May 23, 2018

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

Re: K180403

Trade/Device Name: ENSEAL X1 Tissue Sealer, Curved Jaw Articulating, 37 cm and 45 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, HGI
Dated: April 20, 2018
Received: April 23, 2018

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. 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

510(k) Number (if known)

K180403

Device Name
ENSEAL X1 Tissue Sealer, Curved Jaw Articulating

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, 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.

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

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

Contact
Kweku Biney
Sr. Regulatory Affairs Program Lead
Ethicon Endo-Surgery, Inc.
Telephone: (513) 337-3135
Email: kbiney@its.jnj.com

Date Prepared
February 9, 2018

Device Name
Trade Name: ENSEAL® X1 Tissue Sealer, Curved Jaw Articulating
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 Device
ENSEAL® G2 Tissue Sealers initially cleared under K112033 and K131435 on November 8, 2011 and October 3, 2013 respectively as part of the ENSEAL Tissue Sealing Devices platform.

Recall Information
Ethicon Endo-Surgery, LLC initiated a voluntary recall for the predicate device ENSEAL G2 Tissue Sealers on February 9, 2012 and November 26, 2012. Both recalls have been addressed and are officially closed.

Reference Device
ENSEAL® X1 Tissue Sealers cleared under K172580 on November 20, 2017.

Device Description
The ENSEAL X1 Tissue Sealer, Curved Jaw Articulating 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 instrument
shaft, normally in the straight position, can be articulated using the articulation wheel to gain additional access to tissue and facilitate additional angles across tissue and/or vascular bundles. 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, Curved Jaw Articulating has separate seal and cut capabilities. The lower jaw of the ENSEAL X1 Tissue Sealer, Curved Jaw Articulating 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, Curved Jaw Articulating 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 Sealer, Curved Jaw Articulating 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 the articulation feature, separate energy and cut button, ergonomic differences, jaws configuration, steps for use and separate seal and cut functionality.

**Performance Data**

The following performance data, were provided in support of the substantial equivalence determination.
Biocompatibility testing
Biocompatibility testing was not repeated for the subject device, testing data from the referenced device, K172580 was leveraged for the subject device since both devices share the same materials. Testing on reference device was 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.

Electrical Safety and Electromagnetic Compatibility
Electrical safety and EMC testing were conducted on ENSEAL X1 Tissue Sealer, Curved Jaw Articulating; 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 Sealer, Curved Jaw Articulating were validated to achieve a sterility assurance level of 10^-6 using Ethylene Oxide per ISO 11135. The designated shelf-life for ENSEAL X1 Tissue Sealer, Curved Jaw Articulating is 1-year.

Mechanical Testing
The following mechanical testing were conducted to verify that the ENSEAL X1 Tissue Sealer, Curved Jaw Articulating can perform under worst case scenarios:

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

Shaft Equivalence: To demonstrate equivalence between 37 cm and 45 cm shaft lengths, both lengths were tested for tip compression, jaw gap and impedance. Testing concludes that both shafts are equivalent.

The results of the mechanical testing demonstrated the ability of the ENSEAL X1 Tissue Sealer, Curved Jaw Articulating to perform as well as the predicate device.

Bench Testing
Sealed vessel burst pressure test were evaluated for the ENSEAL X1 Tissue Sealer, Curved Jaw Articulating to support substantial equivalence to the predicate device. The bench testing involved evaluation of the device 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 Study
Testing was performed in an acute porcine study with the ENSEAL X1 Tissue Sealer, Curved Jaw Articulating vs. the predicate device to demonstrate that there was no difference in the tissue effects when using the subject device versus 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 results of the acute study demonstrated the ability of ENSEAL X1 Tissue Sealer, Curved Jaw Articulating to perform as well as the predicate device.
**Survival Animal Study**

Testing was performed in a chronic survival study with the ENSEAL X1 Tissue Sealers, Curved Jaw Articulating versus the predicate device to demonstrate that there was no difference in the tissue effects when using the subject device and the predicate device. The survival testing involved evaluation of the performance and ability of the device to seal and divide vessels up to and including 7 mm. The 30-day survival testing was performed 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 Sealer, Curved Jaw Articulating to perform as well as the legally identified predicate device.

**Conclusion**

The results of the bench and animal testing performed demonstrate that the ENSEAL X1 Tissue Sealer, Curved Jaw Articulating are substantially equivalent to the identified predicate device.