JUN - 8 2011

Section 5: 510(k) Summary

The following information is provided as required by 21 CFR § 807.87 for ENDOPATH ETS 35mm Endoscopic Linear Cutter and Reloads, and ETS-Flex 35mm Endoscopic Articulating Linear Cutter and Reloads 510(k) premarket notification. In response to the Safe Medical Devices Act of 1990, the following is a summary of the safety and effectiveness information upon which the substantial equivalence determination is based.

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

Contact: Linda Hill
Portfolio Leader, Regulatory Affairs
Ethicon Endo-Surgery, Inc.
4545 Creek Road
Cincinnati, OH 45242
Ph: 513-337-7623
Fax: 513-337-2623
E-mail: LHill3@its.jnj.com

Date of Submission: April 18, 2011

Proprietary Name: ENDOPATH ETS 35mm Endoscopic Linear Cutter and Reloads, and ETS-Flex 35mm Endoscopic Articulating Linear Cutter and Reloads

Common Name: Staple, Implantable

Regulatory Class: 21 CFR 878.4750

Product Code: GDW

Predicate Device(s): K961390 35mm ENDOPATH® ETS Endoscopic Linear Cutter and ETS-Flex Endoscopic Articulating Linear Cutter, K020779 35mm ENDOPATH® ETS Endoscopic Linear Cutter and ETS-Flex Endoscopic Articulating Linear Cutter, K070887 ENDOPATH® and Echelon Linear Cutters, Staplers and Reloads

Device Description: The ENDOPATH ETS 35mm Endoscopic Linear Cutter and Reloads, and ETS-Flex 35mm Endoscopic Articulating Linear Cutter and Reloads deliver triple staggered rows of staples while simultaneously dividing the tissue between the rows. The instrument's safety lock-out feature is designed to prevent a spent reload from being refired. The instruments deliver

a staple line that is approximately 35mm long. A staple retaining cap on the reload protects the staple leg points during shipping and transportation.

Intended Use: ENDOPATH ETS 35mm Endoscopic Linear Cutter and Reloads, and ETS-Flex 35mm Endoscopic Articulating Linear Cutter and Reloads have application in general, gynecologic, urologic, and thoracic surgery for transection, resection, and/or creation of anastomoses. The instruments may also be used for transection and resection of liver parenchyma (hepatic vasculature and biliary structures), pancreas, kidney and spleen.

Technological Characteristics: Both the subject and the predicate instruments have a staple line that is approximately 35 mm long and a cut line that is approximately 32 mm long. The instruments are loaded with either a standard, blue reload or a vascular/thin, white reload. ETS 35mm reloads are interchangeable across all 35mm ETS and ETS-Flex instrument codes. The replacement of the plastic sled with the proposed metal sled does not change the mechanical functions or principles of operations of the ENDOPATH ETS Endoscopic Linear Cutter and ETS-Flex Endoscopic Articulating Linear Cutter and Reloads. The new metal sled increases the force to bypass, reducing the likelihood of wedge band bypass failure. The metal sled is stiffer than the plastic part that it replaces and has a higher yield and ultimate strength, thereby reducing the potential for shearing or bypass during firing.

Performance Testing: Bench and simulated use testing, including reliability testing, force to fire and force to failure testing, functional testing, and fragility testing confirm that the subject device performs as intended and is substantially equivalent to the predicate devices.

Clinical Testing: Clinical testing was not performed in support of this submission.

Conclusion: The purpose of this 510(k) is to describe proposed changes in the ENDOPATH ETS 35mm Endoscopic Linear Cutter and Reloads, and ETS-Flex 35mm Endoscopic Articulating Linear Cutter and Reloads product line. The devices are modified from the plastic cartridge sled to a metal cartridge sled with minor dimensional changes. There are no changes to the indications or intended use of the devices. Bench testing confirms that the subject device performs as intended and that the safety or effectiveness of the ENDOPATH ETS 35mm Endoscopic Linear

Cutter and Reloads, and ETS-Flex 35mm Endoscopic Articulating Linear Cutter and Reloads is substantially equivalent to that of the predicates.

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, LLC
% Ethicon Endo-Surgery, Inc
Ms. Linda Hill
4545 Creek Road
Cincinnati, Ohio 45242

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Re: K111111
Trade/Device Name: ENDOPATH ETS 35mm Endoscopic Linear Cutter and Reloads,
ETS-Flex 35mm Endoscopic Articulating Linear Cutter and Reloads
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: II
Product Code: GDW, GAG
Dated: April 18, 2011
Received: April 20, 2011

Dear Ms. Hill:

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): K111111

Device Name: ENDOPATH ETS 35mm Endoscopic Linear Cutter and Reloads, and ETS-Flex 35mm Endoscopic Articulating Linear Cutter and Reloads

Indications For Use

Indications for Use: ENDOPATH ETS 35mm Endoscopic Linear Cutter and Reloads, and ETS-Flex 35mm Endoscopic Articulating Linear Cutter and Reloads have application in general, gynecologic, urologic, and thoracic surgery for transection, resection, and/or creation of anastomoses. The instruments may also be used for transection and resection of liver parenchyma (hepatic vasculature and biliary structures), pancreas, kidney and spleen.

Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 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 K111111