July 19, 2024

Asensus Surgical, Inc.
Madhuvanthi Soundirarajan
Senior Regulatory Affairs Specialist
1 TW Alexander Dr Suite 160
Durham, North Carolina 27703

Re: K233866
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 20, 2024
Received: June 20, 2024

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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.

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,

Mark Trumbore -S
Digitally signed by Mark Trumbore -S
Date: 2024.07.19 14:26:20 -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: 07/31/2026
*See PRA Statement below.*

Submission Number *(if known)*

K233866

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, laparoscopic gynecological surgery, and laparoscopic urological 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.**

# 510(k) Summary
# Senhance Surgical System
# [In accordance with 21 CFR § 807.92]

## Submitter Information


| | |
|---|---|
| **Submitter:** | Asensus Surgical, Inc.<br>1 TW Alexander Drive, Suite 160<br>Durham, NC 27703 |
| **Contact:** | Madhuvanthi Soundirarajan<br>Sr. Regulatory Affairs Specialist<br>Email: msoundirarajan@asensus.com<br>Phone: 352-44-9130 |


| | |
|---|---|
| **Date Summary Prepared:** | 12/11/2023 |

## Subject Device Information

| | |
|---|---|
| **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) |

## Predicate Device Information

| | |
|---|---|
| **Primary Predicate Device:** | Senhance® Surgical System (K223095) |
| **Reference 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 traditional 510(k) submission is to seek clearance for modifications to the indications for use to be expanded to include laparoscopic urological surgery.

## Indication 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, laparoscopic gynecological surgery, and laparoscopic urological 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 (K223095), and similar characteristics to the reference device. 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.

**Substantial Equivalence:**

The subject Senhance Surgical System with the expanded indications for use is substantially equivalent to the legally marketed primary predicate, Senhance Surgical System most recently cleared through K223095, and to the reference device, the Intuitive Surgical da Vinci Si Surgical System, IS3000 (K171699).

The subject Senhance Surgical System has the same intended use, technological characteristics, and principles of operation as the primary predicate. The expanded indications for use for the subject device are supported by real-world clinical evidence and do not raise different questions of safety or effectiveness or alter the fundamental therapeutic use of the system; they also align with the intended user population cleared for the secondary predicate/reference device.

**Performance Data:**

There have been no changes to the device since the previous clearance (K223095), other than the modifications to expand the indications for use to include laparoscopic urological surgery indications. 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 (K223095) are still applicable as there have been no changes to the technological characteristics of the device.

**Cybersecurity Data:**

Cybersecurity information demonstrating compliance with section 524B of the FD&C Act consistent with current "FDA Guidance: Cybersecurity in Medical Devices - Quality System Considerations and Content of Premarket Submissions" was provided in this submission.

**Clinical Data**

To demonstrate that the subject device is safe and effective for the expanded indications for use, the company has collected real-world evidence on the Senhance Surgical System. A retrospective clinical data review was performed using data from the TRUST registry.

Asensus Surgical is sponsoring a clinical registry "TRUST'' and encourages clinical centers in Europe to participate and enter information about the actual use of the Senhance Surgical System and its accessories into the database. This study is a prospective, multi-center patient registry. Sites additionally retrospectively enrolled previously treated patients (after obtaining informed consent) and entered retrospective data into case report forms online.

The TRUST registry aims to enable the collection of real-world evidence on the effectiveness and safety of the Senhance Surgical System and its accessories as it is routinely used within three surgical disciplines: abdominal surgery, gynecological surgery, and urological surgery.

From December 2017 to August 2023, 416 urology cases were performed using the Senhance system at four centers. All patients treated with the Senhance system within this retrospective dataset were eligible for laparoscopic procedures with general anesthesia. The data collection at the sites are still ongoing.

## Systematic Literature Review (SLR)

Clinical data collected from the TRUST registry was compared with the results from 62 peer-reviewed research publications describing the clinical outcomes for laparoscopic urological procedures using three alternative surgical techniques: laparoscopic, open, and robotically assisted surgery. The table below (**Table 18**) summarizes the clinical data on Senhance Surgical System compared to data from the systematic literature review. **Figure 12** and **Figure 13** show the Literature Search Strategy and Inclusion and Exclusion Criteria for the SLR

**Table 18, SLR Data Average and TRUST Registry Data for Urological Procedures**

| | Senhance System (TRUST Registry) | SLR Data Averages | | |
|---|---|---|---|---|
| | | Robotic | Laparoscopy | Open |
| **Length of Stay (Days)** | 5.0 | 2.6 | 3.1 | 6.1 |
| **Surgical Complication** | 0.48% | 2.43% | 2.64% | 1.93% |
| **Conversion rate** | Traditional laparoscopy: 7.1%<br>Open: 0.5% | 3.06% | 3.60% | n/a |

| | Senhance System (TRUST Registry) | SLR Data Averages | | |
|---|---|---|---|---|
| | | Robotic | Laparoscopy | Open |
| **Estimated Blood Loss (mL)** | 261 | 307.23 | 416 | 697 |
| **Readmission rates (30 days)*** | 0.48%† | 7.10% | 10.66% | 17.99% |
| **Reoperation rates (30 days)*** | 0% | 18.09% | 15.18% | 0% |
| **Mortality** | 0% | 0.36% | 0.42% | 0.69% |
| **Postoperative Complication** | 2.4% | 54.19% | 23.49% | 24.87% |
| **Operative Time (mins)** | 197.1 | 178.58 | 124.92 | 176.29 |

***** Both the readmission and reoperation rates were calculated based on information available from adverse event listing notes. Both readmissions occurred during the 12-month follow-up phase after the patient's discharge from the hospital. Therefore, both readmission and reoperation occurred any time between the day of discharge and 12 months after discharge.

