Asensus Surgical, Inc.
Taylor Fisher
Program Manager
1 TW Alexander Drive, Suite 160
Durham, North Carolina 27703

Re: K211325
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: April 30, 2021
Received: April 30, 2021

Dear Taylor Fisher:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K211325

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 21CFR 807.92]

1. Submitter

510(k) Sponsor:	Asensus Surgical, Inc.
Address:	1 TW Alexander Drive, Suite 160 Durham, NC 27703 USA
Contact Person:	Taylor Fisher Program Manager
Contact Information:	Email: tfisher@asensus.com Phone: +1 919.765.8400 Facsimile: +1 919.765.8459
Date Summary Prepared:	7/12/2021

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)
Reference Device:	Intuitive Surgical EndoWrist Instruments (K081137)

4. Device Description:

The Senhance Articulating platform is intended as an addition to the suite of instruments and adapters previously cleared for use with the Senhance® Surgical System ("Senhance system"). These instruments add degrees of freedom near the instrument end effector to allow for additional range of motion for the surgeon when performing laparoscopic tissue manipulations. Two articulating instruments are being added to the suite of instruments –Bipolar Atraumatic Grasper and Needle Driver. The instruments are single use and provided sterile to the end user. The instruments connect to a coupler which in turn connects to the articulating adapter which attaches to the Senhance Manipulator Arm.

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.

Comparison with Predicate Device Intended Use/ Indications for Use:

The Senhance Articulating platform has the identical intended use and indications for use as predicate Senhance Surgical System (K202166).

6. Summary of Technological Characteristics:

The substantial equivalence comparison below shows that the subject Senhance Articulating platform is very similar to the predicate Senhance Surgical System. Many of the subject device's technological characteristics and principles of operation are identical or similar to those of the predicate. Furthermore, a comparison of the subject articulating instruments to a reference device (Intuitive Surgical EndoWrist Instruments, K081137) shows that both the subject and reference devices have similarities in their dimensions and design. Any differences in technological characteristics between the subject and predicate devices have been addressed through a comprehensive set of testing using established test methods and do not raise any different questions of safety and effectiveness.

Table 1. Substantial Equivalence Comparison

Characteristic	Subject Device	Predicate Device
Name	Senhance Articulating Platform for use with the Senhance Surgical System	Senhance Surgical System K202166
Capital Equipment	The subject Senhance system is comprised of three main components: cockpit, manipulator arms, and ISU.	The subject Senhance system is comprised of three main components: cockpit, manipulator arms, and ISU.

Characteristic	Subject Device	Predicate Device
	Cockpit – positioned outside the sterile field, is where the surgeon inputs information through hand and eye movements to direct the motion of the manipulator arms in the surgical field. The surgeon manipulates two cockpit handles to transmit position and jaw actuation movements to the manipulator arms.	**Cockpit** – positioned outside the sterile field, is where the surgeon inputs information through hand and eye movements to direct the motion of the manipulator arms in the surgical field. The surgeon manipulates two cockpit handles to transmit position and jaw actuation movements to the manipulator arms.
	Manipulator Arms - the independent, mechanical support arms that interface with the endoscope and surgical instruments. The manipulator arms produce output movements based on the input movement from the surgeon at the cockpit. The Senhance system is configurable with up to three manipulator arms. Each manipulator arm has a total of six joints: three joints that allow the surgical team to grossly position each manipulator arm above the operating table and three joints for positioning of the instrument interface. The connector in the center of the instrument interface has been removed and a connection port was added to power the new articulating motorized adapter while maintaining the sterile field.	**Manipulator Arms** - the independent, mechanical support arms that interface with the endoscope and surgical instruments. The manipulator arms produce output movements based on the input movement from the surgeon at the cockpit. The Senhance system is configurable with up to three manipulator arms. Each manipulator arm has a total of six joints: three joints that allow the surgical team to grossly position each manipulator arm above the operating table and three joints for positioning of the instrument interface.
	ISU - the communication hub that connects the cockpit inputs to the manipulator arms. The Smart Node contains a high-performance PC that enables the surgeon to command endoscopic motion using software features that apply image processing algorithms to the endoscope video signal.	**ISU** - the communication hub that connects the cockpit inputs to the manipulator arms. The Smart Node contains a high-performance PC that enables the surgeon to command endoscopic motion using software features that apply image processing algorithms to the endoscope video signal.
Surgeon Controls	Touchpad, keyboard, clutch pedal, handles, eye tracker. The trigger/tilt button on the cockpit handle is used to activate articulation of the instrument. The instrument is articulated by rotating the handles about the yaw axis.	Touchpad, keyboard, clutch pedal, handles, eye tracker
Software Architecture	Four software subsystems: LTM, ARM, RHMI, SNIP	Four software subsystems: LTM, ARM, RHMI, SNIP
Software Version	Senhance Software Version 2.5.3.14	Senhance Software Version 2.5.0.22

