May 27, 2022

Asensus Surgical, Inc.
Casey Hinckley
Regulatory Affairs Manager
1 TW Alexander Drive, Suite 160
Durham, North Carolina 27703

Re: K220889
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: May 2, 2022
Received: May 3, 2022

Dear Casey Hinckley:

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
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K220889

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Special 510(k) SUMMARY

Senhance® Articulating Platform

for use with the Senhance Surgical System

[In accordance with 21CFR 807.92]

510(k) Sponsor:	Asensus Surgical, Inc.
Address:	1 TW Alexander Drive, Suite 160 Durham, NC 27703
Contact Person:	Casey Hinckley Regulatory Affairs Manager
Contact Information:	Email: chinckley@asensus.com Phone: 801.310.5491
Date Summary Prepared:	3/22/2022
Proprietary (Trade) Name:	Asensus Surgical® Senhance® Surgical System
Common Name:	Endoscopic Instruments and Accessories
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:	Senhance® Surgical System (K212054)

Device Description:

The Senhance Articulating platform (internally named Articulating Be4) is intended as an addition to the suite of adapters, couplers and instruments previously cleared for use with the Senhance Surgical System ("Senhance System") most recently cleared under K212054 which is being used as the predicate. This submission requests clearance for one (1) new Articulating Adapter and two (2) Articulating Couplers to be used with the existing articulating instruments. A representative image of the assembled adapter and coupler are shown in Figure 1.

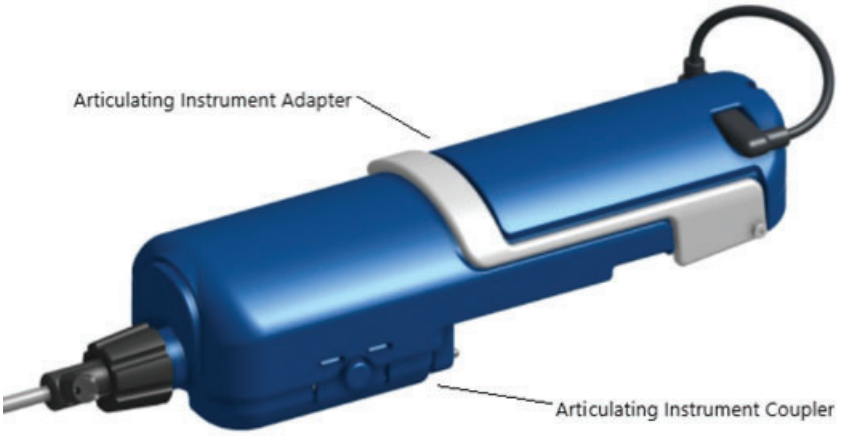

Figure 1, Senhance Articulating Platform

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 platforms proposed adapter and couplers have the same intended use/ indications for use as previously cleared Senhance system under K212054. There are no differences in how the Senhance Articulating platform manipulates the instruments that alter the Senhance system's therapeutic effect or raise different questions of safety or effectiveness.

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 devices' technological characteristics and principles of operation are identical or very similar to those of the predicate. 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	Modified Senhance Articulating Platform for use with the Senhance Surgical System	Senhance Articulating Platform for use with the Senhance Surgical System K212054
Classification/ Product Code	Class II, NAY (System, Surgical, Computer Controlled Instrument)	Class II, NAY (System, Surgical, Computer Controlled Instrument)
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.	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.
Target Population	Adult Patients	Adult Patients
Anatomical Areas of Use	Abdomen and pelvis	Abdomen and pelvis
Software Version	Senhance Software Version 2.7.1.52	Senhance Software Version 2.6.0.282

