October 13, 2017

TransEnterix, Inc.
Stephanie Fitts, Ph.D.
VP, Clinical, Quality and Regulatory Affairs, Chief Compliance Officer
635 Davis Drive, Suite 300
Morrisville, North Carolina 27560

Re: K171120
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: September 15, 2017
Received: September 15, 2017

Dear Dr. Fitts:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Jennifer R. Stevenson -S3

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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)*
K171120

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 in laparoscopic colorectal surgery 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]

I. Submitter

510(k) Submitter:	TransEnterix, Inc.
Address:	635 Davis Drive, Suite 300 Morrisville, NC 27560
Contact Person:	Stephanie M. Fitts, PhD Vice President, RA/QA, Clinical and Compliance
Contact Information:	Email: sfitts@transenterix.com Phone: 919.765.8400 Facsimile: 919.765.8549
Date Summary Prepared:	October 13, 2017

II. Device

Name of Device:	Senhance™ Surgical System
Common or Usual Name:	Endoscopic Instrument Control System Endoscopic Instruments and Accessories
Classification Name:	Endoscope and Accessories (21 CFR 876.1500)
Regulatory Class:	II
Product Code:	NAY (System, Surgical, Computer Controlled Instrument)

III. Predicate Device

	Intuitive Surgical da Vinci Si Surgical System IS3000 (K081137) This predicate has not been subject to a design-related recall
Reference Devices	Stryker (MAKO) RIO Robotic Arm Assisted System (K093425) Stryker Surgical Instruments (K150127) GIMMI GmbH Surgical Instruments (K012660) Bissinger GmbH POWERGRIP Coagulation Forceps (K033177 and K970968)

IV. Device Description:

The Senhance Surgical System is a console-based, multi-arm surgical system which enables a surgeon to remotely control surgical instrumentation during minimally invasive surgery in the lower abdomen and pelvis. The capital equipment is comprised of three main sub-systems as follows:

- **Cockpit** The station where the surgeon inputs information through hand and eye movements to direct the motion of the arms in the surgical field.
- **Manipulator Arms** Independent mechanized support arms that interface with the endoscope and surgical instruments. The manipulator arms produce output movements based on the instructions from the surgeon at the cockpit. The system is configurable with up to three arms.
- **Node** A relay unit which connects the cockpit inputs to the manipulator arms in the system as configured, and converts and transmits the video signals to the 2D/3D monitor on the cockpit console.

Figure 1, below, is a graphical depiction of the main Senhance system components.

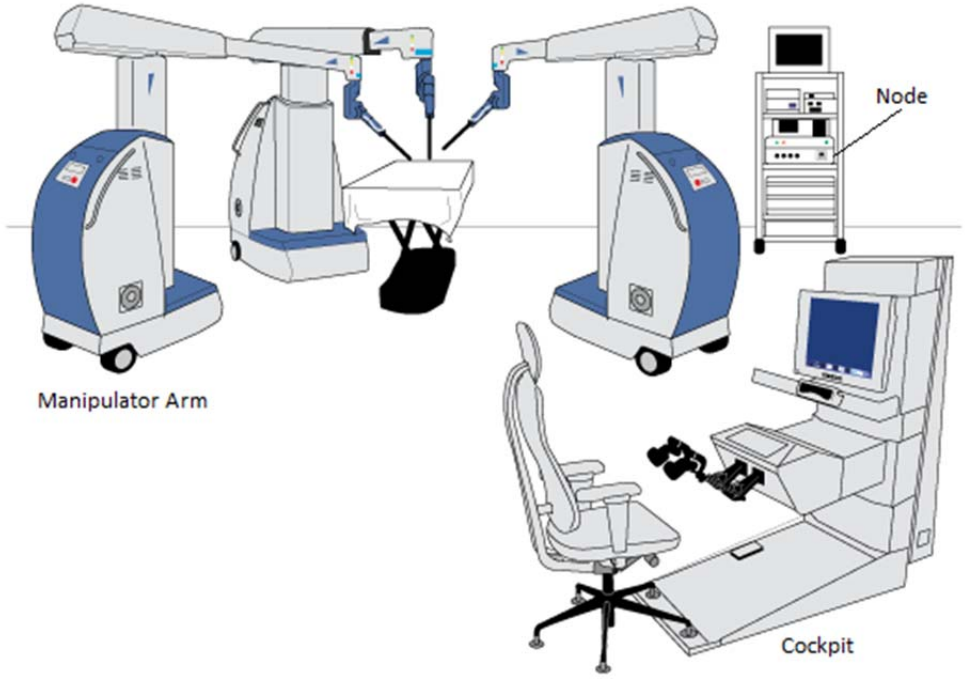

Figure 1. Senhance System

The following are the device safety features:

- Manipulator Arm Brakes
- Indicator Lights
- Audible Alerts
- Trocar Fulcrum
- Hierarchy of Control
- Exceeding Force
- Multiple inputs required at cockpit to initiate motion
- Emergency Stop
- Surgeon presence
- Eye tracking lost gaze stop
- Jog mode velocity restriction

- RFID surgical instrument
- Power loss stoppage

The Senhance system includes a series of surgical instruments (Table 1), which are attached to the manipulator arms by way of corresponding adapters. All adapters and instruments are multi-use components that are steam sterilized by the end user before the first and each subsequent use. The instrument designs are adaptations of standard laparoscopic instruments that are commonly used in surgery. Each instrument type has a corresponding system adapter.

TABLE 1. Senhance Surgical Instruments

PASSIVE INSTRUMENTS	
Johan Grasper	Mixter Dissector
Kocher Grasper	Needle Holder, Left
Allis Grasper	Needle Holder, Right
Strong Grasper	Fundus Grasper
MONOPOLAR INSTRUMENTS	
Maryland Dissector	Curved Metzenbaum Scissors Short Tip
Curved Metzenbaum Scissors	L-Hook Electrode
BIPOLAR INSTRUMENTS	
Large Grasping Forceps	Maryland Dissector
Curved Scissors	

V. 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 in laparoscopic colorectal surgery 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.

VI. Summary of Technological Characteristics:

Robotically-assisted tele-operation is the primary technological principle for both the subject and predicate devices. It is based on the accurate translation of user input to a robotically assisted output. It involves the use of endoscopic instrumentation for manipulation of tissues and vessels in the insufflated body cavity. At a high level, the subject and predicate devices are based on the following same technological elements: *surgeon console* which provides remote manipulators or handles to allow the surgeon to maneuver the surgical instruments and a video monitor for the endoscopic signal, *manipulator arms* which hold the instruments and endoscope based on inputs from the surgeon, and *instruments* which manipulate the tissue of interest.

The eye sensing feature provides the surgeon an optional alternate method to control the endoscope other than using their hands. This feature is similar to the Class II exempt device, the Tobii CEye System Augmentative and Alternative Communication Devices, and complies with ISO 15004-2: 2007-02-15 and IEC 62471: 2006-07. Force feedback provides an optional tactile sensory input to the surgeon control handles to give a sense of tissue elasticity. This feature is similar to that of the reference device Stryker (MAKO) RIO Robotic Arm Assisted System (K093425).

The Senhance Surgical System differs from the predicate in the design of the instrumentation. The predicate utilizes wristed instruments with an additional degree of freedom. The Senhance instruments are similar in design and materials to traditional laparoscopic instrumentation. The instrument reference devices listed (Stryker Surgical Instruments (K150127), GIMMI GmbH Surgical Instruments (K012660), and Bissinger GmbH POWERGRIP Coagulation Forceps (K033177 and K970968)) all have instrument designs and materials which have a long history of safe clinical use.

Table 2 lists the differences between the subject device and the predicate device features.

TABLE 2. Differences between Senhance and Predicate, da Vinci Si (K081137)

Feature	Senhance	Predicate
Surgeon Console	Open Cockpit design	Head-in cockpit
Surgeon Controls	Laparoscopic style grip and motion	Three-finger grip with open surgery motion
Instrument Activation	Dual surgeon inputs for manipulator arm motion (fingers in handles plus clutch pedal)	Dual surgeon inputs for manipulator arm motion (forehead sensor plus finger grip activation)
Endoscope Control	Hand or optional Infrared Eye sensor	Clutch pedal selection and hand control
Force Feedback	Yes	No
Surgeon Display	Active instruments shown	Similar
Robotic Arms	Three separate carts with one arm each	One cart with 3-4 arms
	Manual brake and wheels	Powered brake and wheels
	Exceeding Force Stop –arms stop when excessive force is detected	Arms stop after collision when joints are moved from original position
	Emergency Stop button	Similar
Surgical Instruments	Fulcrum set by force sensor	Fulcrum set by remote center function using potentiometers
	Straight stick standard laparoscopy	Wristed instruments
	Reusable instruments	Reusable instruments
Third Party Endoscope Adapters	Yes	No
Drapes	Third party sterile equipment covers	Same

To establish the substantial equivalence (SE) with the predicate device and address the above listed differences, the subject device was tested in preclinical, usability, and in-vivo testing as summarized in Section VII of this document.