Characteristic	Subject Device	Predicate Device
Instrument Adapters	A new motorized articulating adapter that attaches to the manipulator arm and drives articulation (or "tilt") and rotation of the instrument tip ("roll"). Jaw actuation is the same as the predicate. The articulating adapter is covered by a sterile, disposable drape before each use like the Senhance capital equipment. A new reusable articulating coupler that connects the articulating instruments to the articulating adapter. The articulating adapter is uniquely matched to the articulating instruments. The adapter has an embedded RFID tag which is used by the manipulator arm to identify which adapter is attached to the instrument interface. This allows the icon representing the instrument type to be displayed to the surgeon on the functions area of the cockpit monitor.	Five (5) different types of reusable instrument adapters that connect to the Senhance Surgical Instruments and attach to the manipulator arm(s): passive (non-energized), monopolar, bipolar, ultrasonic, and endoscope. Each adapter is uniquely matched to each instrument or endoscope. Each adapter has an embedded RFID tag which is used by the manipulator arm to identify which adapter is attached to the instrument interface. This allows the icon representing the instrument type or endoscope to be displayed to the surgeon on the functions area of the cockpit monitor.
Equipment Drapes	Single use, sterile equipment drapes cover the manipulator arm and instrument interface. The drapes are classified as Class 2, 510(k)-exempt devices under product code PUI. A new single use, sterile, articulating adapter drape pack is provided to cover and connect the instrument interface and articulating adapter during use. The drapes are classified as Class 2, 510(k)-exempt devices under product code PUI.	Single use, sterile equipment drapes cover the manipulator arm and instrument interface. The drapes are classified as Class 2, 510(k)-exempt devices under product code PUI.
Surgical Instruments	Two new single use, sterile, laparoscopic articulating instruments with an articulating design at the distal tip that simulates the human wrist. The articulating instruments can bend up to 65 degrees when fully articulated. • Bipolar Atraumatic Grasper, Articulating – 5mm diameter x 310mm shaft length • Needle Driver, Articulating – 5mm diameter x 310mm shaft length	A suite of reusable, laparoscopic Senhance Surgical Instruments available in a variety of sizes (diameters and lengths), end effector designs, and energy (passive, monopolar, bipolar, ultrasonic) including: • Bipolar Large Grasping Forceps – 5mm diameter x 310mm shaft length • Needle Holder Left/Right – 5mm diameter x 310mm shaft length
Biocompatibility	The instruments are made from biocompatible metals and plastics with a long history of safe use and demonstrated to be non-toxic, non-	The instruments are made from biocompatible metals and plastics with a long history of safe use and demonstrated to be non-toxic, non-

Characteristic	Subject Device	Predicate Device
	irritating, non-sensitizing, and non-pyrogenic.	irritating, non-sensitizing, and non-pyrogenic.
Instruments Rated Voltage	• 5mm Bipolar Articulating Instrument @ 250 Vpeak	• 5mm Bipolar Instruments @ 500 Vpeak
Compatible Electrosurgical Units (ESUs)	Compatible third-party ESUs include: • Erbe VIO® 300 D • Covidien ForceTriad™ • Covidien/Valleylab Force FX™ • CONMED System 5000™ The ESU connects directly to the articulating instrument using a bipolar ESU accessory cable, rather than to the adapter like with the predicate. The ESU is operated in the usual manner by the ESU's foot pedal positioned near the surgeon at the cockpit. There is no communication between the Senhance system and any ESU.	Compatible third-party ESUs include: • Erbe VIO® 300 D • Covidien ForceTriad™ • Covidien/Valleylab Force FX™ • CONMED System 5000™ ESUs connect to the adapters through monopolar or bipolar cables and provide energy directly to the instruments. The ESU is operated in the usual manner by the ESU's foot pedal positioned near the surgeon at the cockpit. There is no communication between the Senhance system and any ESU.

