March 16, 2023

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

Re: K223095
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: February 13, 2023
Received: February 15, 2023

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 -S

Digitally signed by Mark Trumbore -S
Date: 2023.03.16 14:59:30 -04'00'

Mark Trumbore, Ph.D.
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)*
K223095

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 and pediatric use. It is intended for use by trained physicians in an operating room environment in accordance with the instructions for use.
Use of the device is limited to patients two (2) years of age and older and a weight equal to or above 10kg, who are suitable to be subjected to a conventional endoscopic technique.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

Senhance Surgical System

[In accordance with 21 CFR 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:	March 16, 2023
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)
Primary Predicate Device:	Senhance® Surgical System (K220889)
Secondary Predicate Device:	Intuitive Surgical da Vinci Si Surgical System (K171699)

Device Description:

The Senhance Surgical 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. Each robotic arm can hold either a laparoscopic surgical instrument or an endoscope to facilitate a surgeon remotely operating the instrument from the cockpit.

More specifically, the Senhance Surgical System consists of: a surgeon console (cockpit), which provides remote manipulators or handles to allow the surgeon to maneuver the surgical instruments and a video monitor to display the endoscopic signal; manipulator arms, which hold and maneuver the instruments and endoscope based on inputs from the surgeon; Intelligent Surgical Unit (ISU), which is the system communication hub, connecting the cockpit and manipulator arms; and instruments, which manipulate the tissue of interest.

In addition, force feedback provides an optional tactile sensory input to the surgeon control handles to give a sense of tissue elasticity. An eye tracking feature provides the surgeon an optional method to control the endoscope from the cockpit, rather than using the surgeon control handles. The ISU allows for three additional methods of camera control, in addition to the optional eye tracking method.

The purpose of this submission is to expand the indications for use to include pediatric patients, two (2) years of age and older and a weight equal to or above 10kg.

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 and pediatric use. It is intended for use by trained physicians in an operating room environment in accordance with the instructions for use.

Use of the device is limited to patients two (2) years of age and older and a weight equal to or above 10kg, who are suitable to be subjected to a conventional endoscopic technique.

Summary of Technological Characteristics:

The subject device has the same technological characteristics as the primary predicate device, the Senhance Surgical System (K220889), and similar characteristics to the secondary predicate. Both the subject and predicate devices involve robotically assisted tele-operation as the primary technological principle. It is based on the accurate translation of user inputs to robotically assisted outputs. It involves the use of endoscopic instrumentation for manipulation of tissue and vessels in the insufflated body cavity.

The Senhance Surgical System consists of: a surgeon console (cockpit), which provides remote manipulators or handles to allow the surgeon to maneuver the surgical instruments and a video monitor display the endoscopic signal; manipulator arms, which hold and maneuver the instruments and endoscopic based on inputs from the surgeon; Intelligent Surgical Unit (ISU), which is the system communication hub, connecting the cockpit and manipulator arms; and instruments, which manipulate the tissue of interest.

In addition, force feedback provides optional tactile sensory input to the surgeon control handles to give a sense of tissue elasticity. An eye tracking feature provides the surgeon an optional method to control the endoscope from the cockpit, rather than using the surgeon control handles. The ISU allows for three additional methods of camera control, in addition to the optional eye tracking method.

The Senhance instruments are similar in design and materials to traditional laparoscopic instrumentation.

Since there are no technological differences between the subject Senhance system and the primary predicate, no different questions of safety or effectiveness have been raised.

Performance Data:

There have been no changes to the device since the previous clearance (K220889), only change is to expand the indications for use to allow pediatric use. Extensive bench testing was conducted on the previously cleared Senhance system, and these data remain applicable to the subject device. The previously collected data demonstrated compatibility, mechanical integrity, functionality, reliability, and safe use, addressing verification of key device functions including video signal, endoscope compatibility, surgical instruments, and adapters, as well as validation of the system's camera control and force feedback features.

The recognized consensus standards for the predicate Senhance system (K220889) are still applicable as there have been no changes to the technological characteristics or principles of operation of the device.

