May 25, 2018

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

Re: K180163
Trade/Device Name: TransEnterix Senhance Surgical System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: NAY, GCJ
Dated: April 23, 2018
Received: April 24, 2018

Dear Stephanie 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

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)*
K180163

Device Name
TransEnterix 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 laparoscopic gynecological surgery, colorectal surgery, cholecystectomy, and inguinal hernia repair. 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

K180163

[In accordance with 21 CFR 807.92]

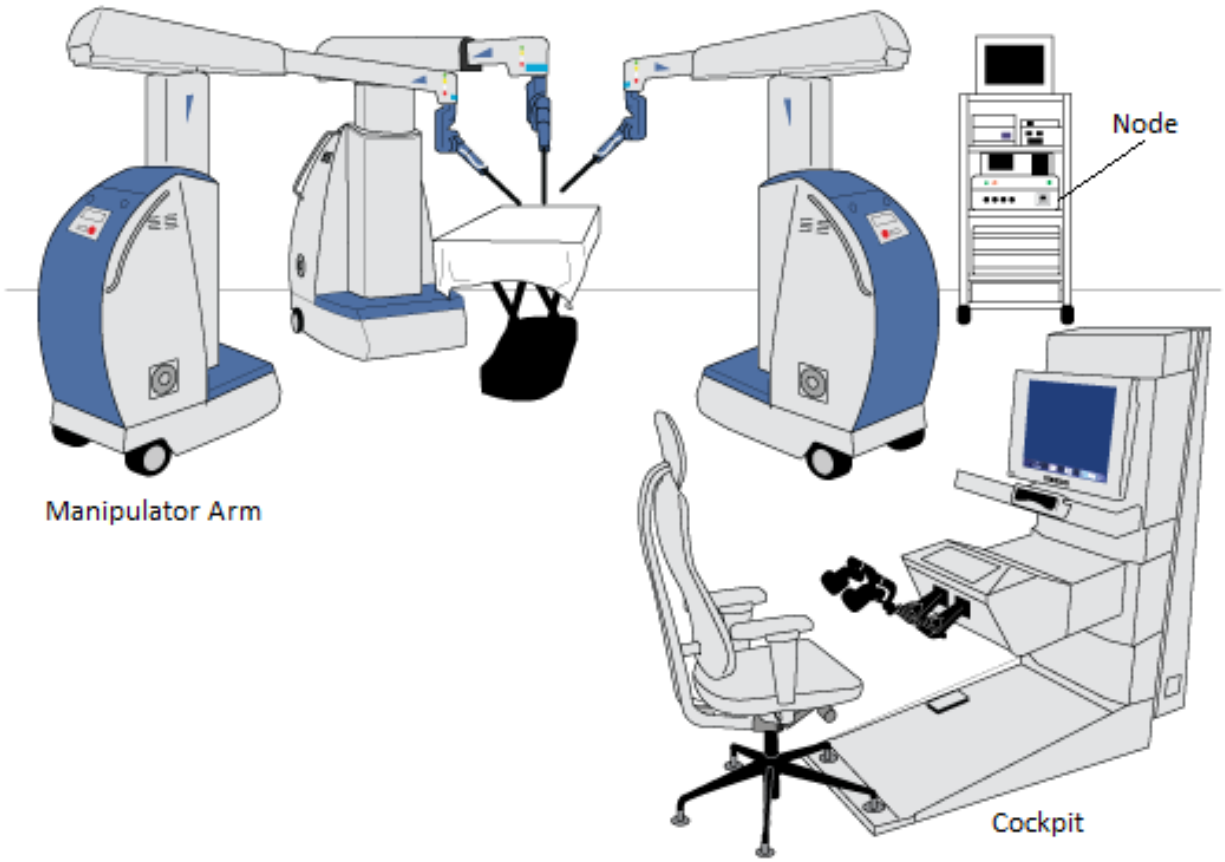
510(k) Sponsor:	TransEnterix, Inc.
Address:	635 Davis Drive, Suite 300 Morrisville, NC 27560
Contact Person:	Stephanie Fitts, Ph.D. Vice President, RA/QA, and Clinical
Contact Information:	Email: sfitts@transenterix.com Phone: 919.765.8400 Facsimile: 919.765.8549
Date Summary Prepared:	May 14, 2018
Proprietary (Trade) Name:	TransEnterix® Senhance™ Surgical System
Common Name:	Endoscopic Instrument Control System 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 (K171120)
Reference Devices:	Intuitive Surgical da Vinci Xi Surgical System (K170713 and K172643)

I. 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 that 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.

The figure below is a graphical depiction of the main Senhance system components.



