March 3, 2021

TransEnterix, Inc.
Kaitlyn Alexander
Regulatory Affairs Manager
635 Davis Drive, Suite 300
Morrisville, North Carolina 27560

Re: K202166
Trade/Device Name: Senhance Surgical System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: NAY

Dear Kaitlyn Alexander:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated March 2, 2021. Specifically, FDA is updating this SE Letter because a valid digital signature with FDA watermark was not included on the SE letter as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Je Hi An, Ph.D. OHT4: Office of Surgical and Infection Control Devices, 240-402-0018, jehi.an@fda.hhs.gov.

Sincerely,

Je An -S Digitally signed by Je An -S

Je Hi An, 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

March 2, 2021

TransEnterix, Inc.
Kaitlyn Alexander
Regulatory Affairs Manager
635 Davis Drive, Suite 300
Morrisville, North Carolina 27560

Re: K202166
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 5, 2021
Received: February 5, 2021

Dear Kaitlyn Alexander:

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,

Je Hi An, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K202166

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 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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

[In accordance with 21CFR 807.92]

1. Submitter

510(k) Sponsor:	TransEnterix, Inc.
Address:	635 Davis Drive, Suite 300 Morrisville, NC 27560
Contact Person:	Kaitlyn Alexander Regulatory Affairs Manager
Contact Information:	Email: kalexander@transenterix.com Phone: 919-765-8400 x8505 Facsimile: 919.765.8459
Date Summary Prepared:	3/1/2021

2. Device

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)

3. Predicate and Reference Devices

Predicate Device:	Senhance® Surgical System (K200049)
Reference Device:	Intuitive Surgical da Vinci Si Surgical System (K171699)

4. 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. The purpose of this submission is to seek clearance for modifications to the indications for use to expand the types of surgical procedures for which the Senhance Surgical System may be used.

In this submission, the indications for use have been expanded to cover laparoscopic general surgical procedures. The new indications for use statement does not create a new intended use for the system.

5. 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.

6. Summary of Technological Characteristics:

The subject device has the same technological characteristics as the predicate device, the Senhance Surgical System (K200049). There are no changes to the technological characteristics of the cleared Senhance Surgical System. 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 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 Senhance instruments are similar in design and materials to traditional laparoscopic instrumentation.

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

7. 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 for the general surgery reconstructive upper abdominal umbrella procedure, Nissen fundoplication. These data demonstrate favorable performance and safety results for the proposed indications.

Nissen Fundoplication Case Series

A retrospective chart review was performed for 34 patients who underwent Nissen fundoplication procedures with the Senhance system. There were no intraoperative complications and few postoperative complications and conversions to standard laparoscopy. No conversions to open technique were necessary.

Data from the Nissen fundoplication case series using the Senhance system were compared with the results from six (6) publications describing the clinical outcomes for two (2) alternative surgical techniques: laparoscopic and robotically assisted surgery (specifically performed by the reference device). The publications were selected based on specific search criteria used in two (2) search engines (PubMed and Medline) by multiple independent reviewers.

The selected publications included: one (1) prospective trial; three (3) randomized clinical trials; and three (3) non-blinded clinical evaluations. The search terms, inclusion/exclusion criteria, and the flowchart depicting the results from these searches are provided in Figure 1, below. Tables 1 and 2, below, provide the retrospective real-world clinical evidence for the subject device along with a detailed summary of the published clinical data on this procedure for the two (2) alternative surgical techniques.

Operative times and complication rates were similar between the retrospective chart review with the Senhance system and the literature. Overall, the comparison of the Senhance Nissen fundoplication surgery clinical data with the findings from the Nissen Fundoplication publications demonstrated that the Senhance system is as safe and effective as the predicate for this clinical use 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

Thus, the representative procedures for the subject Senhance Surgical System are outlined in the table below.

Table 3 – Umbrella and Covered Procedures

Umbrella Procedures	Covered Procedures
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	Myomectomy
General Surgery 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
Cholecystectomy, Inguinal Hernia Repair (Uni and bilateral)	Cholecystectomy, Inguinal Hernia Repair (Uni and bilateral)
Nissen Fundoplication	Hiatal hernia repair, Paraesophageal hernia repair, Sleeve Gastrectomy

