

510(k) Summary

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

MAR 8 2013

Contact Liping Wu, MD, PhD, RAC
Regulatory Affairs Associate II
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Date Prepared March 5, 2013

Device Name

Trade Name:
Ethicon Endo- Surgery ENSEAL G2 Cordless Curved Jaw Tissue Sealer
Common Name: Electrosurgical Cutting and Coagulating Instrument

Classification Names

- Electrosurgical, Cutting & Coagulation & Accessories (21 CFR 878.4400, Product Code PDG)
- Electrocautery, Gynecologic and Accessories (21 CFR 884.4120, Product Code HGI)

Predicate Devices

ENSEAL Vessel Sealing and Hemostasis System cleared under K072177 on August 29, 2007 and K072493 cleared on September 5, 2007. The ENSEAL Vessel Sealing and Hemostasis System include ENSEAL Bipolar Electrosurgical Sealing Devices and an Electrosurgical Generator.

Device Description:

The Ethicon Endo-Surgery ENSEAL G2 Cordless Curved Jaw Tissue Sealer is a sterile, single patient use, self-contained, disposable RF electrosurgical instrument. The cordless hand-held device is powered by a Lithium Ion Polymer (LiPo) battery with an RF (radiofrequency) generator integrated into the device handle and does not require connection to an external generator or power source. The integrated generator provides the required RF energy to seal vessels during a surgical procedure. The battery is a DC power source that is charged during manufacturing; the battery cannot be removed from the device, or be recharged by the user. The device is configured with 3mm curved jaw and is intended to cut, grasp and dissect soft tissue, and coagulate and transect vessels up to and including 7mm in diameter.

Indications for Use:

The EES ENSEAL G2 Cordless Curved Jaw Tissue Sealers are intended for use during open or laparoscopic, general and gynecological surgery to cut and seal vessels, cut, grasp and dissect tissue during surgery.

Indications for use include open and laparoscopic general, gynecological surgical procedures (including urologic, thoracic, plastic and reconstructive, bowel resections, hysterectomies, cholecystectomies, gall bladder procedures, Nissen fundoplication, adhesiolysis, oophorectomies, etc.), or any procedure where vessel ligation (cutting and sealing), tissue grasping and dissection are performed. The devices can be used on vessels up to (and including) 7mm and bundles as large as will fit in the jaws of the instruments.

The devices 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 Ethicon Endo-Surgery ENSEAL G2 Cordless Curved Jaw Tissue Sealers are configured with curved jaws and are intended to coagulate and transect vessels. The instrument consists of a grip housing assembly, a rotating shaft, and a moveable jaw with an I-blade™ knife in the tip. The devices will be available in 14cm, 35cm and 45cm shaft length options, and the instruments can be rotated 360° to facilitate visualization and enable easy access to targeted tissue. The jaw is curved in a normally opened position and can be partially or fully closed by squeezing the Closing Handle. The jaw has teeth for grasping and holding targeted tissue when clamped. Bipolar energy is delivered to the clamped tissue when the Energy Activation Button is pressed. Full activation of the Closing Handle advances the I-blade™ the length of the jaws, and the targeted tissue is compressed, coagulated, and transected. The I-blade™ knife cannot be advanced to transect tissue without fully pressing the Energy Activation Button.

Comparison of Technological Characteristics

| Technological Characteristic | Predicate Devices (K072177 and K072493) | Subject Device ENSEAL G2 Cordless Curved Tissue Sealer |
|------------------------------|---|--|
| Energy type | Bipolar | Bipolar |
| Jaw shape | Curved 3 mm | Curved 3mm |
| Shaft lengths | 14 cm, 35 cm, 45 cm | 14 cm, 35 cm, 45 cm |
| Shaft diameter | 5 mm | 5 mm |
| I-blade | Yes | Yes |
| PTC technology | Yes | Yes |
| Energy Source | Generator | Battery |
| Function | Cut and seal vessels, cut, grasp and dissect tissue | Cut and seal vessels, cut, grasp and dissect tissue |

Performance Data:

Bench testing and laboratory evaluations in an animal model were conducted to demonstrate that the Ethicon Endo-Surgery ENSEAL G2 Cordless Curved Jaw Tissue Sealers perform as intended.

Biocompatibility studies, electrical safety studies, software validation, vessel burst pressure testing and animal acute and survival studies were performed comparing the predicate device to the subject device to support the determination of substantial equivalence. Clearance was not based on human clinical studies.

Conclusions

Based on performance testing and functional similarities to the predicate devices, the Ethicon Endo-Surgery ENSEAL G2 Cordless Curved Jaw Tissue Sealer devices are substantially equivalent to the predicate devices.



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Liping Wu, MD, PhD, RAC
Regulatory Affairs Associate II
4545 Creek Road
Cincinnati, Ohio 45242

March 8, 2013

Re: K123212

Trade/Device Name: Ethicon Endo Surgery ENSEAL G2 Cordless Curved Jaw Tissue Sealers

Regulation Number: 21 CFR 878.4400

Regulation Name: Electrosurgical cutting and coagulation device and accessories

Regulatory Class: II

Product Code: PDG, HGI

Dated: February 11, 2013

Received: February 13, 2013

Dear Liping Wu:

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 go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 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, For

Peter D. Rumm -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): K123212

Device Name: Ethicon Endo Surgery **ENSEAL G2 Cordless Curved Jaw Tissue Sealers**

Indications for Use:

The Ethicon Endo Surgery ENSEAL® G2 Cordless Curved Jaw Tissue Sealers are intended for use during open or laparoscopic, general and gynecological surgery to cut and seal vessels, cut, grasp and dissect tissue during surgery.

Indications for use include open and laparoscopic general, gynecological surgical procedures (including urologic, thoracic, plastic and reconstructive, bowel resections, hysterectomies, cholecystectomies, gall bladder procedures, Nissen fundoplication, adhesiolysis, oophorectomies, etc.), or any procedure where vessel ligation (cutting and sealing), tissue grasping and dissection are performed. The devices can be used on vessels up to (and including) 7mm and bundles as large as will fit in the jaws of the instruments.

The device has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures. Do not use this system for these procedures.

Prescription Use X
(Part 21 CFR 801 Subpart D)

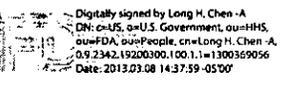
AND/OR

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



for MXM

(Division Sign-Off)
Division of Surgical Devices
510(k) Number K123212