April 13, 2023

Ethicon Endo-Surgery, LLC
Ekta Patel
Senior Regulatory Affairs Program Lead
475 Calle C
Guaynabo, PR 00969

Re: K230387
Trade/Device Name: ENSEAL X1 Curved Tissue Sealers, 25 cm shaft length (NSLX125C); ENSEAL X1 Curved Tissue Sealers, 37 cm shaft length (NSLX137C); ENSEAL X1 Curved Tissue Sealers, 45 cm shaft ength (NSLX137C); ENSEAL X1 Straight Tissue Sealers, 25 cm shaft length (NSLX125S); ENSEAL X1 Straight Tissue Sealers, 37 cm shaft length (NSLX137S)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: February 13, 2023
Received: February 14, 2023

Dear Ekta Patel:

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,

Mark Trumbore -S

Digitally signed by Mark Trumbore -S
Date: 2023.04.13 13:04:03 -04'00'

Mark Trumbore, 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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K230387

Device Name

ENSEAL X1 Curved Tissue Sealers, 25 cm shaft length (NSLX125C);
ENSEAL X1 Curved Tissue Sealers, 37 cm shaft length (NSLX137C);
ENSEAL X1 Curved Tissue Sealers, 45 cm shaft ength (NSLX137C);
ENSEAL X1 Straight Tissue Sealers, 25 cm shaft length (NSLX125S);
ENSEAL X1 Straight Tissue Sealers, 37 cm shaft length (NSLX137S)

Indications for Use *(Describe)*

The ENSEAL X1 Curved Jaw and ENSEAL X1 Straight Jaw Tissue Sealers are bipolar electrosurgical instruments for use with an electrosurgical generator. They are indicated for use during open or laparoscopic surgery.

Indications for use include open and laparoscopic general surgical procedures (including bowel resections, gynecology, gastric, urologic and thoracic surgical procedures) where vessel ligation (sealing and cutting), division of lymphatics, tissue grasping and dissection is performed. The devices can be used on vessels and vascular bundles up to and including 7 mm in diameter.

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.

510(k) Summary

I. SUBMITTER

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

Contact: Ekta Patel
Senior Regulatory Affairs Program Lead
Ethicon Endo-Surgery, Inc.
Phone: 513-337-1124
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Date Prepared: February 13, 2023

II. SUBJECT DEVICES

Trade Name:

- ENSEAL™ X1 Curved Jaw Tissue Sealers
- ENSEAL™ X1 Straight Jaw Tissue Sealers

Common or Usual Name: Electrosurgical, Cutting & Coagulation Instrument
Classification Name: Electrosurgical, Cutting & Coagulation & Accessories
Gynecologic Electrocautery and Accessories
Classification Number: 21 CFR 878.4400, 21 CFR 884.4120
Regulatory Class: II
Product Code: GEI, HGI

III. PREDICATE DEVICES

Predicate Device 510(k) Number	Predicate Device Name	Predicate Device Product Codes
K201066	ENSEAL™ X1 Curved Jaw Tissue Sealers	NSLX125C, NSLX137C, NSLX145C
K201696	ENSEAL™ X1 Straight Jaw Tissue Sealers	NSLX125S, NSLX137S

These predicates have not been subjected to a recall related to these design modifications.

There is no change in the technological characteristics between the Subject devices (ENSEAL™ X1 Curved and Straight Jaw Tissue Sealers) and the Predicate devices (Curved Jaw Tissue Sealers-K201066 and Straight Jaw Tissue Sealers-K201696) which were cleared separately on 01/22/2021 and 12/21/2020.

Table 5-1: Cleared Accessories

Product Code	Device Full Name	510(k) Number
GEN11	Generator G11	K160554
FSW11	Generator G11 Footswitch	K101990

IV. DEVICE DESCRIPTION

The ENSEAL™ X1 Curved and Straight Jaw Tissue Sealers are intended to cut and seal vessels, and to cut, grasp, and dissect tissue during surgery.

The ENSEAL™ X1 Curved and Straight Jaw Tissue Sealers are sterile, single-patient-use surgical instruments used to coagulate and transect vessels up to and including 7 mm in diameter, tissue, and/or vascular bundles. These devices are 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 Curved and Straight JawTissue Sealers have separate seal and cut capabilities. The lower jaw of the ENSEAL™ X1 Curved and Straight Jaw Tissue Sealers 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 Curved and Straight Jaw Tissue Sealer instruments are designed for use exclusively with the Ethicon Generator G11(GEN11), software version 2016-1 or later, or other compatible Ethicon generators. Refer to the Ethicon Generator Operator's Manual for more information.

V. INDICATIONS FOR USE

The ENSEAL™ X1 Curved Jaw and ENSEAL™ X1 Straight Jaw Tissue Sealers are bipolar electrosurgical instruments for use with an electrosurgical generator. They are indicated for use during open or laparoscopic surgery.

Indications for use include open and laparoscopic general surgical procedures (including bowel resections, gynecology, gastric, urologic and thoracic surgical procedures) where vessel ligation (sealing and cutting), division of lymphatics, tissue grasping and dissection is performed. The devices can be used on vessels and vascular bundles up to and including 7 mm in diameter.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Technological Characteristics

The ENSEAL™ X1 Curved and Straight Jaw Tissue Sealers (Subject devices) have the same technological characteristics (i.e., design, material, principle of operations, energy sources etc.) as the predicate devices; ENSEAL® X1 Curved Jaw Tissue Sealers (K201066) and ENSEAL® X1 Straight Jaw Tissue Sealers (K201696). Both the subject and predicate devices are intended to cut and seal vessels, and to cut, grasp, and dissect tissue during surgery.
Similarities and differences with the subject devices compared to the predicate devices cleared under K201066 and K201696 are listed below.

The subject and predicate sealers have the following identical technological characteristics:

- Intended use
- Contraindications
- Materials
- Operational principles
- Sterilization Method
- Packaging
- Shelf-Life

The following differences exist between the subject and predicate sealers:

- Indication for Use

VII. PERFORMANCE DATA:

Bench Performance data was not included as part of this premarket notification. There is no change in the technological characteristics between the subject device ENSEAL™ X1 Curved and Straight Jaw Tissue Sealers and cleared predicates; Curved Jaw Tissue Sealer (K201066) and Straight Jaw Tissue Sealer (K201696).

Animal Testing

An acute animal study was conducted that evaluated the performance of ENSEAL X1 Curved and Straight Jaw Tissue Sealers in gastric procedures.

VIII. CONCLUSION

The testing criteria demonstrates that the subject devices; ENSEAL X1 Curved and Straight Jaw Tissue Sealers perform substantially equivalent to the predicate devices and does not raise new questions of safety and effectiveness.