance® Surgical 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)

3. Predicate and Reference Devices

Predicate Device:	Senhance® Surgical System (K202166)

4. Device Description:

The Senhance® Surgical System (Senhance system) is a multi-arm, console-based robotic system that allows a surgical team to perform laparoscopic surgery in the abdomen and pelvis in a manner similar to a manual laparoscopic approach. The capital equipment of the Senhance system is comprised of the following three main subsystems which are powered separately and connected by means of communications cables:

- Cockpit – The station where the surgeon inputs information through hand and eye movements to direct the arms to move within the surgical field.
- Manipulator Arm(s) – Up to three mechanized instrument support arms that produce output movements based on the instruction from the cockpit or bedside assistant. Each robotic arm can hold either a laparoscopic surgical instrument or an endoscope to facilitate a surgeon remotely operating the instrument from the cockpit.
- Intelligent Surgical Unit (ISU) - The ISU component, which is the communication hub that connects the cockpit inputs to the manipulator arms. The ISU contains a high-performance computer that enables the surgeon to control the endoscope using software features that apply image processing algorithms to the endoscope video signal.

5. Intended Use/ Indications for Use:

The Senhance® Surgical System is intended to assist in the accurate control of laparoscopic instruments for visualization and endoscopic manipulation of tissue including grasping, cutting, blunt and sharp dissection, approximation, ligation, electrocautery, suturing, mobilization, and retraction. The Senhance Surgical System is intended for use in general laparoscopic surgical procedures and laparoscopic gynecological surgery. The system is indicated for adult use. It is intended for use by trained physicians in an operating room environment in accordance with the instructions for use.

6. Summary of Technological Characteristics:

The modified device has either identical or very similar technological characteristics to the predicate. Any differences in technological characteristics do not raise different questions of safety and effectiveness. Software testing and a comprehensive set of performance testing were conducted to demonstrate that the modified device is as safe and effective, and thus substantially equivalent, to the predicate.

6.1. Capital Equipment

Like the predicate, the modified device consists of the same three main system components: cockpit, manipulator arms, and ISU. No design changes have been made to the Senhance capital equipment hardware or its accessories (i.e., surgical instruments and adapters). The surgeon controls of the modified device and predicate are the same. Compliance with EMC and safety standards was previously established for the predicate and test results are applicable to the modified device. Thus, there are no technological differences between the modified device and the predicate hardware.

6.2. Software

Software changes were made in the modified device resulting in a new version of software. The software for the modified device introduces new image processing features and improvements to existing endoscope movement features and implement updates to the graphical user interface displayed on the cockpit monitor.

6.2.1 Follow Me

In the modified Follow Me mode, the surgeon designates two surgical instruments (guide instruments) in the endoscopic view for the camera to follow.

6.2.2 Measurements

Measurements is a new feature that enables the surgeon to take accurate 3D distance measurements within the endoscopic view.

6.2.3 Digital Tags

Digital Tags is a new feature that enables the surgeon to add virtual tags within the endoscopic view to identify and precisely locate landmarks on the tissue.

6.2.4 Image Enhancement and Illumination Indication

Image Enhancement is a new feature that increases the brightness and contrast of the endoscopic view. This feature may be used to illuminate dark areas or increase contrast of areas of interest, such as tissue vasculature.

6.2.5 Image Characterization and Verification

In order to provide accurate distance measurements, characterization of camera parameters is required. Image Characterization is performed through a new calibration procedure performed by service personnel authorized by Asensus Surgical.

Image Characterization Verification (also called calibration verification) is a new procedure that is part of the pre-operative tasks to prepare the Senhance system for a surgical procedure.

6.2.6 Graphical User Interface

Graphical user interface (GUI) changes were made to enable use of the new ISU features, update mode icons and status indicators, and to improve overall aesthetics of the overlays.

6.3. Equipment Drapes

There are no changes to the single use, sterile equipment drapes used with the Senhance system. The equipment drapes continue to be manufactured by the same manufacturer and are considered Class 2, 510(k)-exempt devices. For the drapes provided with the modified device, a sterile calibration verification card is provided with the sterile drapes which is used to verify the camera calibration parameters stored in the ISU software. The camera calibration parameters are required for use of certain ISU features.

7. Performance Data:

The following performance testing of the modified device was conducted to demonstrate substantial equivalence to the predicate.

7.1. Bench Testing:

Bench testing of the modified Senhance system evaluated the performance of the new and modified ISU features, GUI changes, and the overall use of the Senhance system. Functional performance tests utilizing well-established test methodology verified that the ISU features and Senhance system performed as intended.

7.2. Electrical Safety and Compatibility:

The modified Senhance Surgical System complies with the current versions of IEC 60601-1 (Basic safety and essential performance), IEC 60601-1-2 (Electromagnetic disturbances), IEC 60601-2-18 (Endoscopic equipment interactions), and IEC 60601-2-2 (High frequency surgical equipment).

7.3. Software Verification and Validation Testing:

The software was fully verified and validated in accordance with well-established software development processes and test methodology used for the predicate. There are no unresolved software anomalies/bugs that impact safety or effectiveness of the modified device. Documentation was provided as recommended in FDA's Guidance for Industry and FDA Staff "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices". The software is considered as a "major" level of concern.

7.4. Pre-Clinical Design Validation:

Design validation of the modified device was conducted to ensure that the devices perform as intended according to defined user needs and intended uses when used in a simulated use environment. A single-center, un-blinded, observational, simulated use design validation evaluation of the modified Senhance system was conducted with users who represented the intended primary user population. The design validation was conducted in a simulated patient model using well-established test methodology used for the predicate. All applicable user level requirements were assessed and found to be met.

8. Conclusions

The modified Senhance Surgical System is as safe and effective as the predicate Senhance Surgical System (K202166). The modified device has the same intended use/ indications for use and either identical or very similar technological characteristics and principles of operation as the predicate. Any differences in technological characteristics between the modified device and predicate have been addressed through a comprehensive set of testing using well-established test methods and do not raise any different questions of safety and effectiveness. Thus, the assessment and testing results support a determination of substantial equivalence to the predicate in terms of safety, efficacy, and performance.