Table 2. Reference Device Comparison

Characteristic	Subject Device	Reference Device
Name	Senhance Articulating Instruments	Intuitive Surgical EndoWrist Instruments for use with da Vinci Si Surgical System/ IS3000 (K081137)
Instrument Classification	Single Use Disposable (Gamma Sterilization)	Reusable, programmed with a maximum number of surgical procedures. They must be cleaned, and steam sterilized by the end user between uses.
Articulated Instrument Types and Dimensions	Two laparoscopic articulating instruments with an articulating design at the distal tip that simulates the human wrist: • Bipolar Atraumatic Grasper, Articulating – 5mm diameter x 310mm shaft length • Needle Driver, Articulating – 5mm diameter x 310mm shaft length	A variety of articulating instruments consisting of graspers, dissectors, needle drivers, scissors, monopolar energy, bipolar energy, and clip appliers. The EndoWrist instruments have an articulating design at the distal tip that simulates the human wrist and include: • Bipolar grasper – 8mm diameter x ~310mm shaft length) • Need driver – 8mm diameter x ~310mm shaft length
Degrees of Articulation	0 degrees (straight) to 65 degrees (fully articulated)	0 degrees (straight) to 90 degrees (fully articulated)

7. Performance Data:

The following performance testing of the Senhance Articulating platform was conducted to demonstrate substantial equivalence of the device to the predicate.

Biocompatibility Testing: The Senhance Articulating instruments are considered tissue contacting for a limited duration of less than 24 hours for contact with tissue or bone. The articulating instruments were assessed in accordance with the FDA Guidance for Industry and FDA Staff on Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process", and ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process". Testing demonstrated that the patient-contacting portions of the Senhance Articulating instruments are non-toxic, non-irritating, non-sensitizing, and non-pyrogenic and do not result in an unacceptable adverse biological response resulting from contact of the devices' materials with the body.

Reprocessing, Cleaning, and Sterilization: The reusable coupler has cleaning instructions that were validated based on the guidelines outlined in AAMI TIR30:2011. A steam sterilization validation study was conducted in accordance with the FDA's Guidance for Industry and FDA Staff "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling" and the FDA recognized consensus standards ANSI/AAMI/ISO 17665-1:2006/(R)2013 and ANSI/AAMI/ISO 14937:2009/(R)2013. The coupler was validated to a Sterility Assurance Level of 10^{-6} using the half cycle testing validation method.

The articulating adapter is non-sterile capital equipment and is used with a sterile equipment drape. The drape remains intact throughout the procedure and thereby maintains a sterile barrier. A cleaning compatibility study confirmed that the agents used during cleaning/disinfection are compatible with the materials of construction and markings of the adapter.

The single use articulating instruments are provided sterile to the end user via gamma irradiation. Gamma irradiation at a minimum dose of 25 kGy was validated per FDA recognized consensus standards ISO 11137-1:2006, ISO 11137-2:2013, and ISO 11137-3:2017 and demonstrated a Sterility Assurance Level of 10^{-6}. The packaging has been validated to maintain sterility for the stated shelf life of the device.

Bench Testing: Bench testing evaluated the performance of the Senhance Articulating instruments as well as compatibility of the Senhance Articulating platform when used with the Senhance Surgical System. The following tests confirmed that the articulating instruments perform as intended after tests of mechanical integrity under conditions of simulated use and that the Senhance system performs as intended when used with the subject Senhance Articulating platform:

- Cantilever Bending Reliability
- Jaw Actuation Reliability

- Jaw Compensation
- Electrosurgical Unit (ESU) Compatibility
- Sterile Drape Reliability

Electrical Safety and Compatibility: The Senhance Articulating platform used in conjunction with the Senhance system comply 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).

Software Verification and Validation Testing: Software verification and validation were successfully conducted on the latest Senhance software version that supports the Senhance Articulating platform. 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.

Pre-Clinical Design Validation: Design validation of the Senhance Articulating platform was conducted to ensure that the devices perform as intended according to defined user needs and intended uses when used with the Senhance system in a simulated use environment. A single-center, un-blinded, observational, simulated use design validation evaluation of the Senhance system used in conjunction with Senhance Articulating platform was conducted with users who represented the intended primary user population. The design validation was conducted in a simulated patient model. All applicable user level requirements were assessed and found to be met.

Usability Testing: Modifications to the existing Senhance system Usability Engineering file were made based on the addition of the new articulating platform. A summative usability validation study was performed with final instructions for use and training materials. In a simulated use environment, the surgical teams were able to independently perform all critical tasks without use errors that would lead to harm. This study demonstrated that the overall residual risk of use errors with the Senhance Articulating platform have been mitigated to an acceptable level. The Senhance Articulating platform used in conjunction with the Senhance system can be used without use errors or problems that could result in serious harm.

Conclusions

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