510(k) Summary of Safety and Effectiveness

Company Ethicon Endo-Surgery, LLC
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Contact c/o Marcia Arentz, MBA, MS, RAC, CQA
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OCT 0 3 2013

Date: Sep 26, 2013

Device Name: Trade Name: ENSEAL® Tissue Sealing Devices
Common Name: Electrosurgical Cutting and Coagulation Instruments

Classification Names:
Electrosurgical, Cutting & Coagulation & Accessories (21CFR878.4400, Product Code GEI)
Electrocautery, Gynecologic and Accessories (21 CFR 884.4120, Product Code HGI)

Classification: Class II

Predicate Devices:

K113572:	LigaSure™ Curved Small Jaw, Open Sealer/Divider LF1212
K072177:	ENSEAL® Round Tip Tissue Sealing Devices
K072493:	ENSEAL® Round Tip Tissue Sealing Device (45 cm shaft length)
K123141:	ENSEAL® Trio Tissue Sealing Device
K112033:	ENSEAL® G2 Tissue Sealers

Device Description:
The Ethicon Endo-Surgery ENSEAL® Tissue Sealers are sterile, biopolar electrosurgical instruments for single patient use. They are designed to seal and cut vessels, and to cut, grasp and dissect soft tissue during open and laparoscopic surgery. The instrument shaft can be rotated using the rotation knob to facilitate visualization and enable easy access to targeted tissue. The power cord is permanently attached to the device and connects the instrument to the generator. The devices are offered in different shaft lengths with curved or straight blade geometries to accommodate the needs of the surgeon.

Intended Use Statement:

The ENSEAL® 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® 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.

The subject ENSEAL® devices are the same ENSEAL® tissue sealing devices that were cleared in prior 510(k) submissions. The intended use remains the same; to cut and seal vessels and to cut, grasp and dissect tissue during surgery. This submission is to support the addition of a specific indication, the use of the devices in ENT surgical procedures, to the indications for use statement for the ENSEAL® devices. The use of ENSEAL® devices in ENT procedures is supported by demonstration of substantial equivalence to the legally marketed predicate device that was cleared previously for use in ENT procedures.

The differences in the wording of the indications for use statements between the subject and predicate devices are grammatical and do not alter the intended use of these surgical devices to cut and seal vessels and to cut, grasp and dissect tissue during surgery.

Technological Characteristics:

The predicate and subject devices all use bipolar electrosurgical technology to seal vessels and are provided sterile, for single patient use. The subject ENSEAL®devices for which the specific ENT indication was evaluated are identical in their patient contacting materials and use the same energy source (generator) as the previously cleared predicate ENSEAL® devices. There was one minor change to the activation button in the ENSEAL® G2 Tissue Curved and Straight Sealing devices but this change does not affect hemostasis or thermal spread.

Performance Data:

Bench testing comparing the vessel sealing capability of the predicate (LigaSure Small Jaw device with ENT indication) and subject device (ENSEAL® tissue sealing device) demonstrated equivalent performance. Preclinical laboratory evaluations of ENT surgical

procedures in an animal model, including comparative acute studies to evaluate hemostasis and thermal spread, demonstrated that the ENSEAL® Tissue Sealing devices perform equivalently or better than the predicate device. Data from a successful 30-day chronic survival study was submitted in support of the use of ENSEAL® tissue sealing devices for use in ENT procedures. No clinical studies were required to support a finding of substantial equivalence.

Conclusion:

The results of the bench testing and preclinical testing demonstrate that the ENSEAL®Tissue Sealing devices are as safe and as effective as the predicate devices in cutting and sealing vessels in ENT surgical procedures, and cutting, grasping and dissecting tissue during surgery. The subject and predicate devices demonstrate similar thermal spread profiles. The results from testing support the substantial equivalence of the ENSEAL® Tissue Sealing devices to the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

October 3, 2013

Ethicon Endo-Surgery, Incorporated
c/o Ms. Marcia Arentz, MBA, MS, RAC, CQA
Regulatory Affairs Portfolio Leader
4545 Creek Road
Cincinnati, Ohio 45242

Re: K131435
Trade/Device Name: EnSeal Tissue Sealing Devices
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: September 25, 2013
Received: September 30, 2013

Dear Ms. Arentz:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Mark N. Melkerson -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131435

Device Name: EnSeal Tissue Sealing Devices

Indications for Use (revised):

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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).

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Long H. Chen -A — Digitally signed by Long H. Chen -A
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Long H. Chen -A, 0.9.2342.19200300.100.1.1=1300369016
Date: 2013.10.03 07:33:59 -04'00'

For MXM

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K131435