Table 3 lists some of the Senhance technological features along with a reference device which includes a similar feature.

TABLE 3. Senhance Features and Reference Devices with Similar Feature.

Senhance Feature	Reference Device with Similar Feature or Standard Used to Test Safety of the Given Feature
Handle to Instrument Movement, Straight shaft design and standard end effectors	Stryker Surgical Instruments (K150127) GIMMI GmbH Surgical Instruments (K012660)
Standard port placement and size	Bissinger GmbH POWERGRIP Coagulation Forceps (K033177 and K970968)
Haptic force feedback to handles	Stryker (MAKO) RIO Robotic Arm Assisted System (K093425)
Eye sensing camera control	Radiation safety testing per ISO 15004-2: 2007-02-15 and IEC 62471: 2006-07

The compatibility of the features listed in the above table was established as a part of usability testing and during the design validation process.

VII. Performance Data

The following performance testing of the Senhance Surgical System was conducted to support substantial equivalence to the predicate device.

Biocompatibility testing: The biocompatibility evaluation for the Senhance Surgical System was conducted on all patient contacting instruments in accordance with the FDA Guidance for Industry and FDA Staff "Use of International Standard ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" issued on June 16, 2016 , and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The battery of testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation/Inflammatory Response (IR)
- Acute Systemic toxicity
- Pyrogenicity

The instruments are considered tissue contacting for a limited duration of less than 24 hours for contact with tissue or bone.

Cleaning, Disinfection (Reprocessing) and Sterilization Validation: The capital equipment was validated through cleaning effectiveness, cleaning compatibility and low level disinfection testing. Cleaning effectiveness and low-level disinfection studies were conducted on non-draped areas of the Senhance manipulator arm. These studies were based on the guidelines outlined in AAMI TIR12:2010, ANSI/AAMI TIR30:2011, and ANSI/AAMI ST58:2013. The reusable instruments and adapters were the subject of a cleaning effectiveness study based on the guidelines outlined in AAMI TIR12:2010 and ANSI/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" issued on: March 17, 2015 and the FDA recognized consensus standards ANSI/AAMI/ISO 17665-1:2006/(R)2013 and ANSI/AAMI/ISO 14937:2009/(R)2013.

Electrical safety and electromagnetic compatibility (EMC): Electrical safety and EMC testing were conducted on the Senhance Surgical System. The system complies with the IEC 60601-1:2012 standard for basic safety and essential performance of medical electrical equipment and IEC 60601-1-2:2014 collateral standard for EMC. High frequency electrical safety requirements were evaluated per IEC 60601-2-2 2009/COR1:2014 and applicable safety requirements for the endoscopic equipment were evaluated per IEC 60601-2-18:2009.

Software Verification and Validation Testing: Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "major" level of concern.

Bench testing: Bench testing evaluated the mechanical performance of the system and included the following:

- Instruments Dynamic Cantilever Testing
- Instruments Jaw Grasping Reliability and Force to Jaw Failure
- Shears Reliability
- Video Signal Verification
- System Latency
- Robotic arm and surgical instrument motion accuracy
- Video Signal Latency
- Force Feedback
- Eye Sensing [ISO 15004-2:2007 Ophthalmic Instruments - Fundamental Requirements and Test Methods Part 2: Light Hazards Protection and IEC 62471:2006 Photobiological safety of lamps and lamp systems]
- Transit and Packing Testing
- Drape Compatibility
- Endoscope Compatibility
- ESU Compatibility

Human Factors/ Usability Engineering Testing: The Senhance Surgical System underwent full summative human factors (usability) testing. The study was conducted in accordance with the FDA Guidance for Industry and FDA Staff "Applying Human Factors and Usability Engineering to Medical Devices" issued on February 3, 2016. In this study, realistic team-based scenarios were evaluated. Sixteen (16) teams of 3 users were evaluated in performing use tasks in a porcine wet lab environment which was simulated to reflect the actual intended conditions of use. The teams, which consisted of one surgeon, one surgical assistant and one nurse, were trained per the training program intended for use at market introduction which includes individual and team based training exercises. After a training decay period of between overnight and seven days, the team was evaluated by an independent usability investigator while performing surgical tasks in a porcine model. All study endpoints confirmed that the Senhance system can be used by surgeons, surgical assistants, and nurses in an operating room environment without patterns of preventable use errors that may cause harm when the system is in use during laparoscopic surgery.

Animal Testing: Pre-clinical Design Validation: A single-center, un-blinded, observational, simulated use study of the Senhance System was conducted with representative users. Four (4) teams of trained subjects (one surgeon and one surgical assistant per team) performed surgical tasks on a live porcine model. The teams performed serosal bladder incision with repair, oophorectomy, total laparoscopic hysterectomy, gastric serosal incision with repair, cholecystectomy, and nephrectomy.