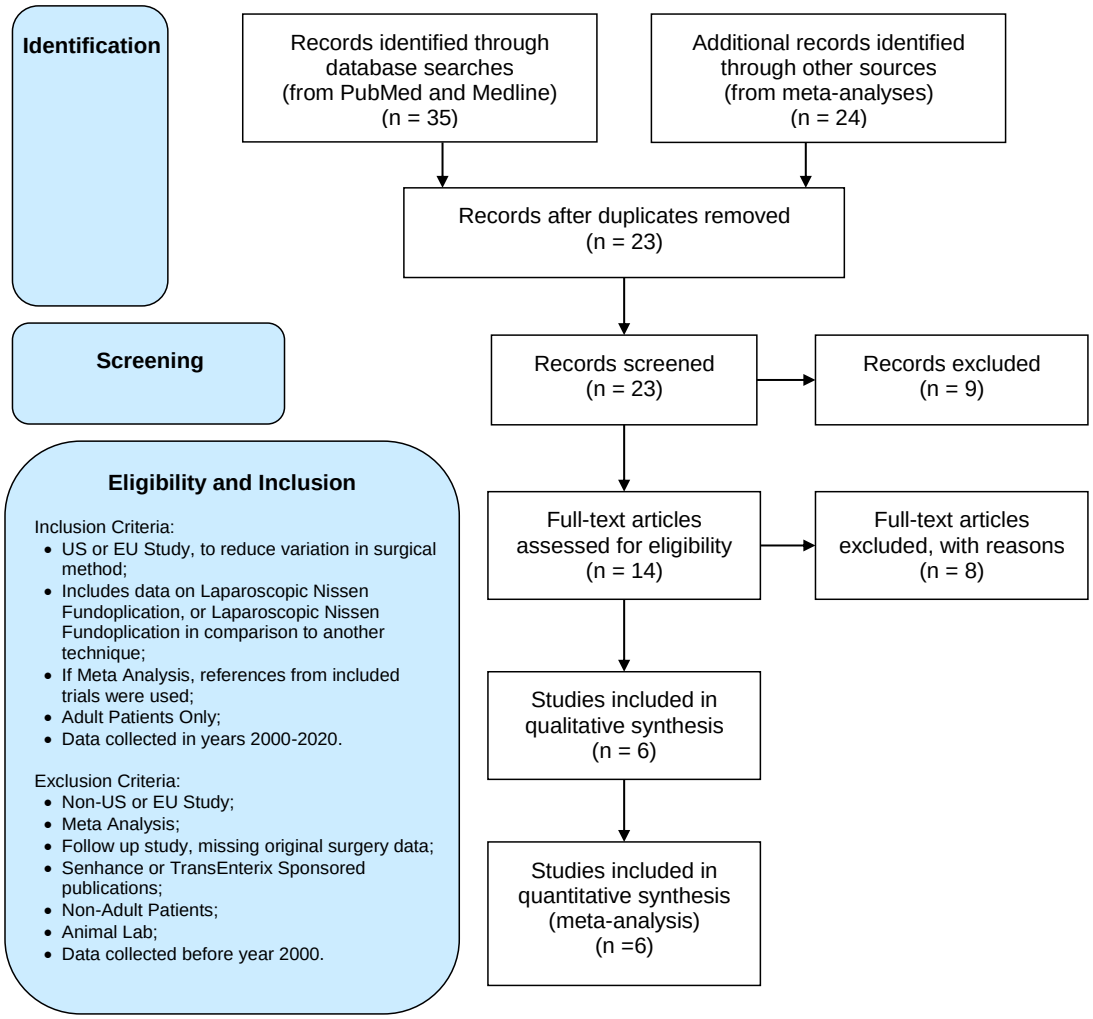
PRECAUTION: Clinical data for the representative specific labeled uses was based on evaluation of the device as a surgical tool that assists in the accurate control and performance of coordinated surgical tasks in the form of specific surgical procedures. Therefore, safety and effectiveness considerations 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.

8. Conclusions:

The clinical analysis of the subject Senhance Surgical System demonstrates that the device is as safe and effective for the additional surgical procedures as the predicate, Senhance Surgical System (K200049).

The subject Senhance Surgical System has the same intended use as the predicate 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 predicate device. Performance data of the device in these new procedures indicate there is no new issue of safety or effectiveness. Thus, the subject Senhance Surgical System is substantially equivalent to the predicate device.

Figure 1 – Search Criteria and Flowchart for Nissen Fundoplication Literature Search



PubMed and Medline Search Terms: Robotic AND laparoscopic "Nissen fundoplication".

Table 1 – Comparison of Clinical Endpoints for Senhance and Traditional Laparoscopic Surgical Approach for Nissen Fundoplication

