K101520

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510(k) SUMMARY

DEC 10 2010

Company Ethicon Endo-Surgery, Inc
4545 Creek Road
Cincinnati, OH 45242

Contact Ruth Ann Wood
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Date Prepared May 28, 2010

Device Name

- Trade Name: Ethicon Endo-Surgery EnSeal LCJ Tissue Sealer
- Common or Usual Name: Electrosurgical open instruments and accessories
- Classification name: Electrosurgical Cutting and Coagulation Device and Accessories (per 21 CFR section 878.4400) and Gynecologic Electrocautery and Accessories (per 21 CFR 884.4120).

Predicate Devices

SurgRx EnSeal Tissue Sealers, K072177

Device Description

The Ethicon Endo-Surgery EnSeal LCJ Tissue Sealer is a sterile, single patient use device. The functionality is the same as the predicate devices.

Intended Use

The EnSeal LCJ Tissue Sealing Device is indicated for bipolar coagulation and mechanical transection of tissue during open procedures.

It is a bipolar electrosurgical instrument for use with an electrosurgical generator. It is intended for use during open, general and gynecological surgery to cut and seal vessels, cut, grasp and dissect tissue during surgery.

Indications for use include open, 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 is performed. 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 Sealing 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.

Technological Characteristics

The Ethicon Endo-Surgery EnSeal LCJ Tissue Sealer is the same as the predicate devices 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. Differences with the device in this submission are improved ergonomic handle, larger shaft, jaw diameter, and jaw length/shape.

Performance Data

Bench and animal testing was performed to ensure the devices function as intended and meet design specifications.

Conclusions

Based on performance testing and functional similarities to the predicate devices, the Ethicon Endo-Surgery EnSeal LCJ Tissue Sealer devices are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Ethicon Endo-Surgery, Inc.
% Ms. Ruth Ann Wood
4545 Creek Road ML#132
Cincinnati, Ohio 45242

DEC 10 2010

Re: K101520
Trade/Device Name: Ethicon Endo-Surgery EnSeal® LCJ Tissue Sealer
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI, HGI
Dated: December 2, 2010
Received: December 3, 2010

Dear Ms. Wood:

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" (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
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement DEC 10 2010

510(k) number (if known): K101520

Device Name: Ethicon Endo-Surgery EnSeal® LCJ Tissue Sealer

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Prescription Use__X__ (Per 21 CFR 801 Subpart D	AND/OR	Over-The-Counter Use_____ (Per 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)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K101520