



Food and Drug Administration
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September 9, 2016

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

Re: K160554

Trade/Device Name: EnSeal X1 Large Jaw Tissue Sealer, Ethicon Generator 11
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: August 2, 2016
Received: August 3, 2016

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,


Christopher J. Ronk -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

Indications for Use

510(k) Number (if known)

K160554

Device Name

EnSeal X1 Large Jaw Tissue Sealer

Ethicon Generator 11

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.

Ethicon Generator 11:

The Generator G11 provides radiofrequency power to drive Enseal electrosurgical instruments that are used during open or laparoscopic general and gynecological surgery to cut and seal vessels and to cut, grasp, and dissect tissues. In addition, the generator provides power to drive Harmonic ultrasonic surgical instruments that are indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. Enseal and Harmonic instruments when used with the Generator G11 have not been shown to be effective for sterilization procedures or tubal coagulation. Do not use these instruments 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**

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Date Prepared: September 9, 2016

Device Common Name: Electrosurgical Cutting and Coagulation Device and Accessories
Electrosurgical & Ultrasonic Surgical Generator

Trade Name: Enseal[®] X1 Large Jaw Tissue Sealer
Generator 11

Classification Name: Electrosurgical Cutting and Coagulation Devices and Accessories,
Gynecologic Electrocautery and Accessories
(Enseal[®] X1 Large Jaw Tissue Sealer)
Electrosurgical Cutting and Coagulation Devices and Accessories,
Gynecologic Electrocautery and Accessories; Instrument,
Ultrasonic Surgical
(Generator 11)

Device Class: Class II (Enseal[®] X1 Large Jaw Tissue Sealer)
Class II (Generator 11)

Product Code: GEI, HGI (Enseal[®] X1 Large Jaw Tissue Sealer)
GEI, HGI, LFL (Generator 11)

Classification Regulation: 21 CFR section 878.4400, 21 CFR 884.4120
(Enseal[®] X1 Large Jaw Tissue Sealer)
21 CFR 878.4400, 21 CFR 884.4120 & Unclassified (LFL)
(Generator 11)

Panel: General and Plastic Surgery, Gynecologic Electrocautery and
Accessories

Primary Predicate: Predicate - Ligasure Impact Curved, Large Jaw, Open
Sealer/Divider, K123444

Additional Predicates: Predicate - Ethicon Endo-Surgery Generator 11, K141122
Predicate - Generator 11 Footswitch, K141122
Predicate - Generator 11 Cart, K141122
Predicate - Harmonic and Enseal Connectors, K141122

Device Description

The Enseal[®] X1 Large Jaw Tissue Sealer instrument 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 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 to the generator.

The device system has three essential components: the generator, the footswitch and the subject device. The Generator 11 supplies energy to the Enseal[®] electrosurgical instruments and Harmonic[®] ultrasonic surgical instruments. The generator utilizes a touchscreen display interface and has a receptacle port that accepts either Enseal[®] or Harmonic[®] devices. Connectors (one for Enseal[®] and one for Harmonic[®] devices) are used to enable the generator to power currently cleared surgical instruments. The Generator 11 hardware has not changed since the predicate device was cleared under K101990. The Enseal[®] X1 Large Jaw Tissue Sealer instrument is designed for use exclusively with the Ethicon Generator G11 (GEN11) software version 2016-1 or later, which has been updated to increase the maximum Power output to 200W.

Indications for UseEnseal[®] 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.

Generator 11

The Generator 11 provides radiofrequency power to drive Enseal electro-surgical instruments that are used during open or laparoscopic general and gynecological surgery to cut and seal vessels and to cut, grasp and dissect tissues. In addition, the generator provides power to drive Harmonic ultrasonic surgical instruments that are indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. Enseal and Harmonic instruments when used with the Generator 11 have not been shown to be effective for sterilization procedures or tubal coagulation. Do not use these instruments for these procedures

Technological Characteristics and Differences

The Enseal[®] X1 Large Jaw Tissue Sealer is the same as the predicate devices in that they are electro-surgical bipolar vessel sealing instruments used to cut and seal vessels, cut, 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 energy and cut button location, ability to fully rotate the shaft, force to fire, ergonomic differences, shaft configuration and overall shaft length, and both devices use different generators to power the devices. The subject Enseal[®] X1 Large Jaw Tissue Sealer Device only uses the Generator 11 (GEN11) as its power source, and the device utilizes software version 2016-1 or later to enable a maximum power output of 200W.

Performance Data

Bench testing and laboratory evaluations were conducted to demonstrate that the Enseal[®] X1 Large Jaw Tissue Sealer performed as intended.

Sterilization

Both the subject and predicate devices are sterilized via ethylene oxide as a sterilization method and both devices are sterilized to the same sterility assurance level.

Biocompatibility

The biocompatibility evaluation for the Enseal[®] X1 Large Jaw Tissue Sealer device was conducted in accordance with the following standards: ISO 10993:2009, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process and FDA Blue Book Memorandum #G95-1: Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing". The device passed the following tests:

- ISO Cytotoxicity
- ISO Sensitization
- ISO Intracutaneous Reactivity
- ISO Acute System Toxicity

EMC

Electrical safety and EMC testing were conducted on the Enseal[®] X1 Large Jaw Tissue Sealer device; the system complies with IEC 60601-1-2:2007 for electromagnetic compatibility and IEC 60601-1:2005 and IEC 60601-2-2:2009 for electrical safety.

Bench

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 for the aforementioned tests. Data generated from the bench testing met the predetermined acceptance criteria.

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. The results of the study 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.

Conclusion

The indications for use for the subject device and the predicate device are similar. The results of the bench testing and laboratory evaluations in an animal model demonstrate that the Enseal[®] X1 Large Jaw Tissue Sealer device is as safe and effective and performs as well as the identified legally marketed predicate device for cutting and coagulating soft tissue and sealing vessels up to 7 mm in diameter, as measured *in situ*. Moreover, applicable software verification and validation testing was completed per FDA Guidance for industry and staff “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices” and “General Principles of Software Validation; Final Guidance for Industry and FDA Staff.”