January 22, 2021

Ethicon Endo-Surgery, LLC
% Kweku Biney
Senior Regulatory Affairs Program Lead
Ethicon Endo-Surgery, Inc.
4545 Creek Road
Cincinnati, Ohio 45242

Re: K201696
Trade/Device Name: ENSEAL X1 Tissue Sealer, Straight Jaw, 25 cm Shaft Length, ENSEAL X1 Tissue Sealer, Straight Jaw, 37 cm Shaft Length
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: December 17, 2020
Received: December 21, 2020

Dear Kweku Biney:

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,

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

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)*
K201696

Device Name
ENSEAL® X1 Tissue Sealer, Straight Jaw, 25 cm shaft length; ENSEAL® X1 Tissue Sealer, Straight Jaw, 37 cm shaft length

Indications for Use *(Describe)*

The ENSEAL X1 Tissue Sealers are bipolar electrosurgical instruments for use with an electrosurgical generator. They are intended for use during open or laparoscopic surgical procedures to cut and seal vessels, and to cut, grasp and dissect tissue during surgery.

Indications for use include open and laparoscopic general, gynecological, urologic, thoracic, and ENT surgical procedures or any procedure where vessel ligation (cutting and sealing), tissue grasping, dissection, and division of vessels, lymphatics, and tissue bundles is performed (e.g. bowel resections, hysterectomies, gall bladder procedures, Nissen Fundoplication, adhesiolysis, and oophorectomies). The devices can be used on vessels up to and including 7 mm and bundles as large as will fit in the jaws of the instruments.

The ENSEAL X1 Tissue Sealers have not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures. Do not use this system for these procedures.

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

K201696

Company

Ethicon Endo-Surgery, LLC
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Guaynabo, PR 00969

Contact

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Ethicon Endo-Surgery, Inc.
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Date Prepared

January 21, 2021

Device Name

Trade Name: ENSEAL® X1 Tissue Sealer, Straight Jaw, 25 cm shaft length
ENSEAL® X1 Tissue Sealer, Straight Jaw, 37 cm shaft length

Common Name: Electrosurgical Cutting and Coagulating Instruments

Note: The name ENSEAL X1 Tissue Sealer(s) as used in this submission refers to the straight jaw version of the device on the ENSEAL X1 platform.

Classification Name

- Electrosurgical, Cutting & Coagulation & Accessories (21 CFR 878.4400, Product Code GEI)
- Electrocautery, Gynecologic and Accessories (21 CFR 884.4120, Product Code HGI)

Regulatory Class

Class II

Predicate Device

ENSEAL G2 Tissue Sealers initially cleared under K112033 on November 8, 2011 and last cleared under K131435 on October 3, 2013 as part of the ENSEAL Tissue Sealing Devices

Reference Device

ENSEAL X1 Tissue Sealer cleared under K172580 on November 20, 2017. The K172580 submission included both straight and curved jaw versions of the device.

Device Description

The ENSEAL X1 Tissue Sealer instrument is a sterile, single patient use surgical instrument to coagulate and transect vessels up to and including 7mm in diameter, tissue and/or vascular bundles. This device is for soft tissue only. The instrument consists of a grip housing assembly, a rotating shaft, a moveable jaw, and a knife. The instrument shaft can be rotated 360˚ to facilitate visualization and enable easy access to targeted tissue. The jaws are in a normally-opened position and can be partially or fully closed by squeezing the closing handle. The jaws are designed for grasping and holding targeted tissue when clamped. The ENSEAL X1 Tissue Sealer has separate seal and cut capabilities. The lower jaw of the ENSEAL X1 Tissue Sealer can be used in the open or closed position to deliver energy based on the electrode configuration and jaw design. Bipolar energy is delivered when the SEAL button or the MIN foot pedal is pressed. Pressing the CUT button advances the knife the length of the jaws to cut the targeted tissue. The power cord is permanently attached to the device and connects the instrument to the generator. The ENSEAL X1 Tissue Sealer instrument is designed for use exclusively with the Ethicon Generator G11 (GEN11) software version 2016-1 or later, packaged separately.

Indications for Use

The ENSEAL X1 Tissue Sealers are bipolar electrosurgical instruments for use with an electrosurgical generator. They are intended for use during open or laparoscopic surgical procedures to cut and seal vessels, and to cut, grasp and dissect tissue during surgery.

Indications for use include open and laparoscopic general, gynecological, urologic, thoracic, and ENT surgical procedures or any procedure where vessel ligation (cutting and sealing), tissue grasping, dissection, and division of vessels, lymphatics, and tissue bundles is performed (e.g. bowel resections, hysterectomies, gall bladder procedures, Nissen Fundoplication, adhesiolysis, and oophorectomies). The devices can be used on vessels up to and including 7 mm and bundles as large as will fit in the jaws of the instruments.

The ENSEAL X1 Tissue Sealers have not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures. Do not use this system for these procedures.

