SEP 15 2009

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510(k) Summary

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

Contact Abhilasha Mukherjee, RAC
Regulatory Affairs Associate II
Ethicon Endo-Surgery, Inc.
Telephone: (513) 337-3623
Fax: (513) 337-2584
Email: AMukher5@its.jnj.com

Date Prepared August 19, 2009

Device Name Trade Name: Ethicon Endo-Surgery Linear Cutter and Selectable Cartridges
Common or Usual Name: Cutter/Stapler and Cartridges
Classification Name: Staple, Implantable

Predicate Device Proximate Linear Cutter with Safety Lock-Out and Cartridges (cleared under K020779)

Device Description The Ethicon Endo-Surgery Linear Cutter is a sterile, single patient use instrument used in open surgical procedures. The instrument delivers six staggered rows of staples, three on either side of the cut line. The instrument is shipped without a cartridge loaded into the instrument. The cartridge must be loaded as a separate step prior to use. The instrument has a safety lock-out feature that is designed to prevent an instrument without a cartridge or a used cartridge from being fired.

Each Ethicon Endo-Surgery Selectable Cartridge contains six staggered rows of staples and an integrated knife located in the safety housing. The selectable staple height feature provides the ability to use one cartridge for compressed tissue with thicknesses of 1.5mm, 1.8mm or 2.0mm. The staple retaining cap on the cartridge protects the staples during shipping and transportation.

Indications for Use The Ethicon Endo-Surgery Linear Cutter and Selectable Cartridges has application in gastrointestinal, gynecologic, thoracic, and pediatric surgery for transection, resection, and the creation of anastomoses and can be used with staple line or tissue buttressing materials.

Technological Characteristics The Ethicon Endo-Surgery Linear Cutter and Selectable Cartridge incorporates a new selectable staple height feature, which enables the surgeon to use one cartridge for compressed tissue with thicknesses of 1.5mm, 1.8mm or 2.0mm. This ability eliminates the need for multiple cartridges (a blue cartridge for compressed tissue with a thickness of 1.5mm, a gold cartridge for compressed tissue with a thickness of 1.8mm and a green cartridge for compressed tissue with a thickness of 2.0mm), which is required when using the predicate device. The cartridge contains six staggered rows of staples with an integrated knife located in the safety housing.

Performance Data Bench testing and preclinical laboratory evaluation in an animal model was performed to demonstrate that the new devices will perform as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

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Ethicon Endo-Surgery, LLC
% Ethicon Endo-Surgery, Inc.
Ms. Abhilasha Mukherjee, RAC
4545 Creek Road
Cincinnati, Ohio 45242

Re: K092577
Trade Name: Ethicon Endo-Surgery Linear Cutter and Selectable Cartridges
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Product Code: GDW, GAG
Dated: August 19, 2009
Received: August 21, 2009

Dear Ms. Mukherjee:

This letter corrects our substantially equivalent letter dated September 15, 2009

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.

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.

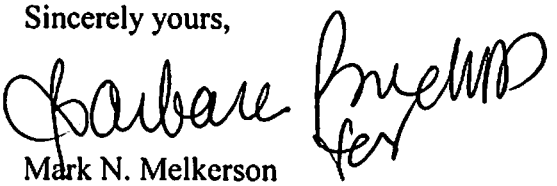
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



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

Enclosure

K092577

Indications for Use

510(k) Number (if known): _____

Device Name: **Ethicon Endo-Surgery Linear Cutter and Selectable Cartridges**

Indications for Use:

The Ethicon Endo-Surgery Linear Cutter and Selectable Cartridges has application in gastrointestinal, gynecologic, thoracic, and pediatric surgery for transection, resection, and the creation of anastomoses and can be used with staple line or tissue buttressing materials.

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)

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

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(Posted November 13, 2003)