	Senhance System		Traditional Laparoscopic Approach					
	Cohort 1	**Cohort 2**	**Draaisma WA, et al. 2006 [1]**	**Melvin WS, et al. 2002 [2]**	**Nakadi IE, et al. 2006 [3]**	**Morino M, et al. 2006 [4]**	**Muller-Stich BP, et al. 2007 [5]**	**Heemskerk J, et al. 2007 [6]**
General Information								
Country of Origin	Germany	Netherlands	Netherlands	USA	Belgium	Italy	Germany	Netherlands
Number of cases (n)	18	16	25	20	11	25	20	11
Clinical Outcomes								
Length of Hospital Stay (days) *Mean (range)*	5 (3-6)	2 (1-4)	3^ (1-13)	1 (1-2)	4.1 (Range not reported)	2.9 (2-6)	3.3 (Range not reported)	4 (Range not reported)
Intraoperative Complications	0	0	7 (28%)	0	Not Reported	0	2 (10%)	0
Transfusion Rate/Estimated Blood Loss (mL)	0 *	14 (Range 0-50)	45 (Range 0-200)	Not Reported	Not Reported	Not Reported	Not Reported	0
Conversion Rate	2 (11%) †	4 (25%) †	2 (8%)	0	0	0	0	0
Readmission Rates	0	2 (13%)	0	0	0	0	0	Not Reported
Reoperation Rates	1 (6%)	0	0	1 (5%)	0	Not Reported	0	1 (9%)
Mortality	0	0	0	0	0	0	0	0
Post-Operative Complications	5 (14.7%) for N=34		3 (11%)	0	4 (36%)	0	4 (20%)	2 (18%)
Operative Time *Mean (range)*	111.5 (68-194) for N=34		95^ (60-210)	97.1 (45-168)	96 (Range not reported)	91.1 (72-106)	102 (75-152)	173 (Range not reported)

*Only reported for 16 of 18 patients.
^Median Reported
† Senhance cases completed using hybrid technique of robotically-assisted and traditional laparoscopy.

[1] Draaisma WA, Ruurda JP, Scheffer RCH, et al.Randomized clinical trial of standard laparoscopic versus robot-assisted laparoscopic Nissen fundoplication for gastro-oesophageal refluxdisease. Br J Surg 2006; 93: 1351–1359.
[2] Melvin WS, Needleman BJ, Krause KR, et al. Computer-enhanced vs. standard laparoscopic antireflux surgery. JGastrointest Surg 2002; 6(1): 11–15.
[3] Nakadi IE, Melot C, Closset J, et al. Evaluation of da Vinci Nissen fundoplication clinical results and cost minimization. World JSurg 2006; 30(6): 1050–1054.
[4] Morino M, Pellegrino L, Giaccone C, et al. Randomized clinical trial of robot-assisted versus laparoscopic Nissen fundoplication.Br J Surg 2006; 93: 553–558
[5] Muller-Stich BP, Reiter MA, Wente MN, et al. Robot-assisted versus conventional laparoscopic fundoplication: short-term outcome of a pilot randomized controlled trial. Surg Endosc 2007; 21: 1800–1805.
[6] Heemskerk J, van Gemert WG, Greve JW, Bouvy ND. Robot-assisted versus conventional laparoscopic Nissen fundoplication: a comparative retrospective study on costs and time consumption. Surg Laparosc Endosc Percutan Tech. 2007 Feb;17(1):1-4. doi: 10.1097/01.sle.0000213756.76761.b7. PMID: 17318044.

Table 2 – Comparison of Clinical Endpoints for Senhance and Robotically Assisted Surgical Approach for Nissen Fundoplication

	Senhance System		Robotically Assisted Surgical Approach					
	Cohort 1	**Cohort 2**	**Draaisma WA, et al. 2006**	**Melvin WS, et al. 2002**	**Nakadi IE, et al. 2006**	**Morino M, et al. 2006**	**Muller-Stich BP, et al. 2007**	**Heemskerk J, et al. 2007**
General Information								
Country of Origin	Germany	Netherlands	Netherlands	USA	Belgium	Italy	Germany	Netherlands
Number of cases (n)	18	16	25	20	9	25	20	11
Clinical Outcomes								
Length of Hospital Stay (days) *Mean (range)*	5 (3-6)	2 (1-4)	3^ (2-6)	1 (1-2)	4.4 (Range not reported)	3.0 (2-7)	2.9 (0.4-1.7)	4 (Range not reported)
Intraoperative Complications	0	0	4 (16%)	0	Not Reported	0	1 (5%)	0
Transfusion Rate/Estimated Blood Loss (EBL) (mL)	0 *	14 (Range 0-50)	20 (Range 0-200)	Not Reported	Not Reported	Not Reported	Not Reported	0
Conversion Rate	2 (11%) †	4 (25%) †	0 **	0	1 (11%)	1 (4%)	0	0
Readmission Rates	0	2 (13%)	0	0	0	0	0	Not Reported
Reoperation Rates	1 (6%)	0	0	0	0	Not Reported	0	0
Mortality	0	0	0	0	0	0	0	0
Post-Operative Complications	5 (14.7%) for N=34		0	0	3 (33%)	0	5 (25%)	4 (36%)
Operative Time *Mean (range)*	111.5 (68-194) for N=34		120^ (80-180)	140.9 (88-271)	137 (Range not reported)	131.3 (90-162)	88 (60-150)	220 (Range not reported)

*Only reported for 16 of 18 patients.
^Median Reported
† Senhance cases completed using hybrid technique of robotically-assisted and traditional laparoscopy.
**Note that this paper states that all robot-assisted procedures were completed by laparoscopy, however, there were no unplanned conversions.