November 22, 2019

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

Re: K192877
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: October 7, 2019
Received: October 8, 2019

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,

Jitendra Virani
Acting 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)*

K192877

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Senhance® 3 mm Monopolar Hook Instrument and Adapter

[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 Senior Regulatory Affairs Specialist
Contact Information:	Email: kalexander@transenterix.com Phone: 919-765-8400 x8505 Facsimile: 919.765.8459
Date Summary Prepared:	10/4/2019

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:	TransEnterix Senhance® Surgical System (K191482)
Reference Device:	TransEnterix Senhance® Surgical System (K181517)

4. Device Description:

The Senhance® 3 mm Monopolar L-Hook Electrode instrument and adapter are intended as additions to the suite of monopolar hook instruments and adapters initially cleared for use with the TransEnterix Senhance Surgical System through K171120 (October 13, 2017) and then expanded through K191482 (July 11, 2019). The subject instrument and adapter are modifications of the predicate TransEnterix Senhance 5 mm Monopolar L-Hook Electrode instrument and adapter FDA cleared through K191482.

Like the predicate devices, the subject devices are multi-use surgical devices that are cleaned and steam sterilized by the end user before the first use and after each use. The subject and predicate instruments consist of a polymer coated stainless steel shaft with an electrode at the distal end and a ceramic collar between the two to provide monopolar insulation. In order to be used with the Senhance Surgical System, the typical manual laparoscopic handle at the proximal end of the instrument is removed and replaced by a connector that mates with an adapter. The adapter provides the mechanism which allows the instrument to interface with the robotic manipulator arm of the Senhance Surgical System. Each instrument is laser marked with a unique identification number that matches its corresponding adapter.

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 Monopolar L-Hook Electrode instrument and adapter have the same intended use/ indications for use as previously cleared for the Senhance system through K180163 (May 25, 2018). There are no differences in how the subject devices are used that alter the Senhance system's therapeutic effect or raise different questions of safety or effectiveness.

6. Technological Characteristics:

The Senhance Monopolar L-Hook Electrode instrument is very similar to the predicate devices cleared through K191482, with differences only in instrument diameter, length, materials of construction, and voltage ratings. The subject adapter is equivalent to the predicate monopolar hook adapter in overall design characteristics. The only differences for the new adapter are RFID programming and the content of the laser marking.

Performance Data:

Performance testing of the Senhance Monopolar L-Hook Electrode instrument and adapter was conducted in order to support substantial equivalence to the predicate devices and

demonstrated that the technological differences between the subject devices and predicate devices do not raise any different questions of safety or effectiveness.

Performance testing included mechanical verification, validation of cleaning effectiveness, biocompatibility evaluation, electrical safety, and electrosurgical unit (ESU) compatibility. Due to the similarity of the subject devices to the predicate devices, no other testing was necessary.

The following performance testing was conducted for the devices in this submission.

Biocompatibility testing: The Senhance Monopolar L-Hook Electrode instrument is categorized as tissue contacting for a limited duration of less than 24 hours for contact with tissue or bone. The instrument was assessed 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*. Testing demonstrated that the patient-contacting portions of the Senhance Monopolar L-Hook Electrode instrument are non-toxic, non-irritating, and do not result in an unacceptable adverse biological response resulting from contact of the device's materials with the body.

Reprocessing, Cleaning, and Sterilization: The reusable Senhance Monopolar L-Hook Electrode instrument was tested for cleaning effectiveness to confirm the overall effectiveness of the prescribed cleaning procedures. The cleaning procedures and test protocols for the testing are consistent with the procedures and protocols utilized for the predicate instrument. The test results demonstrated that the cleaning procedures allows for the subject instrument to be effectively cleaned according to the processing instructions provided in the labeling.

Performance Testing: Testing evaluated the performance of the Senhance Monopolar L-Hook Electrode instrument as well as compatibility of the subject devices when used with the Senhance Surgical System. Mechanical verification testing confirmed that the subject devices perform as intended after tests of mechanical integrity under conditions of simulated use. Additionally, ESU compatibility testing demonstrated that all third-party ESUs that are compatible with the Senhance system are also compatible with the subject devices.

Electrical Safety and Compatibility: The monopolar hook instrument fulfilled all applicable requirements to demonstrate compliance with the current electrical safety standards, IEC 60601-2-2, *Medical electrical equipment Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories*, and IEC 60601-2-18, Medical Electrical Equipment - Part 2-18: *Particular Requirements For The Basic Safety And Essential Performance Of Endoscopic Equipment*.

7. Conclusions/ Substantial Equivalence:

The data acquired from the performance testing of the Senhance 3 mm Monopolar L-Hook Electrode instrument and adapter, as summarized herein, demonstrate that the devices are as safe and effective and perform similarly to the predicate devices cleared through K191482. The intended use/ indications for use for the subject devices are identical to those for the cleared

Senhance Surgical System. The subject instrument and adapter do not raise any new issues of safety or effectiveness when compared to the predicate devices, thus, they are substantially equivalent to the predicate devices.