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

II. 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 laparoscopic gynecological surgery, colorectal surgery, cholecystectomy, and inguinal hernia repair. 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.

III. Summary of Technological Characteristics

This 510(k) is for a labeling modification only, to include inguinal hernia repair and cholecystectomy procedures under the cleared list of procedures for the Senhance Surgical System. There are no changes to the technological characteristics of the cleared Senhance Surgical System proposed in this submission. The comparison of the subject device technological characteristics to the predicate device and reference device is provided in **Table 2** below.

Table 2. Technological Comparison to Predicates

Feature	Senhance (Subject Device, K180163)	Senhance (Predicate Device, K171120)	da Vinci Xi (Reference Devices, K170713 & K172543)
Surgeon Console	Open Cockpit design	Open Cockpit design	Head-in cockpit
Surgeon Controls	Laparoscopic style grip and motion	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 (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	Hand or optional Infrared Eye sensor	Clutch pedal selection and hand control
Force Feedback	Yes	Yes	No
Surgeon Display	Active instruments shown	Active instruments shown	Similar
Robotic Arms	Three separate carts with one arm each	Three separate carts with one arm each	One cart with 4 arms
	Manual brake and wheels	Manual brake and wheels	Powered brake and wheels
	Exceeding Force Stop – arms stop when excessive force is detected	Exceeding Force Stop – arms stop when excessive force is detected	Arms stop after collision when joints are moved from original position
	Emergency Stop button	Emergency Stop button	Similar
Surgical Instruments	Fulcrum set by force sensor	Fulcrum set by force sensor	Fulcrum set by remote center function using potentiometers
	Straight stick standard laparoscopy	Straight stick standard laparoscopy	Wristed instruments
	Reusable instruments	Reusable instruments	Reusable instruments
Third Party Endoscope Adapters	Yes	Yes	No
Drapes	Third party sterile equipment covers	Third party sterile equipment covers	Same

The subject Senhance System has undergone software revision since the predicate Senhance System was cleared in K171120 to add the following 3 non-end user related features:

- **Software Compatibility Check Feature:** This feature queries and retrieves all software component version levels for TransEnterix-created binary files. The gathered binary files are compared against expected versions, and if any discrepancies are found during the check, the system displays a version incompatibility error message on the cockpit monitor. The check is performed at system startup and any time an arm is newly connected to an active system.

- **R&D Mode:** This function was added to allow the system to enable or disable specific features to facilitate unrestricted continued software development of the system. The R&D Mode feature will only be enabled once a "development config" file is placed on a component of the system. This file can only be placed on a component through physically deconstructing the component and interacting with the PCs internal to the

device, or through the Node's service port which is only accessible by authorized and trained personnel using a password protected interface.

- **Service function for Automated Instrument Calibration:** Instrument calibration is a time-consuming task that is normally performed by Field Service to calibrate the jaw open and close ranges for designated "grasping" surgical instruments. This feature automates that process to save time during a field service visit.

The subject device is substantially similar in technological characteristics to the predicate Senhance device. When used for the additional laparoscopic surgeries proposed, the substantial equivalence has been demonstrated through the clinical data, summary of which is included in this document.

The bench, usability, pre-clinical and in-vivo data provided for Senhance device under K171120 are applicable to the subject device since in terms of technology and intended use the subject device remains similar to the predicate cleared under K171120. These data along with additional clinical data presented under the subject submission demonstrate the subject device is substantially equivalent to the predicate device. Moreover, the clinical data provided for subject device for laparoscopic inguinal hernia and cholecystectomy procedures had similar outcomes when compared with the reference device, da Vinci Xi Surgical System, and standard laparoscopic technique.

IV. Software Verification and Validation

The subject Senhance System has undergone software revision to add the following 3 non-end user related features: Software Compatibility Check Feature, R&D Mode, and Service function for Automated Instrument Calibration. These features are described above in Section III.

Software verification and validation testing were conducted for the changed portions of the architecture including regression testing and integration testing for the revised code. 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" including re-presentation of unchanged specifications and test reports submitted with the predicate device submission K171120. The software for this device was considered as a "major" level of concern.