Technological Characteristics

The ENSEAL® X1 Tissue Sealers are the same as the predicate device in that they are electrosurgical bipolar vessel sealing instruments used to cut and seal vessels, grasp and dissect tissues during surgery, and utilize the same technology. Differences with the device as compared to the predicate device within this submission include separate energy and cut button, ergonomic differences, jaws configuration (different patient contact materials), steps for use and separate seal and cut functionality (Table 1-1).

Performance Data

Bench testing and laboratory evaluations in an animal model including acute and 30-day chronic

survival studies were conducted to demonstrate that the ENSEAL® X1 Tissue Sealer performs as intended.

Biocompatibility testing

The biocompatibility of materials used in the ENSEAL X1 Tissue Sealers was evaluated based on ISO 10993-1: "Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing" and on FDA guidance "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.

Electromagnetic Compatibility and Electrical Safety

Electrical safety and EMC testing were conducted on the ENSEAL X1 Tissue Sealers; the system complies with IEC 60601-1-2 for electromagnetic compatibility and IEC 60601-1 and IEC 60601-2-2 for electrical safety.

Sterilization/Shelf-Life

The ENSEAL X1 Tissue Sealers were validated to achieve a sterility assurance level of 10^{-6} using Ethylene Oxide per ISO 11135. The designated shelf-life for the ENSEAL X1 Tissue Sealers is 5-years.

Mechanical Testing

The following mechanical testing were carried out to verify that the ENSEAL X1 Tissue Sealers performed as expected:

- Axial Jaw Retention Strength
- Compression System Stress Test
- Hinge Pin Weld Strength

The results of the mechanical testing demonstrated the ability of the ENSEAL X1 Tissue Sealers to perform as expected and risks associated with mechanical failures is minimized.

Bench Testing

Sealed vessel burst pressure test was evaluated for the ENSEAL X1 Tissue Sealers to support substantial equivalence to the predicate device. The bench testing involved evaluation of the devices performance and ability to seal and divide vessels up to 7 mm. Porcine arteries were used in this testing. The left and right burst values, standard deviation and the mean were recorded. Data generated from the bench testing met the predetermined acceptance criteria.

Acute Animal Testing

Testing was performed in an acute porcine study with the ENSEAL X1 Tissue Sealers versus the predicate device to investigate differences in the tissue effects when using the subject device and the predicate device. Moreover, the acute testing involved evaluation of the devices performance and ability to seal and divide vessels up to and including 7 mm. The acute testing was performed in four animals for each device targeting arteries, veins and vessel pedicles less than or equal to 7mm in diameter. The results of the acute study demonstrated the ability of the ENSEAL X1 Tissue Sealers to perform as well as the legally identified predicate device.

Chronic/ Survival Animal Testing

Testing was performed in a chronic survival study with the ENSEAL X1 Tissue Sealer versus the predicate device to investigate differences in the tissue effects between the subject device and the predicate device. Moreover, the survival testing involved evaluation of the devices performance and ability to seal and divide vessels up to and including 7 mm. The 30 (±2) day survival testing was performed in ten animals for each device targeting arteries, veins and vessel pedicles less than or equal to 7mm in diameter. The results of the survival study demonstrated the ability of the ENSEAL X1 Tissue Sealers to perform as well as the historical performance of the legally identified predicate device.

Clinical Testing

This premarket notification does not rely on human clinical trial data to demonstrate substantial equivalence.

Conclusion

The results of the bench and pre-clinical animal testing performed demonstrate that the ENSEAL X1 Tissue Sealer is substantially equivalent to the identified predicate device.

Table 1-1: Technological Characteristics Table

Characteristics/ specification	**ENSEAL X1 Tissue Sealer (K201696)**	**ENSEAL G2 Curved Jaw Tissue Sealer (Predicate device, K131435)**
Sterility Method	Ethylene Oxide Sterilization	Gamma Irradiation (Co^{60})
Sterility Assurance Level (SAL)	10^{-6}	Same
Patient Use	Single Use	Same
Radiofrequency (RF) Max Power	120 Watts	45 Watts
RF Max Voltage	90 Vrms	85 Vrms
RF Max Current	3 Amps	1.4 Amps
RF Electrosurgical Output	Bipolar, no neutral electrode	Same
Shaft Diameter	5.5 mm	Same
Jaw Types	Straight	Curved
Jaw Length	Straight: 21 mm	Curved: 19 mm
Jaw Width	Straight: 5 mm	Curved: 3 mm
Shaft Lengths	25 & 37 cm	14, 25, 35 & 45 cm
Jaw compression mechanism	Compression is provided by closing the handle	Compression is provided as the I-BLADE is advanced
Packaging	Rigid blister and Tyvek	Same
Energy Activation Method	Foot or Hand Switch	Same
Vessel Seal Performance	240 mmHg Burst Pressure	Same
Maximum Indicated Vessel Size	7 mm	Same
Handle Type	Ergonomic ‘Squeeze’ Grip	Same
Handle Type / Latch function	Latch at full closure	No latch at full closure