The procedures were non-survival. The surgical teams performed tasks representing major user needs which included: Patient and Trocar Placement, Initial Endoscope and Instrument Attachment, Initial Endoscope and Instrument Insertion, Cockpit Setup, Communication, Laparoscopic Procedure, Feature-specific Laparoscopic Tasks, Instrument Removal and Detachment, Incision Site Evaluation, and Emergency Access. The surgical tasks from the Senhance system's indications for use were performed according to the demands of the specific surgical procedure. All surgical procedures were successfully completed, and all essential user requirements were assessed and found to be met by the system.

Clinical Data: The gynecological laparoscopic surgery data were from a prospective non-randomized clinical trial for 150 patients undergoing surgery with the Senhance system. The colorectal laparoscopic surgery data were from a retrospective chart review (referred to as real world evidence or RWE) of 45 patient's medical records of colorectal surgery.

The Gynecological Laparoscopic Surgery Data

The gynecological study enrolled 150 subjects with surgical indications that included ovarian cyst removal (39%), cancer prophylaxis (2%), uterine fibroids (3%), benign or early stage uterine and adnexal cancer (43%) and advanced uterine/adnexal cancer (13%). The majority (57%) of patients reported a previous abdominal/pelvic surgery with 33% specifically reporting a previous gynecological surgery. The patients enrolled had an average Body Mass Index (BMI) of 24.4 kg/m^2. Ten conversions to manual laparoscopy were reported and all were included as intraoperative complications in the results. Two conversions were associated with serious adverse events at the time of surgery: one patient converted to laparoscopy for bladder perforation requiring repair and one patient who developed subcutaneous emphysema due to the anesthetic technique. Neither of the events was device related according to the investigator's assessment. The remaining conversions were due to patient anatomy or surgeon preference. No blood transfusions or other complications were reported in the intra-operative timeframe. Post-operatively an additional six serious adverse events (4%) were reported including one wound dehiscence, two infections, one suspected pleurisy requiring hospitalization, and one rapid onset anemia. One patient returned to the operating room after pathology confirmed a cancer diagnosis was included conservatively as an adverse event, but was not a true re-operation. None of these serious adverse events was considered device related according to the investigators.

Data were extrapolated from two umbrella procedures: total laparoscopic radical hysterectomy and myomectomy. This allowed labeling for representative specific covered gynecological procedures (listed in Table 4) without the need to provide clinical data for the covered procedures.

TABLE 4. Umbrella and Covered Procedures for Laparoscopic Gynecology

Representative Procedures	
Umbrella Procedures	Covered Procedures
Laparoscopic radical/total hysterectomy, cyst removal, salpingectomy, oophorectomy	benign/ simple total laparoscopic hysterectomy, lymphadenectomy, endometriosis resection, adnexectomy, omentectomy, parametrectomy, lysis of adhesions
Myomectomy	Myomectomy

The data from the gynecology procedures are shown below in Table 5.

TABLE 5. Gynecological Surgery Data with *Senhance* by Surgery Group

	Mono/Bilateral salpingo-oophorectomy, cyst removal	Myomectomy	Total Hysterectomy	Total Hysterectomy plus adjacent structures (radical)
Number of pts	62	4	64	20
Complication Non-serious (Clavien Dindo I-II)*	16	0	14	15
Serious Complication (Clavien Dindo III)*	0	0	8	0
Estimated Blood Loss (mL)	<63	0 (minimal)	<144	<112
Intra-op Adverse Events / Complications	0	0	2	0
Transfusions*	0	0	0	0
Mortality*	0	0	0	0
Conversion to Lap (n, %)	0	0	5 (3.3%)	5 (3.3%)
Reoperation rates (n, %)	0	0	2 (1.3%)	0
Readmission rates (n, %)	0	0	3 (2%)	0
Operative Time (min) †	26.1 (26.3)	57.7 (15.5)	157 (61.1)	221 (86)
Hospital Length of Stay** (days)	1 (1-3)	1.5 (1-3)	2 (1-5)	2 (1-5)

*through 30 days † Mean (SD) ** median (range)

Data from the gynecological study of 150 patients using the Senhance System were compared with the results from eight peer-reviewed research publications describing the clinical outcomes for more than 8000 gynecological operations using the predicate device. Substantial equivalence was determined by comparing the following procedural endpoints to the predicate device: length of hospital stay, intraoperative complications, estimated blood loss (transfusions), post-operative complications (through 30 days), readmission rates, reoperation rates, mortality, operative time, and conversion rates (from RASD to open or traditional laparoscopic). Overall, the comparison of the provided gynecological surgery clinical data with the predicate published literature data demonstrated that the Senhance system is as safe and effective as the predicate device for its intended use.

