510(k) SUMMARY

[In accordance with 21CFR 807.92]

I. Submitter

510(k) Sponsor:	TransEnterix, Inc.
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Date Summary Prepared:	12/21/2018

II. Device

Proprietary (Trade) Name:	Senhance™ Ultrasonic 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)

III. Predicate Device:

	Intuitive Surgical 5mm Harmonic ACE Curved Shears (K112584)
Reference Device	BOWA Lotus Ultrasonic System 4 (K151101)

IV. Device Description:

The Senhance Ultrasonic System is an energized instrument system which delivers ultrasonic energy to the tissue of interest for soft tissue incisions. It is designed to be used with the Senhance Surgical System which precisely manipulates laparoscopically based instruments in surgery.

The Senhance Ultrasonic System is composed of five components:

1. The Dissector which interfaces with the tissue of interest
2. The Transducer which converts electrical energy into ultrasonic energy
3. The Senhance Adapter which physically attaches the instrument to the Senhance Surgical Robotic System manipulator arm
4. The Ultrasonic Generator which controls the energy settings to be delivered to the tissue
5. The Footswitch

The system components are presented in Figure 1 below:

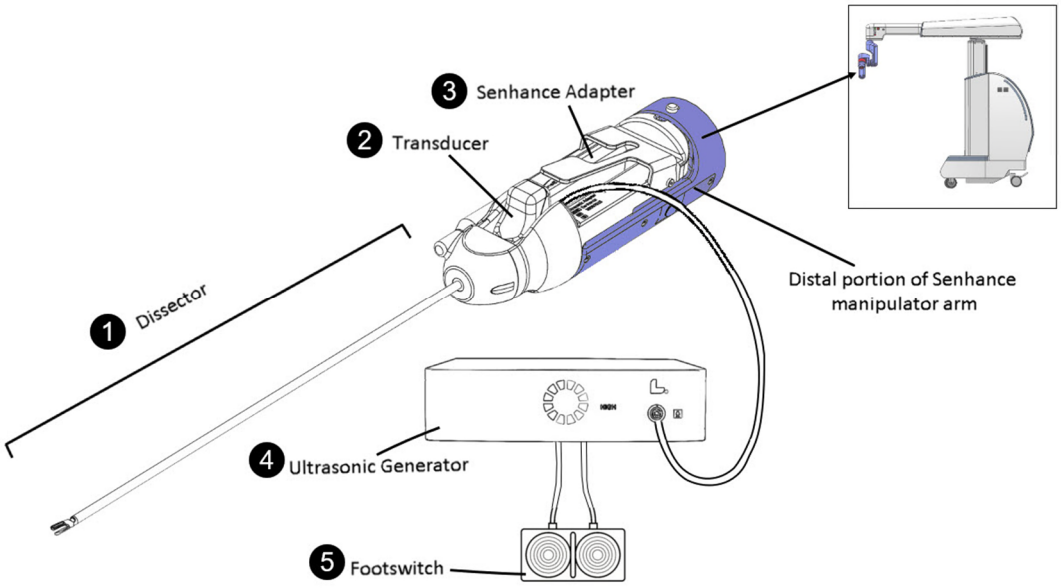

Figure 1: The Senhance Ultrasonic System Components

V. Intended Use/ Indications for Use:

The Senhance Ultrasonic System and accessories are indicated for soft tissue surgical incisions when bleeding control and minimal thermal injury are important. The Senhance Ultrasonic Surgical System and accessories are indicated for use with the Senhance Surgical System.

Comparison with Predicate Device Intended Use/ Indications for Use:

The Senhance Ultrasonic System has the same intended use as the predicate Intuitive Surgical 5mm Harmonic ACE Curved Shears as cleared in K112584. The da Vinci Harmonic ACE Curved Shears are intended for soft tissue incisions when bleeding control and minimal thermal injury are desired. It is designed to be used in conjunction with the da Vinci Surgical Systems (Models IS1200, IS2000 and IS3000) and a compatible Ethicon Endo-Surgery Generator and Handpiece. Thus the intended use (soft tissue incisions when bleeding control and minimal thermal injury are important/desired) is the

same and both systems reference the larger robotically assisted surgical device system with which they are intended to be used.