V. Clinical Data

In supplement to the previously submitted clinical data in K171120, the company has collected data on the Senhance Robotic System for cholecystectomy and inguinal hernia procedures as part of three studies. In sum, data has been collected on 76 inguinal hernia repair procedures and 40 cholecystectomy procedures with the Senhance Robotic System. These data demonstrate results that support substantial equivalence to the predicates for the proposed indications.

Cholecystectomy Case Series

Two retrospective chart reviews were performed for 40 patients who underwent cholecystectomy procedures with the Senhance Robotic System. There were few intraoperative and postoperative complications and two conversions to standard laparoscopy. No conversions to open technique, reoperations or readmissions related to the procedure were necessary.

Table 3. Cholecystectomy Data - Senhance, Predicate Robotic and Laparoscopic

	Senhance - Imperial College N=20	**Senhance - Hamburg University N=20**	**Reference da Vinci System ǂ N=1435**	**Laparoscopic arm from meta-analysis (Huang et al)* N=921**
Complication Non-serious (Clavien Dindo I-II) (n, %) or % range	6, 30%	0	0-25%	Not Reported
Serious Complication (Clavien Dindo III) (%)	0	0	0-4%	0-10%
Estimated Blood Loss (mL)	Minimal	Not Reported	Not Reported	12-14 mL
Intra-op Adverse Events / Complications (n, %) or % range	1 (intraop bleeding), 5%	0	0-5%	0-33.3%
Transfusions (%)	0	0	0-2%	0
Mortality (%)	0	0	0-0.5%	0
Conversion to Laparoscopy (n, %) or % range	1, 5%	1, 5%	0-12.5%	N/A
Conversion to Open (n, %) or % range	0	0	unknown	0-15.7%
Reoperation rates (n, %) or % range	0	0	0-4%	Not Reported
Readmission rates (n, %)	3, 15%	0	0-4%	0-4.3%
Median Operative Time in min (range)	86.5 (44-129)	71.5 (34-197)	91.7 (50-152)	115.3 (65-141)
Hospital Length of Stay (days)	0 (1 pt remained overnight)	2**	1-5	2.2 (range 1.0-5.1)

ǂ Reference da Vinci data compiled from 19 papers obtained from structured PubMed literature search years 2000-2018

* Huang et al. Robotic cholecystectomy versus conventional laparoscopic cholecystectomy: A meta-analysis. Surgery. 2017 Mar;161(3):628-636. doi: 10.1016/j.surg.2016.08.061

** 2-day hospital stay per protocol

For the data provided under the heading entitled “Reference da Vinci System” and a PubMed search was conducted using specific Medical Subject Heading (MeSH) terms for the years 2000-2018 which yielded 61 robotic papers of interest. A pre-determined excision criteria was used to filter the results to the final set of 19 peer-reviewed research publications describing the clinical outcomes for more than 1400 cholecystectomy robotically assisted surgery operations.

A meta-analysis publication (Huang et al) was used for the laparoscopic comparison. This publication summarized 13 trials for the outcomes of interest and reported on over 900 cholecystectomies performed by manual laparoscopic technique.

When comparing results from the Senhance System and the literature, all outcomes measures demonstrated comparable results. Overall, the comparison of the provided cholecystectomy surgery clinical data with the published literature data from other surgical techniques demonstrated that the Senhance System is as safe and effective as the predicate device for its intended use.

Inguinal Hernia Repair Surgery Data

A retrospective chart review was performed for 64 patients who underwent inguinal hernia repair procedures with the Senhance Robotic System. These patients underwent 76 transabdominal preperitoneal (TAPP) inguinal hernia repairs, including bilateral hernias and recurrent hernia after previous surgical repair. No significant intraoperative or postoperative complications were observed in the 64 patients. Two cases had to be converted to standard laparoscopic technique. No reoperations or readmissions related to the procedure were necessary.