Characteristic	Subject Device	Predicate Device
Articulating Instrument Adapter	Motorized articulating adapter that attaches to the manipulator arm and drives articulation (or "tilt") and rotation of the instrument tip ("roll"), while jaw actuation continues to be driven by actuation of the trolley pin in the adapter like the predicate. The articulating adapter is covered by a sterile, disposable drape before each use like the Senhance capital equipment. The adapter has a pocket compartment and latch for attaching the articulating instrument couplers.	Motorized articulating adapter that attaches to the manipulator arm and drives articulation (or "tilt") and rotation of the instrument tip ("roll"), while jaw actuation continues to be driven by actuation of the trolley pin in the adapter like the predicate. The articulating adapter is covered by a sterile, disposable drape before each use like the Senhance capital equipment.
Articulating Instrument Couplers	Reusable instrument specific articulating couplers that connect the articulating instruments to the articulating adapter.	Reusable articulating coupler that connects the articulating instruments to the articulating adapter.
Equipment Drapes	Single use, sterile, articulating adapter drape pack is provided to cover the articulating adapter during use. The pack includes an instrument interface drape with a right-angle USB Type-C cable connector, an articulating adapter drape with an integrated USB Type-C cable and a tear-away portion to further ensure the preservation of the sterile barrier. The drapes are manufactured by DAS Medical and are classified as Class 2, 510(k)-exempt devices under product code PUI.	Single use, sterile, articulating adapter drape pack is provided to cover the instrument interface and articulating adapter during use. The pack includes an instrument interface drape with a right-angle USB Type-C cable connector and an articulating adapter drape with an integrated USB Type-C cable. The drapes are manufactured by DAS Medical and are classified as Class 2, 510(k)-exempt devices under product code PUI.

Characteristic	Subject Device	Predicate Device
Articulating Instruments	Single use, sterile, laparoscopic articulating instruments with an articulating design at the distal tip that simulates the human wrist. The 5mm x 310mm articulating instruments include a bipolar grasper and needle driver.	Single use, sterile, laparoscopic articulating instruments with an articulating design at the distal tip that simulates the human wrist. The 5mm x 310mm articulating instruments include a bipolar grasper and needle driver.
Biocompatibility	The instruments are made from biocompatible metals and plastics with a long history of safe use and demonstrated to be non-toxic, non-irritating, non-sensitizing, and non-pyrogenic.	The instruments are made from biocompatible metals and plastics with a long history of safe use and demonstrated to be non-toxic, non-irritating, non-sensitizing, and non-pyrogenic.

Performance Data:

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

Bench Testing:

Test	Summary
Bench Testing	Bench testing evaluated the performance of the Senhance Articulating instruments as well as compatibility of the Senahance Articulating platform when used with 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. ● Sterile Drape Reliability ● Cantilever Bending Reliability ● Jaw Actuation Reliability ● Coupler Use Life

Reprocessing, Cleaning, and Sterilization:

Test	Summary
Reprocessing/ Cleaning	A cleaning effectiveness validation study was conducted consistent with the procedures and protocols utilized for the previously cleared coupler used with the Senhance Surgical System to confirm the overall effectiveness of the prescribed cleaning procedures. The test results demonstrated that the cleaning procedures for the modified articulating couplers allow them to be

	effectively cleaned according to the processing instructions provided in the labeling.
Sterilization	A validation of the steam sterilization process for the modified articulating couplers was conducted to demonstrate a Sterility Assurance Level (SAL) of at least 10^{-6}.

Electrical Safety and Compatibility:

Test	Summary
Electrical Safety Testing	The Senhance Articulating platform used in conjunction with the Senhance system comply with 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:

Test	Summary
Software	Software testing was conducted to demonstrate that the Senhance system software continues to reliably operate as designed with the addition of the new adapter and couplers.

Design Validation:

Test	Summary
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:

Test	Summary
Usability Testing	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.

Conclusions/ Substantial Equivalence:

The data acquired from the performance testing and software testing of the Senhance Articulating platforms adapter and couplers, as summarized herein, demonstrate that the devices are as safe and effective and perform similarly to the predicate devices cleared under K212054. The intended use/ indications for use for the subject devices are identical to those cleared under K212054. The Senhance Articulating platforms adapter and couplers do not raise any new issues of safety or effectiveness when compared to the predicate devices, thus, they are substantially equivalent to the predicate devices.