VI. Summary of Technological Characteristics:

The Senhance™ Ultrasonic System has the same basic technological characteristics as the predicate Intuitive Surgical 5mm Harmonic ACE curved Shears cleared under K112584. Both systems robotically manipulate a variant of a standard manual laparoscopic instrument that delivers ultrasonic energy to the tissue of interest. The Intuitive Surgical predicate adapted the Harmonic ACE manual laparoscopic instrument (K042777) and the Senhance Ultrasonic System is an adaptation of the BOWA Lotus manual laparoscopic system cleared under K151101.

The Senhance Ultrasonic system includes some technological characteristics that differ from the predicate device. The end effector design is different (12mm shear versus 14mm shear for the predicate) and there are different materials of construction. The wavelength of the ultrasonic energy differs between the systems as well as its mode (torsional for Senhance versus linear for Harmonic ACE). See the table below for a description of the technological differences among the subject, predicate and reference device systems.

	Subject Device Senhance Ultrasonic System	**Predicate Device Intuitive Surgical 5mm Harmonic ACE Curved Shears (K112584)**	**Reference Device BOWA Lotus Ultrasonic System 4 (K151101)**
Manipulation Method	Robotic	Robotic	Manual
Method of Activation	Footswitch – not integrated to robotic system	Footpedal – integrated to robotic system	Footswitch or handpiece buttons
End Effector Design	12mm Curved Shear	14mm Curved Shear	12mm Curved Shear
End Effector packaging and Sterility	Single Use Disposable (EO Sterilization) SAL 10^{-6}	Single Use Disposable (EO Sterilization) SAL 10^{-6}	Single Use Disposable (EO Sterilization) SAL 10^{-6}
End Effector Dimensions	Shaft Diameter: 5.5mm Shaft Length: 349mm	Shaft Diameter: 5.5mm Shaft Length: 360mm	Shaft Diameter: 5.5mm Shaft Length: 340mm
Ultrasonic Mode	Torsional	Linear	Torsional
Ultrasonic Wavelength	35 to 37 kHz	55.5 kHz	35 to 37 kHz
Generator	Rebranded Lotus Series 4 generator	Ethicon Harmonic ACE generator	Lotus Series 4 generator

Performance testing demonstrated that the technological differences between the Senhance System and the predicate device did not raise any different questions of safety or effectiveness. The end effectors are both made of biocompatible materials that are either effectively provided sterile to the end user or can be effectively cleaned and sterilized by the end user. Both systems effectively create soft tissue incisions with effective hemostasis and minimal thermal damage to adjacent tissues.

VII. Performance Data

The following performance testing of the Senhance Ultrasonic System was conducted to support the substantial equivalence of the device.

Biocompatibility testing: The biocompatibility evaluation for the Senhance Ultrasonic System relied on testing for the manual reference device and newly performed testing. All patient contacting devices were 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," as recognized by FDA. The dissector and transducer are considered tissue contacting for a limited duration of less than 24 hours for contact with tissue or bone.

Cleaning, Disinfection (Reprocessing) and Sterilization Validation: The reusable transducer and adapter have cleaning instructions that have been validated based on the guidelines outlined in AAMI TIR12:2010 and ANSI/AAMI TIR30:2011. A steam sterilization validation study was conducted in accordance with the FDA's Guidance for Industry and FDA Staff "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling" issued on: March 17, 2015 and the FDA recognized consensus standards ANSI/AAMI/ISO 17665-1:2006/(R) 2013 and ANSI/AAMI/ISO 14937:2009/(R)2013. Both items were validated to a Sterility Assurance Level of 10^{-6} using the Half Cycle Testing validation method.