Table 4. Inguinal Hernia Repair Surgery - Senhance, Reference da Vinci System and Laparoscopic

Outcome	Senhance System N=64^	Reference da Vinci System N=652**	Laparoscopic Cohort N=3457*
Patient Demographics			
Mean age, (y ± SD or range)	54.5 ± 16.3	55.8 ± 15.6	34.91 – 62.3
Female, n (%) or % range	10 (15.6%)	64 (9.8%)	0 – 6.1%
Mean BMI, kg/m2 (± SD) or range	25.9 ± 3.1	27.3 ± 5.1	22.4 – 26.8
Length of Stay			
Inpatient (days, mean ± SD or range)	1.04 ± 0.2 days†	3.01 ± 4.65 (n=52)	0.8 - 5 days
Outpatient (hours)	n/a	7.16 ± 3.01	
Intraoperative Complications, n (%) or % range	0 (0%)	2 (0.3%)	0 – 8%
Transfusions, n (%)			
Intraoperative	0	0	Not Reported
Perioperative	0	2 (0.3%)	
Postoperative Complications, n (%) or % range	1 (1.6%)	15 (2.3%)	0-36% (reported as total time period)
Postop to discharge	0	28 (4.3%)	
Post discharge to 30 days			
Readmission Rates, n (%)	0	23 (3.5%)	Not Reported
Reoperation Rates, n (%) or % range			0-2.5% (reported as total time period)
Postop to discharge	0	3 (0.5%)	
Post discharge to 30 days	0	0	
Mortality, n	0	0	0
Operative Time, min, avg ± SD/range			
Unilateral repair	44 ± 17.4	79.7 ± 31.7	32.6 – 110
Bilateral repair	79 ± 23.7		
All Complications, n (%) or % range	1 (1.6%)	45 (6.9%)	7.9 – 8.7%

^ All performed via TAPP method

†One patient in each group was hospitalized for 2 days. All other patients were admitted for 1 day.

*Data from eleven (11) publications referenced in Bittner, et al., "Update of guidelines on laparoscopic (TAPP) and endoscopic (TEP) treatment of inguinal hernia (International Endohernia Society", Chapter 4: "TEP versus TAPP: which is better?" Surg Endosc 29:289-321 (2015).

** Data from 510(k) summary K170713

Data from the inguinal hernia repair case series using the Senhance system were compared with the results from over 650 robotic surgeries using the reference da Vinci system and over 3400 inguinal hernia repair operations performed using standard laparoscopic technique.

Operative times and complication rates were similar between the Senhance System retrospective chart review and the literature. Longer term endpoints such as inguinal hernia repair recurrence and chronic pain were not assessed

in this study, and thus no claims regarding these outcomes data should be inferred. Overall, the comparison of the provided inguinal hernia repair surgery clinical data with the published literature data demonstrated that the Senhance System is as safe and effective as the predicate device for its intended use.

Clinical data were not provided for all of the representative, specific procedures. Instead, clinical data were provided for the most complex/highest risk representative, specific procedures of Total Radical Hysterectomy, and Low Anterior Resection Total Mesorectal Excision (referred to as the "umbrella" procedures). The data on these "umbrella" procedures were extrapolated to cover the less complex/lower risk procedures (referred to as "covered" procedures) so published clinical data on the covered procedures were not provided. Clinical data were provided for Myomectomy, Cholecystectomy, and Inguinal Hernia Repair yet these data did not act as umbrella procedures to cover any other procedure. Thus, the Representative Procedures for the Senhance System are outlined in **Table 5** below.

Table 5. Umbrella and Covered Procedures

Representative Procedures		
Surgical Specialties /Procedures	Umbrella Procedures	Covered Procedures
Laparoscopic Gynecological Procedures	Laparoscopic radical/total hysterectomy, cyst removal, salpingectomy, oophorectomy	benign/ simple total laparoscopic hysterectomy, lymphadenectomy, endometriosis resection, adnexectomy, omentectomy, parametrectomy, lysis of adhesions
	Myomectomy	
Laparoscopic Colorectal 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
Specific Laparoscopic Procedures	Cholecystectomy	
	Inguinal Hernia Repair (Uni and bilateral)	

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.

VI. Conclusions

The clinical analysis of the TransEnterix Senhance System, as summarized herein, demonstrates that the device is as safe and effective for the two additional umbrella procedures as the predicate Senhance System cleared in K171120.

The Senhance System has the same intended use and its expanded indications for cholecystectomy and inguinal hernia repair do not affect the safety or effectiveness of the device compared to predicate device. In addition, the Senhance System has identical technological characteristics and principles of operation as the predicate device.

Analysis and clinical performance of the device in these new procedures indicate that no new issues of safety or effectiveness have been raised for the expanded claim. Thus, the Senhance System is substantially equivalent.