December 6, 2018

TransEnterix, Inc.
Michele Jans
Sr. Manager, Regulatory Affairs
635 Davis Drive, Suite 300
Morrisville, North Carolina 27560

Re: K183098
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
Dated: November 6, 2018
Received: November 7, 2018

Dear Michele Jans:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

Long H. Chen -S

Digitally signed by Long H. Chen -S
Date: 2018.12.06 12:49:08 -05'00'

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)*
K183098

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 Bipolar Surgical Instruments and Adapters

[In accordance with 21CFR 807.92]

510(k) Sponsor:	TransEnterix, Inc.
Address:	635 Davis Drive, Suite 300 Morrisville, NC 27713
Contact Person:	Michele Jans Sr. Manager, Regulatory Affairs
Contact Information:	Email: mjans@transenterix.com Phone: 919.765.8420 Facsimile: 919.765.8459
Date Summary Prepared:	12/5/2018
Proprietary (Trade) Name:	TransEnterix® Senhance™ Surgical System
Common Name:	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 Devices:	TransEnterix® Senhance™ Surgical System (K181517)
Reference Devices	Bissinger Powergrip Bipolar Coagulation Forceps (K033177) TransEnterix® Senhance™ Surgical System (K171120)

Device Description:

The Senhance 3 mm bipolar surgical instruments and adapters are additions to the suite of bipolar instruments and adapters previously cleared for use with the Senhance Surgical System (K181517). The instrument designs are adaptations of standard laparoscopic instruments that are commonly used in surgery. Each instrument type has a corresponding system adapter. All instruments and adapters are multi-use devices that are steam sterilized by the end user before the first use and after each use. The Senhance 3 mm bipolar instruments include:

- Bipolar Maryland Dissector – diameter 3 mm / length 280 mm
- Bipolar Grasping Forceps - diameter 3 mm / length 280 mm

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 3 mm bipolar instruments and adapters have the same intended use/ indications for use as previously cleared for the Senhance system under K181517. There are no differences in how the 3mm bipolar devices are used that alter the Senhance system's therapeutic effect or raise different questions of safety or effectiveness.

Technological Characteristics:

The Senhance 3 mm bipolar instruments and adapters are very similar to the predicate devices cleared under K181517, with differences in diameter, length, and voltage ratings. The patient contacting instruments are made of the same biocompatible materials as the Reference devices.

Performance Data:

Performance testing of the Senhance 3 mm bipolar instruments and adapters was conducted to support substantial equivalence to the predicate device and demonstrated that the technological differences between the 3 mm bipolar instruments and adapters and the predicate devices did not raise any different questions of safety or effectiveness.

Testing and evaluation included mechanical verification, validation of cleaning and sterilization, electrical safety, electrosurgical unit compatibility, software verification and validation, and design validation.

The 3 mm bipolar devices are cleaned and sterilized in the same way as the predicate devices. Due to the similarity of the subject devices to the predicate devices, no other testing was necessary.

The testing conducted for the devices in this submission is summarized below:

Bench Testing:

Test	Summary
Mechanical Verification Testing for 3 mm Bipolar Instruments and Adapter	Demonstrated that the devices perform as intended when subjected to tests of mechanical integrity under conditions of simulated use. • Cantilever Bending Reliability Testing • Instrument Jaw Output Force Reliability Testing and Jaw Force to Failure Testing • Bipolar Jaw Spreading Force
Verification of ESU Compatibility	Demonstrated that all third-party electrosurgical units (ESUs) that are compatible with the Senhance Surgical System are also compatible with the 3 mm bipolar instruments and adapters. Testing compared the rated voltage of the instruments with each ESU's manufacturer settings.

Reprocessing, Cleaning, and Sterilization:

Test	Summary
Reprocessing/ Cleaning	A cleaning effectiveness validation study was conducted consistent with the procedures and protocols utilized for the previously cleared adapters used with the Senhance Surgical System to confirm the overall effectiveness of the prescribed cleaning procedures. The test results demonstrated that the cleaning procedures for the 3 mm bipolar adapters allow them to be effectively cleaned according to the processing instructions provided in the labeling.
Sterilization	A validation of the steam sterilization process for the 3 mm bipolar adapters was conducted to demonstrate a Sterility Assurance Level (SAL) of at least 10^{-6}.

Electrical Safety and Compatibility:

Test	Summary
Electrical Safety Testing	The 3 mm bipolar instruments and adapters fulfilled all applicable requirements to demonstrate that the instruments are compliant with the current electrical safety standard, IEC 60601-2-2:2017, 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.

Software:

Test	Summary
Software	Software testing was conducted to demonstrate that the Senhance system software continues to reliably operate as designed with the addition of the new instruments and adapters.

Design Validation:

Test	Summary
Design Validation	Design Validation was conducted to ensure that the subject 3 mm bipolar instruments and adapters perform as intended according to defined user needs and intended uses, and to support substantial equivalence to the predicate devices cleared under K181517. The design validation was conducted in a porcine model, which was used to simulate key human anatomy. This validation used production-equivalent instruments and adapters in a simulated use environment,

Conclusions/ Substantial Equivalence:

The data acquired from the performance testing and software testing of the Senhance 3 mm bipolar instruments and adapters, as summarized herein, demonstrate that the devices are as safe and effective and perform similarly to the predicate devices cleared under K181517. The intended use/ indications for use for the subject devices are identical to those cleared under K181517. The Senhance 3 mm bipolar instruments and adapters 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.