



October 9, 2018

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

Re: K181517

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: September 4, 2018
Received: September 6, 2018

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/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,

**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

Indications for Use

510(k) Number (if known)
K181517

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**Additional Senhance 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: Kaitlyn Alexander
Regulatory Affairs Specialist

Contact Information: Email: kalexander@transenterix.com
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Date Summary Prepared: 10/5/2018

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 (K171120)
TransEnterix® Senhance™ Surgical System Indication Expansion (K180163)

Device Description:

The Senhance “Additional” surgical instruments and adapters are intended as additions to the predicate suite of instruments and adapters previously cleared for use with the TransEnterix Surgical System (Model Senhance™ - K171120 and K180163). All instruments and adapters are multi-use components that are steam sterilized by the end user before the first use and after each use. The instrument designs are adaptations of standard laparoscopic instruments that are commonly used in surgery. Each instrument type has a corresponding system adapter.

Additional Senhance Surgical Instruments

Passive End Effector	Diameter/ Length (mm)	Monopolar End Effector	Diameter/ Length (mm)	Bipolar End Effector	Diameter/ Length (mm)
<ul style="list-style-type: none"> Atraumatic Single Action Grasper Cobra Grasper DeBakey Grasper Needle Holder Straight 	3/ 280	<ul style="list-style-type: none"> Monopolar Maryland Dissector Monopolar Metzenbaum Scissors 	3/ 280	None	None
<ul style="list-style-type: none"> Johan Grasper 15 mm Tip Kocher Grasper Allis Grasper Strong Grasper Mixer Dissector Needle Holder Left Needle Holder Right Fundus Grasper 	5/ 240	<ul style="list-style-type: none"> Monopolar Maryland Dissector Monopolar Metzenbaum Scissors 18 mm Tip Monopolar Metzenbaum Scissors 15 mm Tip 	5/ 240	<ul style="list-style-type: none"> Bipolar Large Grasping Forceps Bipolar Maryland Dissector Bipolar Curved Scissors Bipolar Shaft 	5/ 250
<ul style="list-style-type: none"> Babcock Forceps Weck® Hem-o-lok® ML Clip Applier 	5/ 240 5/ 310 5/ 410	None	None	<ul style="list-style-type: none"> Bipolar Curved Grasping Forceps 	5/ 250 5/ 310

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 Additional surgical instruments and adapters have the same intended use/ indications for use as previously cleared for the Senhance system under K180163, which expanded the original clearance under K171120 to include cholecystectomy and inguinal hernia repair. There are no differences in how the Additional devices are used that alter the Senhance system's therapeutic effect or raise different questions of safety or effectiveness.

Technological Characteristics:

The Additional instruments and adapters are very similar to the predicate devices cleared under K171120, with some differences in length, diameter, end effector types, and voltage ratings.

Performance Data:

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

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

Due to the similarity of the subject devices to the predicate devices, new usability and clinical testing were not necessary.

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

Bench Testing:

Test	Summary
Verification of Senhance System Force Feedback Response	Demonstrated that the Senhance system provides force feedback by measuring the forces presented to the device and conveying the force information proportionally to the user.
Verification of Force Feedback Stability and Sensitivity	Demonstrated that the force feedback feature of the Senhance system properly dampens the haptic response signals from the Additional instruments to the cockpit handles.
Verification of Senhance Manipulator Arm Fulcrum Feature	Demonstrated that the fulcrum feature of the Senhance system can be properly established for the Additional instruments.

Test	Summary
Verification of ESU Compatibility	Demonstrated that all third-party electrosurgical units (ESUs) that are compatible with the Senhance system are also compatible with the Additional instruments and adapters. Testing compared the rated voltage of the instruments with each ESU's manufacturer settings.
Mechanical Verification Testing for Additional Instruments and Instrument Adapters	<p>Demonstrated that the devices perform as intended when subjected to tests of mechanical integrity under conditions of simulated use.</p> <ul style="list-style-type: none"> • Cantilever Bending Reliability Testing • Instrument Jaw Output Force Reliability Testing and Force to Jaw Failure Testing
Clip Applier Ligation Performance	Demonstrated that the burst pressure of clips delivered by the Senhance Weck® Hem-o-lok Clip Applier when used with the Senhance system was not statistically different than the burst pressure of clips delivered by the legally marketed Teleflex Medical Hem-o-Lok® Clip Applier were not statistically different.

Biocompatibility:

Test	Summary
Biocompatibility	<p>Biocompatibility evaluation and testing were performed to demonstrate that the patient-contacting portions of the subject Additional instruments:</p> <ul style="list-style-type: none"> • meet all applicable safety requirements related to material toxicity and biological responsiveness of limited contacting devices. • do not result in an unacceptable adverse biological response resulting from contact of the devices' materials with the body. <p>The results demonstrated that these components met the requirements of ISO 10993-1 with regard to Cytotoxicity, Sensitization, Irritation/Inflammatory Response (IR), Acute Systemic Toxicity, and Pyrogenicity.</p>

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 instruments and adapters used with the Senhance system to confirm the overall effectiveness of the prescribed cleaning procedures. The test results demonstrated that the cleaning procedures for the Additional instruments and adapters allow them to be effectively cleaned according to the processing instructions provided in the labeling.
Sterilization	A validation of the steam sterilization process was conducted to demonstrate a Sterility Assurance Level (SAL) of at least 10^{-6} .

Electrical Safety and Compatibility:

Test	Summary
Electrical Safety and Electromagnetic Compatibility Testing	The Additional electrosurgical instruments 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 Additional 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 K171120. 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 TransEnterix® Additional Senhance™ Surgical Instruments and Adapters, as summarized herein, demonstrate that the devices are as safe and effective and perform similarly to the predicate devices cleared under K171120. The intended use/ indications for use for the subject devices are identical to those cleared under K180163. The Additional 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.