November 20, 2017

Ethicon Endo-Surgery, LLC
% Ryoji Sakai
Manager Regulatory Affairs
Ethicon Endo-Surgery, Inc.
4545 Creek Road
Cincinnati, Ohio 45242

Re: K172580
   Trade/Device Name: ENSEAL X1 Tissue Sealers
   Regulation Number: 21 CFR 878.4400
   Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
   Regulatory Class: Class II
   Product Code: GEI, HGI
   Dated: August 25, 2017
   Received: August 28, 2017

Dear Ryoji Sakai:

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. 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); good
manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);
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 the CDRH's
Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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

K172580

Device Name
ENCEAL X1 Tissue Sealers

Indications for Use (Describe)
The ENCEAL 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, plastic and reconstructive, 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 ENCEAL 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)

- [x] 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

Company  Ethicon Endo-Surgery, LLC
          475 Calle C
          Guaynabo, PR 00969

Contact  Ryoji Sakai
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          Ethicon Endo-Surgery, Inc.
          Telephone: (513) 337-8586
          Email: rsakai3@its.jnj.com

Date Prepared  August 25, 2017

Device Name
Trade Name: ENSEAL® X1 Tissue Sealers
Common Name: Electrosurgical Cutting and Coagulating Instruments

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 Devices
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 Devices
ENSEAL X1 Large Jaw Tissue Sealer cleared under K160554 on September 9, 2016 and K163548 on February 14, 2017

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 7 mm 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 ENSEAL X1 Tissue Sealer has a curved jaw and a straight jaw configuration. 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, plastic and reconstructive, 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 devices 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.

**Performance Data**

Bench testing and laboratory evaluations were conducted to demonstrate that the ENSEAL X1 Tissue Sealers performed as intended.

**Biocompatibility Testing**


**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 1-year.

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

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

The results of the mechanical testing demonstrated the ability of the ENSEAL X1 Tissue Sealers to perform as well as the legally identified predicate device.

**Bench Testing**
Sealed vessel burst test were 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 maximum and minimum 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 vs. the predicate device to demonstrate that there was no difference 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 two 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.

**Survival Animal Testing**
Testing was performed in a chronic survival study with the ENSEAL X1 Tissue Sealers vs. the predicate device to demonstrate that there was no difference in the tissue effects when using 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-day survival testing was performed in five 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 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 animal testing performed demonstrate that the ENSEAL X1 Tissue Sealers are substantially equivalent to the identified predicate device.