Colorectal Laparoscopic Surgery Data

The colorectal surgery data from a retrospective chart review study on 45 patients undergoing colorectal surgeries were provided. Surgical indications were colorectal cancer (66%), endoscopically unresectable adenoma (4.4%), complicated inflammatory bowel disease (18%) and diverticular disease (11%). Twenty-three patients underwent right hemicolectomy, 9 left hemicolectomy, 12 lower anterior resection including Low Anterior Resection Total Mesorectal Excision (LAR/TME), and 1 colectomy.

Data was extrapolated from the umbrella procedure of LAR/TME. This allowed labeling for representative specific covered colorectal procedures (listed in Table 6) without the need to provide clinical data for the covered procedures.

TABLE 6. Umbrella and Covered Procedures for Laparoscopic Colorectal

Representative Procedures	
Umbrella Procedure	Covered Procedures
Low Anterior Resection Total Mesorectal Excision (LAR/TME), Colectomy (Right, Left, Total)	Colectomy (Transverse, Hemi & Sigmoidectomy), Small Bowel Resection, Rectopexy, Abdominoperineal Resection (APR), Appendectomy

The data from the colorectal procedures are shown below in Table 7.

TABLE 7. Colorectal Surgery Data with *Senhance* by Surgery Type

	Right Hemicolectomy	Left Hemicolectomy	LAR including LAR/TME	Total Colectomy
Number of pts	23	9	12	1
Complication Non-serious (Clavien Dindo I-II)	8	3	2	1
Serious Complication (Clavien Dindo III)	2	0	0	0
Estimated Blood Loss (mL)	<20	< 50	< 50	< 50
Intra-op Adverse Events / Complications	0	0	0	0
Transfusions	0	0	0	0
Mortality*	0	0	0	0
Conversion to Lap (n, %)	1 (2.2%)	2 (4.4%)	0	0
Reoperation rates (n, %)	0	0	0	0
Readmission rates (n, %)	1 (2.2%)	0	0	0
Anastomotic leak	1	0	0	0
Surgical Margins R0 (%)	100	100	100	100
Operative Time (min) †	222 (175-307)	247 (200-299)	359 (274-501)	279
Hospital Length of Stay (days) †	5 (3-13)	6 (4-14)	6 (3-19)	5

*through 30 days † mean (range)

There were three conversions to standard laparoscopy. Two conversions were for complicated diverticular disease and one was secondary to mesocolic bleeding. No conversions to laparotomy or open surgery were reported. The post-operative serious complication rate for all patients was 4.4% (2 patients) which included an anastomotic leak leading to abscess requiring a drain placement, and an intraluminal bleed requiring endoscopic clips. No patient underwent reoperation and none of the adverse events were considered device related by the investigators.

Data from the retrospective case series review of 45 (real world evidence) patients undergoing colorectal procedures in a real world setting using the Senhance system were compared with the results from 11 peer-reviewed research publications describing the clinical outcomes for more than 5000 colorectal operations performed using the predicate device. Substantial equivalence was determined by comparing the following procedural endpoints to the predicate device: length of hospital stay, conversion rates (from RASD to open or traditional laparoscopic), intraoperative complications, estimated blood loss (transfusions), adverse events / all complications, anastomotic leak rate, re-admission rates, reoperation rates, mortality, operative time, and surgical margins. Overall, the comparison of the provided colorectal surgery clinical data with the predicate published literature data demonstrated that the Senhance system is as safe and effective as the predicate device for its intended use.

PRECAUTION: Clinical data for the representative specific labeled uses was based on evaluation of the device as a surgical tool that assists in the accurate control and performance of coordinated surgical tasks in the form of specific surgical procedures. Therefore, safety and effectiveness considerations were limited to validating the indications for use and do not imply that any outcomes related to surgeon training, skill or proficiency were considered. Outcomes related to the treatment of cancer (i.e. local recurrence, disease-free survival, overall survival), or any specific treatment for underlying disease or patient condition were not evaluated.

VIII. Conclusions

The Senhance Surgical System has the same intended use as the predicate device. There are technological differences between the subject device and the predicate device, Intuitive Surgical da Vinci Si Surgical System IS3000 (K081137). The non-clinical testing supported the safety and functionality of the device. The clinical testing supported the indications for use. Overall, the performance testing data demonstrate the device is substantially equivalent to the predicate device.