The disposable dissector is provided sterile to the end user via ethylene oxide sterilant in a fixed rigid chamber (FDA Established Category A). Sterility validation established the Sterility Assurance Level of 10^{-6} per EN ISO 11135-1:2014 with EO and ECH residuals meeting the acceptance criteria per EN ISO 10993-7:2008.

Bench Testing: Bench testing included system integrations of the Ultrasonic System with the Surgical System as well as tests to determine any effects of the adaptation of the instrument to the ultrasonic energy delivered. The following tests confirmed compatibility of the systems and that the ultrasonic energy delivery to tissue is comparable to that provided by the reference system.

- Cantilever bend stiffness characterization
- Force Feedback Response Linearity, Sensitivity and Stability
- Fulcrum Accuracy
- Jaw output force verification
- Mechanical reliability of the dissector
- Thermal spread characterization of end effector and adjacent tissue
- Tissue effects – vessel sealing burst pressure comparison
- Tissue effects – lesion size comparison on soft tissues

As both the reference and predicate have demonstrated safe and effective use for soft tissue dissections, the subject device has demonstrated equivalence with the predicate.

Electrical Safety and Compatibility: The Senhance Ultrasonic System components as well as the Senhance Surgical System comply with current versions of IEC 60601-1 (Basic safety and essential performance), IEC 60601-1-2 (Electromagnetic disturbances), and IEC 60601-2-2 (High frequency surgical equipment). Previous testing and analysis demonstrate electrical safety and electromagnetic compatibility of the Senhance Ultrasonic system in the operating room environment. Although the system does not contain an endoscopic vision system, the effects of the energy delivered on the vision system in use concurrently with the system was evaluated using IEC 60601-2-18 (Endoscopic Equipment). The testing verified that the devices when used concurrently do not cause interference in the vision system signal.

Software Verification and Validation Testing: Software verification and validation were conducted on both the Senhance Surgical System software modification which supported the extension to incorporate the Senhance Ultrasonic System components and also the Senhance Ultrasonic Generator. Documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices". The software was considered as a "major" level of concern

Pre-Clinical Design Validation: Design Validation of the Senhance Ultrasonic system was conducted to ensure that the system conforms to defined user needs and intended uses 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.

Four (4) teams of trained subjects (one surgeon and one surgical assistant per team) performed surgical tasks and procedures on a live porcine model, which most closely represents the human anatomy for the given procedures. The procedures were non-survival and did not include any animal endpoints. Users were divided into two surgical specialties: gynecological and general surgery. Two gynecological teams each performed a bilateral salpingo-oophorectomy, and a hysterectomy. Two general surgical teams each performed a cholecystectomy, dissection of short gastric vessels and a liver wedge resection. All pre-determined acceptance criteria were met.

VIII. Conclusions

The Senhance™ Ultrasonic System has the same intended use as the predicate device. There are technological differences between the subject device and the predicate device, but these raise no different questions of safety or effectiveness. Further, the device is an adaptation of the BOWA Lotus manual laparoscopic system cleared under K151101. The performance testing supported the safety and functionality of the device and demonstrate the device is substantially equivalent to the predicate device.

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)*
K182121

Device Name
Senhance Ultrasonic System

Indications for Use *(Describe)*
The Senhance Ultrasonic System and accessories are indicated for soft tissue surgical incisions when bleeding control and minimal thermal injury are important. The Senhance Ultrasonic System and accessories are indicated for use with the Senhance Surgical System.

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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January 11, 2019

TransEnterix, Inc.
Stephanie Fitts
VP, Clinical, Quality and Regulatory Affairs
635 Davis Drive, Suite 300
Morrisville, North Carolina 27650

Re: K182421
Trade/Device Name: Senhance Ultrasonic System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: NAY
Dated: November 30, 2018
Received: December 4, 2018

Dear Stephanie Fitts:

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