DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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May 18, 2015

Ethicon Endo-Surgery, LLC
Ms. Christina Canter
Senior Associate, Regulatory Affairs
4545 Creek Road
Cincinnati, Ohio 45242

Re: K150026
Trade/Device Name: Endopath® ETS-Flex45 Endoscopic Articulating Linear Cutter
Endopath® ETS-Flex45 No-Knife Articulating Linear Stapler
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: Class II
Product Code: GDW
Dated: April 16, 2015
Received: April 17, 2015

Dear Ms. Canter:

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 contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150026

Device Name
Endopath® ETS-Flex45 Endoscopic Articulating Linear Cutter
Endopath® ETS-Flex45 No-Knife Articulating Linear Stapler

Indications for Use *(Describe)*
The Endopath ETS-Flex45 Endoscopic Articulating Linear Cutter, ETS-Flex45 No-Knife Articulating Linear Stapler and reloads are intended for transection, resection, and/or creation of anastomoses. The instruments have application in multiple open or minimally invasive general, gynecologic, urologic, thoracic, and pediatric surgical procedures. They can be used with staple line buttressing material. The instrument may also be used for transection and resection of liver parenchyma (hepatic vasculature and biliary structures), pancreas, kidney and spleen.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Company: Ethicon Endo-Surgery, LLC
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Date Prepared: January 06, 2015

Device Name
Trade Name**:** Endopath® ETS-Flex45 Endoscopic Articulating Linear Cutter and Endopath® ETS-Flex45 No-Knife Articulating Linear Stapler
Common Name: Surgical Stapler

Classification Name: Staple, Implantable

Regulation Number: 21CFR 878.4750

Product Code: GDW

Marketed Predicate Device
Endopath® ETS-Flex45 Endoscopic Articulating Linear Cutter and
Endopath® ETS- Flex45 No-Knife Articulating Linear Stapler
(K070887, K061156, K020079, K002398, K961390)

Device Description
The Endopath® ETS-Flex45 Endoscopic Articulating Linear Cutter is a sterile, single patient use instrument that delivers staples while simultaneously dividing tissue between rows. The instruments provide a staple line that is approximately 45 mm long and a cut line that is approximately 41 mm long. An articulation lever on the device enables bilateral movement of the instrument jaws.

The Endopath® ETS-Flex45 No-Knife Articulating Linear Stapler is a sterile, single patient use instrument that delivers staples but does not divide tissue. The instruments provide a staple line that is approximately 45 mm long. An articulation lever on the device enables bilateral movement of the instrument jaws.

Indications for Use

The Endopath ETS-Flex45 Endoscopic Articulating Linear Cutter, ETS-Flex45 No-Knife Articulating Linear Stapler and reloads are intended for transection, resection, and/or creation of anastomoses. The instruments have application in multiple open or minimally invasive general, gynecologic, urologic, thoracic, and pediatric surgical procedures. They can be used with staple line buttressing material. The instrument may also be used for transection and resection of liver parenchyma (hepatic vasculature and biliary structures), pancreas, kidney and spleen.

Technological Characteristics

The subject devices are modifications of the legally marketed predicate devices. The primary design change is the addition of a reload 'lock-out' feature to prevent the device from being fired when a reload is improperly loaded or if no reload is placed into the device. The changes described in this submission do not affect the intended use of the devices or alter fundamental scientific technology of the devices.

Performance Data

Bench testing including staple form quality and staple height, staple line integrity, force to close, compatibility with buttress material, lock out reliability and lockout withstand force were performed to confirm that the subject devices perform as intended and are substantially equivalent to the predicate devices.