Clinical Data:

To demonstrate that the subject device is safe and effective for the expanded indications for pediatric patients, the company has collected real-world evidence on the Senhance Surgical System for the pediatric population. The data demonstrates favorable performance and safety results for the proposed indication.

A retrospective clinical data review was performed for the thirty-two (32) pediatric patients that underwent surgery with the Senhance system. There was only one intra-operative complication; it was resolved without the need for conversion and with no post-operative consequences. There were total of five (5) post-operative complications and four (4) conversions to standard laparoscopy. No conversions to open surgery were necessary.

Table 1. Age Cohort and Surgical Procedures Performed for Retrospective Clinical Data

Age Cohort	Age Summary	Weight Summary	Surgical Procedures Performed
2-12	Min – 2 Max – 12 Median – 5 Mean - 5	Min – 12 kg Max – 38 kg Median – 20 kg Mean – 21.25 kg	• Hernia inguinalis - 10 • Nissen fundoplication - 1 • Ladd's procedure - 1 • Ileostomie - 1 • Hellor-Dor - 1 • Appendectomy - 1
13-18	Min - 13 Max - 18 Median - 15 Mean - 15	Min - 40 kg Max - 117 kg Median - 59 kg Mean - 62 kg	• Hernia inguinalis - 1 • Nissen fundoplication - 3 • Cholecystectomy - 4 • Coecostomy with chait - 2 • Ileocoecal resection - 2 • Proctocolectomie with ileopouchanale anastomose (IPAA) - 1 • Appendectomy - 2

Systematic Literature Review:

Pediatric data collected from the hospital were compared with the results from peer-reviewed research publications describing the clinical outcomes for more than 7660 pediatric procedures using three alternative surgical techniques: laparoscopic, open and robotically assisted surgery.

Table 2. Retrospective Clinical Data Compared to Literature Review Data

	Senhance System	Literature Review Averages		
		Robotic	Laparoscopy	Open
Length of Stay (days)	3.88	2.63	2.75	3.3
Surgical Complication (%)	3.13	1.91	5.91	1.65
Estimated Blood Loss (ml)	10.78	22.74	18.2	28.34
Conversion Rate (%)	12.50	2.55	1.04	N/A
30 Day Readmission Rates (%)	3.13	6.83	5	7.14
30 Day Re-operation Rates (%)	6.25	7.04	4	7
Mortality (%)	0	0.50	0	N/A
Post-operation Complication (%)	15.62	16.90	9.46	6.92
Operative Time (min)	141.47	195	158	183

