DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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February 14, 2017

Ethicon Endo-Surgery, LLC
Mr. David Locke
Senior Regulatory Affairs Specialist
4545 Creek Rd.
Cincinnati, Ohio 45242

Re: K163548
Trade/Device Name: ENSEAL X1 Large Jaw Tissue Sealer
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI, HGI, LFL
Dated: January 27, 2017
Received: January 30, 2017

Dear Mr. Locke:

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 Part 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 Parts 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jennifer R. Stevenson -S

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K163548

Device Name
EnSeal X1Large Jaw Tissue Sealer

Indications for Use *(Describe)*
Enseal® X1 Large Jaw Tissue Sealer
The Enseal® X1 Large Jaw Tissue Sealer instrument is a dedicated bipolar electrosurgical instrument intended for use in open surgical procedures where ligation and division of vessels is desired. It is a bipolar instrument for use with the Ethicon Generator G11 (GEN11). It is intended for use during open surgery to cut and seal vessels, cut, grasp, and dissect tissue during surgery. Indications for use include open general, gynecologic, urologic, thoracic, and vascular procedures. These procedures include hysterectomies, colectomies, Nissen fundoplication, adhesiolysis, oophorectomies, etc. The devices can be used on vessels (arteries, veins, pulmonary vasculature, lymphatics) up to and including 7 mm and tissue bundles.

The Enseal® X1 Curved Large Jaw instrument has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures. Do not use this system for these procedures.
The efficacy of the Enseal® X1 Curved Large Jaw instrument for the indication of contraceptive tubal coagulation (permanent female sterilization) has not been evaluated and is unknown. The design of the EnSeal® Tissue Sealing Device is significantly different from bipolar designs that are marketed for the indication of contraceptive tubal coagulation. The design differences may affect the efficacy of the procedure and failure rates may not be comparable.

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

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Date Prepared:	February 14, 2016
Device Common Name:	Electrosurgical Cutting and Coagulation Device and Accessories
Trade Name:	ENSEAL® X1 Large Jaw Tissue Sealer
Classification Name:	Electrosurgical Cutting and Coagulation Devices and Accessories, Gynecologic Electrocautery and Accessories
Device Class:	Class II
Product Code:	GEI, HGI, LFL
Classification Regulation:	21 CFR section 878.4400, 21 CFR 884.4120
Panel:	General and Plastic Surgery, Gynecologic Electrocautery and Accessories
Primary Predicate:	ENSEAL® X1 Large Jaw Tissue Sealer, K160554

Device Description

The Enseal® X1 Large Jaw Tissue Sealer device is a sterile, single patient use surgical instrument used 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 curved 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. Bipolar energy is delivered when the seal button (blue button) or MIN foot pedal is pressed. Pressing the cut button advances the knife the length of the jaws to cut the targeted tissue. It should be noted that this device has independent seal and cut capabilities. The power cord is permanently attached to the device and connects the instrument directly to the Generator 11. The Enseal® X1 Large Jaw Tissue Sealer device is designed for use exclusively with the Ethicon Generator G11 (GEN11) software version 2016-1 or later, packaged separately.

Indications for Use

Enseal® X1 Large Jaw Tissue Sealer

The Enseal® X1 Large Jaw Tissue Sealer instrument is a dedicated bipolar electrosurgical instrument intended for use in open surgical procedures where ligation and division of vessels is desired. It is a bipolar instrument for use with the Ethicon Generator G11 (GEN11). It is intended for use during open surgery to cut and seal vessels, cut, grasp, and dissect tissue during surgery. Indications for use include open general, gynecologic, urologic, thoracic, and vascular procedures. These procedures include hysterectomies, colectomies, Nissen fundoplication, adhesiolysis, oophorectomies, etc. The devices can be used on vessels (arteries, veins, pulmonary vasculature, lymphatics) up to and including 7 mm and tissue bundles.

Contraindications: The Enseal® X1 Curved Large Jaw instrument has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures. Do not use this system for these procedures. The efficacy of the Enseal® X1 Curved Large Jaw instrument for the indication of contraceptive tubal coagulation (permanent female sterilization) has not been evaluated and is unknown. The design of the EnSeal® Tissue Sealing Device is significantly different from bipolar designs that are marketed for the indication of contraceptive tubal coagulation. The design differences may affect the efficacy of the procedure and failure rates may not be comparable.

Technological Characteristics and Differences

The Enseal® X1 Large Jaw Tissue Sealer is the same as the predicate Enseal® X1 Large Jaw Tissue Sealer device in that they are electrosurgical bipolar vessel sealing instruments used to cut and seal vessels, cut, grasp and dissect tissues during surgery, and utilize the same technology and have the exact same intended use and indications for use. The only difference between the subject device and the predicate device is a change in the device EEPROM (Electrically Erasable Programmable Read-Only Memory) parameters such that it allows for slightly reduced sealing times on tissue. The subject Enseal® X1 Large Jaw Tissue Sealer Device only uses the Generator 11 (GEN11) as its power source.

Performance Data

Ex-vivo Bench Testing

Sealed vessel burst test were evaluated for Enseal® X1 Large Jaw Tissue Sealer device 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. The maximum and minimum values, standard deviation and the mean were recorded. Data generated from the bench testing met the predetermined acceptance criteria. Moreover, thermal profile testing was completed and demonstrated equivalence to the predicate device.

Acute Animal (Porcine) Testing
Testing was performed in an acute animal study with the Enseal® X1 Large Jaw Tissue Sealer 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 as well as lymphatics testing. The results of all studies demonstrated the ability of the subject device (NSLX120L) to perform as well as the legally identified predicate device.

Survival Animal (Porcine) Testing
Testing was performed in survival animal studies with the Enseal® X1 Large Jaw Tissue Sealer vs. the predicate device to demonstrate that the tissue effects were not different than 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 results of the study demonstrated the ability of the subject device (NSLX120L) to perform as well as the legally identified predicate device.

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

Biocompatibility
No new issues of biocompatibility are raised with regard to the Enseal® X1 Large Jaw Tissue Sealer device.

Sterilization/Shelf-Life
The Enseal® X1 Large Jaw Tissue Sealer device was validated to achieve a sterility assurance level of 10^{-6} using Ethylene Oxide per ISO 11135. The designated shelf-life for the Enseal® X1 Large Jaw Tissue Sealer at launch is 2 years.

Electrical Safety and Electromagnetic Compatibility (EMC)
Electrical safety and EMC testing were conducted on the Enseal® X1 Large Jaw Tissue Sealer device. The device complies with the IEC 60601-1 standard for electrical safety and the IEC 60601-1-2 standard for electromagnetic compatibility.

Conclusion
The indications for use for the subject device and the predicate device are the same. The modification to the predicate device revealed no issues of safety and effectiveness as demonstrated through design verification and validation studies. The subject Enseal® X1 Large Jaw Tissue Sealer is as safe and effective as the predicate Enseal® X1 Large Jaw Tissue Sealer device.