†Follow-up was performed on only 122 patients in Zagreb and 17 patients in Minsk. Hence the missing values were not included in the n% calculation.

## Conclusion

The clinical analysis of the subject Senhance Surgical System demonstrated that the device is safe and effective for use in urological surgical procedures, which is comparable to that indicated for the secondary predicate (Intuitive da Vinci Si Surgical System, K171699).

The subject Senhance Surgical System has the same intended use as the predicates and its expanded indications for use do not affect the safety or effectiveness of the device. In addition, the subject device has the same technological characteristics and principles of operation as the primary predicate device. Analysis and clinical performance of the device with urological procedures indicate that no new issues of safety or effectiveness are raised for the expanded claim. Thus, the subject Senhance Surgical System is substantially equivalent to the predicate device.

**Figure 12 Flowchart for literature search**

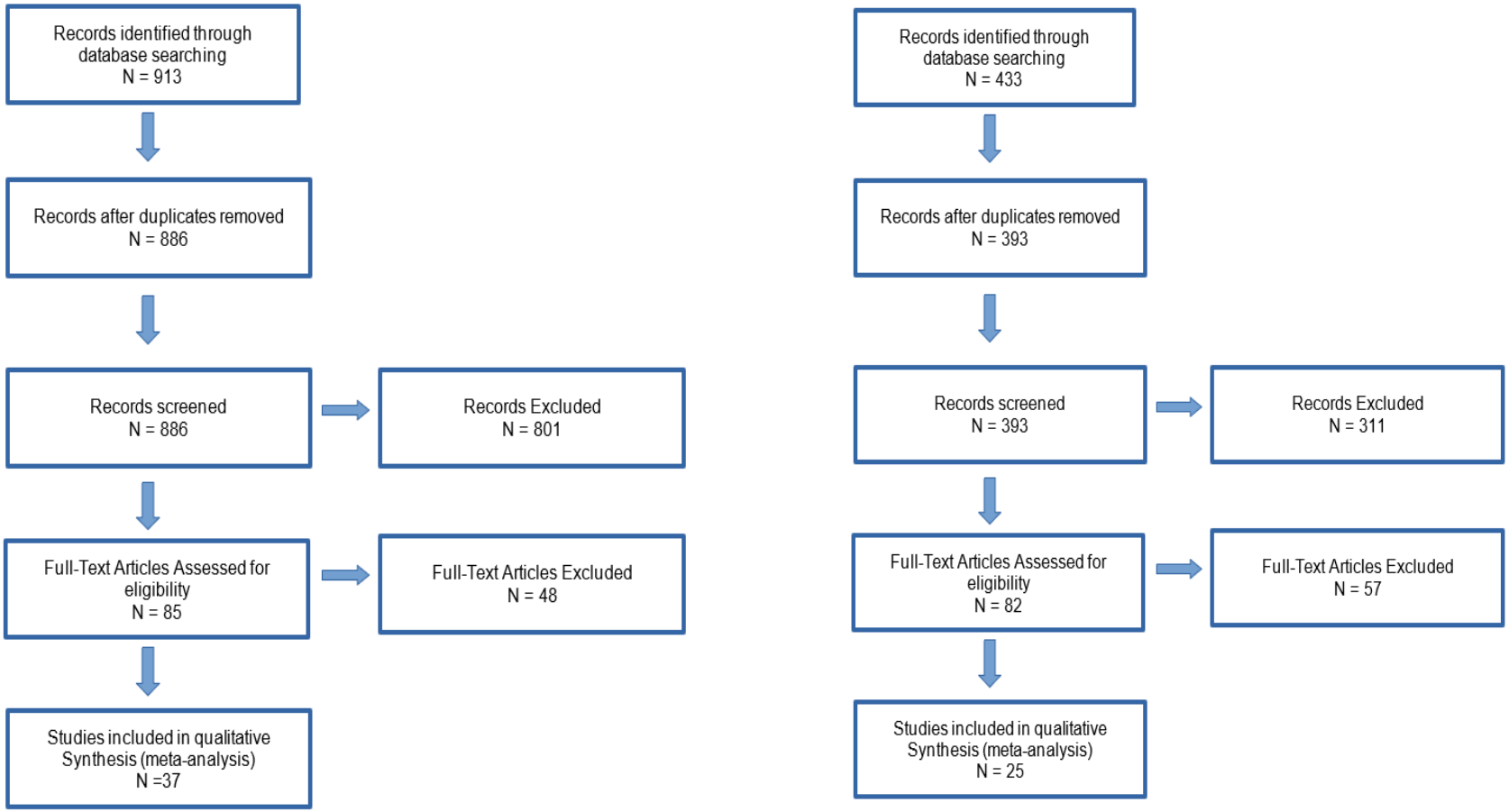

**Figure 13 Inclusion and exclusion criteria for literature search**

**Inclusion Criteria**

- US or EU Study, to reduce variation in surgical method
- Adult and pediatric patients only
- Studies on robotic-assisted laparoscopy
- LOE ≤3*
- Studies on urological procedures
- Data collected 2018 – August 17, 2023
- Study is a prospective randomized controlled trials on robotic assisted laparoscopy, comparative study reporting on robotic assisted urological cases versus minimally invasive, laparoscopic urological surgery, or open surgery, and/or cohort or case series publications.

**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
- Animal studies