



March 9, 2020

TransEnterix, Inc.  
Kaitlyn Alexander  
Regulatory Affairs Manager  
635 Davis Drive, Suite 300  
Morrisville, North Carolina 27650

Re: K200049

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: January 9, 2020  
Received: January 9, 2020

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Long Chen, 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

## Indications for Use

510(k) Number (if known)

K200049

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

[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](mailto:kalexander@transenterix.com)  
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Facsimile: 919.765.8459

Date Summary Prepared: 01/09/2020

### 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 Device:

Predicate Device Senhance® Surgical System (K192877)

Reference Device AutoLap System (K152848)

### 4. Device Description:

The purpose of this submission is to seek clearance for an alternate Node component called the Smart Node (to be marketed as the Intelligent Surgical Unit (ISU)), which introduces enhanced image processing features and augments the endoscope movement capabilities of the

TransEnterix® Senhance® Surgical System. The Smart Node adds three new methods of camera control for the surgeon operating at the Senhance Cockpit.

#### **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 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.

#### **Comparison with Predicate Device Intended Use/ Indications for Use:**

The Senhance Surgical System with Smart Node has the same intended use/ indications for use as previously cleared for the predicate Senhance Surgical System (K192877).

#### **6. Summary of Technological Characteristics:**

The subject device has the same basic technological characteristics as the predicate Senhance Surgical System (K192877). In sum, the subject and predicate devices involve robotically-assisted tele-operation as the primary technological principle. 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 tissue and vessels in the insufflated body cavity. The device 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; node, which is the system communication hub, connecting the cockpit and manipulator arms; and instruments, which manipulate the tissue of interest. The Senhance instruments are similar in design and materials to traditional laparoscopic instrumentation.

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, other than using their hands. The Senhance Smart Node allows for three new optional methods of camera control, in addition to the optional eye tracking method.

Performance testing demonstrated that the technological differences between the Senhance Surgical System with Smart Node and the predicate device did not raise any different questions of safety or effectiveness.

#### **7. Performance Data:**

Performance testing of the Senhance system with Smart Node was conducted to support the substantial equivalence to the predicate device. The following performance tests were conducted:

**Bench Testing:** Bench testing evaluated the performance of the Senhance Smart Node as well as the overall use of the Senhance Surgical System with Smart Node. The following tests confirmed that the Senhance system and the Smart Node perform as intended after tests of compatibility, reliability, functionality, safety, and efficacy.

**Electrical Safety and Compatibility:** The Senhance Surgical System with Smart Node comply with the current versions of IEC 60601-1 (Basic safety and essential performance), IEC 60601-1-2 (Electromagnetic disturbances), and IEC 60601-2-18 (Endoscopic equipment interactions).

**Software Verification and Validation Testing:** Software verification and validation were conducted on the Senhance system software modifications to support the subject Smart Node. Documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff "Guidance for the Content of Premarket Submissions for Software Controlled in Medical Devices" and "Guidance for the Content of Premarket Submissions for Management of Cybersecurity in Medical Devices". The software was considered as a "major" level of concern.

**Pre-Clinical Design Validation:** Design validation of the Senhance system with Smart Node was conducted to ensure that the device performs as intended according to defined user needs and intended use in a simulated use environment. A single-center, un-blinded, observational, simulated use design validation evaluation of the Senhance system was conducted with users who represented the intended primary user population. The design validation was conducted in a live porcine model, which most closely represents the human anatomy for the given procedures. All user level requirements were assessed and found to be met.

**Usability Testing:** Modifications to the existing Senhance system Usability Engineering file were made based on the new features and functionality of the Smart Node. A confirmatory summative study was performed with final instructions and training materials. In a simulated use environment, the users were able to independently perform all critical tasks without use errors that would lead to harm.

## **8. Conclusions**

The Senhance Surgical System with Smart Node is as safe and effective as the predicate Senhance Surgical System (K192877). The subject device has the same intended uses/ indications for use and similar technological characteristics and principles of operation as its predicate device. The minor technological differences between the subject device and predicate device raise no different questions of safety or effectiveness. The performance testing supported the safety and functionality of the device and demonstrate that the device is substantially equivalent to predicate device.