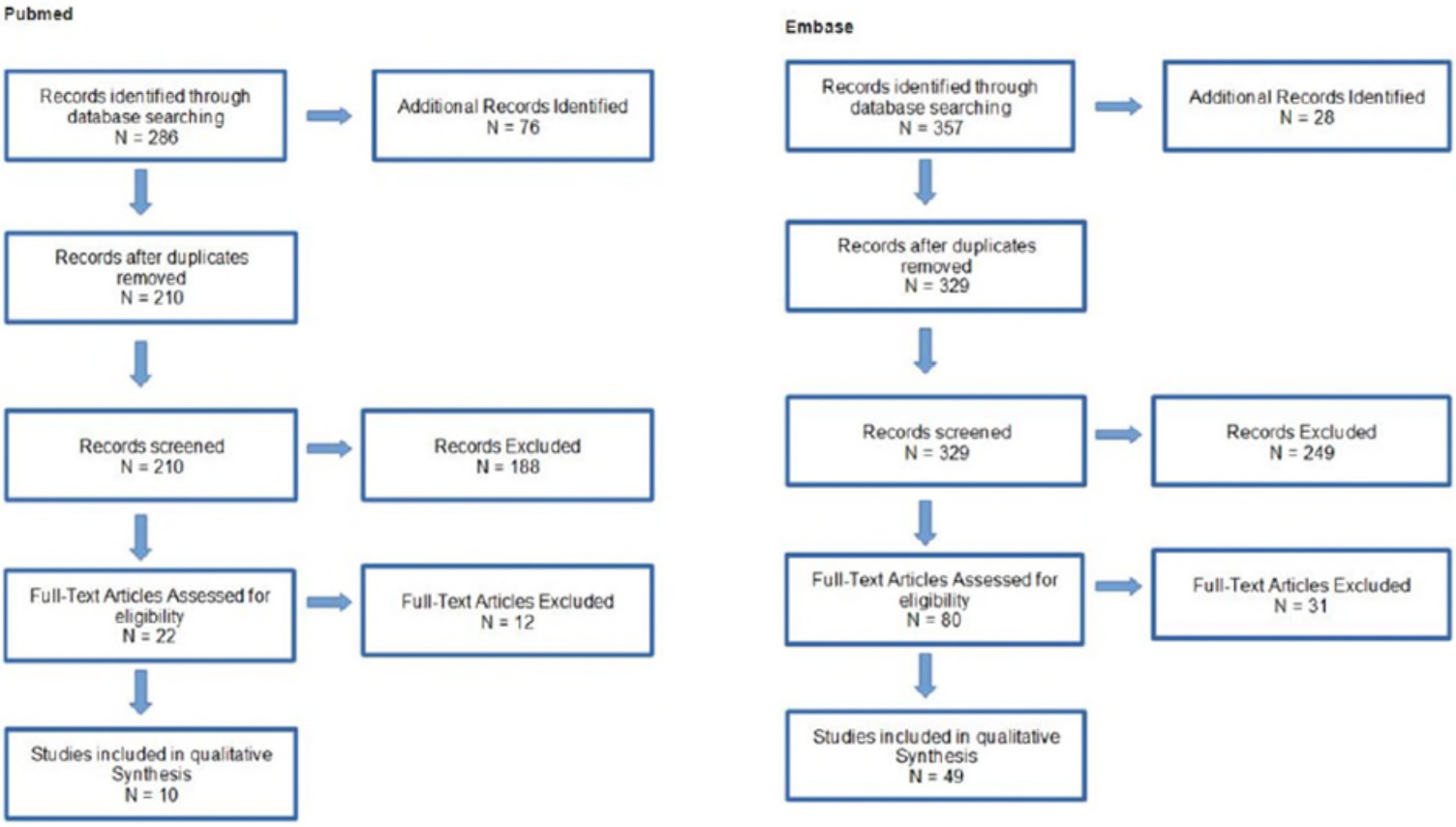
Conclusion:

Operative times and complication rates were comparable between the retrospective clinical data with the Senhance system and the systematic literature review. Overall, the comparison of the Senhance system pediatric data with the published literature data from other surgical techniques demonstrates that the Senhance system is safe and effective for clinical use in the pediatric population based on the following endpoints:

- Length of Hospital Stay
- Intraoperative Complication Rates
- Estimated Blood Loss (EBL) Volumes and Blood Transfusion Rates
- Conversion Rates
- Readmission Rates
- Reoperation Rates
- Mortality Rates
- Postoperative Complication Rates
- Operative Times

In conclusion, the clinical analysis of the subject Senhance Surgical System demonstrates that the device is as safe and effective as its predicate for patients who are at least two (2) years of age and 10kg or higher in weight.

Figure 1. Search criteria and flowchart for literature search



The following filters were applied to narrow the searches to relevant publications:

Inclusion Criteria:

US or EU study, to reduce variation in surgical method.
Pediatric and young adults (≤21 years) patients only
Studies on robotic assisted laparoscopy
LOE ≤3b
Studies on gynecology (OR) urology (OR) general surgery
Data collected 2000 – Present.
Study is an RCT on robotic assisted laparoscopy and/or comparative study reporting on robotic assisted pediatric cases versus minimally invasive/laparoscopic pediatric surgery)

Exclusion Criteria

Non-US or EU study
Meta-Analysis/SLRs (summary data from meta-analysis/SLRs were excluded, however, the references from the meta-analysis/SLRs were analyzed for inclusion as selected articles)
Publications not on robotic assisted laparoscopic procedure
Publication is an HTA that was not published in a peer reviewed journal.
Follow up study, missing original surgery data.
Adult only or adult data not reported separately.
Animal studies