K110049
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510(k) Summary

FEB 10 2011

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

Contact: Dennis Hahn, RAC
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Date Prepared: January 6, 2011

Device Name: Reusable Linear Stapler and Disposable Reload
Common or Usual Name: Linear Stapler and Reload
Classification Name: Staple, Implantable

Predicate Device: PROXIMATE® Reloadable Linear Stapler and Reload (cleared under K020779)

Device Description: The Reusable Linear Stapler and Disposable Reload is a surgical stapling device used throughout the alimentary tract an in thoracic surgery for transection and resection of internal tissues. The device delivers two staggered rows of titanium alloy staples in a 40 mm staple line to approximate internal tissues. Staple height is adjustable to compensate for tissue thicknesses from 1.5 mm to 2.5 mm. The device consists of two components: the Reusable Linear Stapler Handle (ADLH) and the disposable Linear Stapler Reload (ADL40R).

Indications for Use: The Reusable Linear Stapler and Disposable Reload has application throughout the alimentary tract and in thoracic surgery for transection and resection of internal tissues

Contraindications:

- Do not use on the heart, aorta, coronary, carotid or pulmonary arteries or veins, the superior or inferior vena cava, common internal or external iliac arteries or veins, or the brachiocephalic trunk.
- Do not use the ADLH (and corresponding reload ADL40R) on tissue with a thickness that requires an instrument setting of less than 1.5 mm or greater than 2.5 mm.
- Do not use the instruments on ischemic or necrotic tissue.
- Do not use the instruments on solid organs, such as liver or spleen, where attempted compression would be destructive.
- Do not use when surgical stapling is contraindicated.

Technological Characteristics: The Reusable Linear Stapler and Disposable Reload consists of two components: the reusable handle and the disposable reload. The handle can be used for 200 applications. The reload, which is designed for a single use, is made up of two staggered rows of staples with a length of 40 mm. The staple height can be adjusted to accommodate a compressed tissue thickness of 1.5 mm to 2.5 mm. A spent reload indicator warns when the reload must be discarded.

Performance Data: Bench testing was conducted to demonstrate and verify the performance of the disposable reload and the reusable handle after 200 simulated uses. Test results demonstrated the bench testing acceptance criteria were met.

Animal (tissue) testing was conducted to evaluate the pressure tolerance of an anastomotic stoma created in porcine colon. Testing results demonstrated that staple lines created by the linear stapler device met the leak pressure acceptance criteria.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Ethicon Endo-Surgery, LLC
% Ethicon Endo-Surgery, Inc.
Mr. Dennis Hahn, RAC
Director, Regulatory Strategic Initiatives
4545 Creek Road
Cincinnati, Ohio 45242

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Re: K110049
Trade/Device Name: Reusable Linear Stapler and Reload
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: II
Product Code: GDW
Dated: January 6, 2011
Received: January 7, 2011

Dear Mr. Hahn:

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

510(k) Number (if known): K110049

Device Name: **Reusable Linear Stapler and Reload**

Indications for Use:

The Reusable Linear Stapler and Disposable Reload has application throughout the alimentary tract and in thoracic surgery for transection and resection of internal tissues.

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)

David Krause for MKM

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

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