



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

Ethicon Endo-Surgery, Inc.
Mr. Edwin O. Billips
Senior Associate, Regulatory Affairs
4545 Creek Road
Cincinnati, OH 45242-2839

JUL 27 2015

Re: K002398
Trade/Device Name: Endopath ETS45 Endoscopic Linear cutters; Flex 45
Endoscopic Articulating Linear cutters; ETS Compact-Flex 45
Articulating Linear cutter; ETS Flex 45 No-Knife Articulating
Linear staplers, and ETS Compact-Flex 45 No-Knife
Articulating Linear staplers
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: OCW
Dated (Date on orig SE ltr): August 3, 2000
Received (Date on orig SE ltr): August 7, 2000

Dear Mr. Billips,

This letter corrects our substantially equivalent letter of November 3, 2000.

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 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>. 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,


Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K002398

Page ____ of ____

510(k) Number (if known): K002398Device Name: ENDOPATH® ETS45 Linear Cutters, Staplers and Reloads Product Family

Indications For Use:

The ENDOPATH® ETS45 Endoscopic Linear Cutters, the ETS-Flex45 Endoscopic Articulating Linear Cutters, and the ETS Compact- Flex45 Articulating Linear Cutter are intended for transection, resection, and/or creation of anastomoses. The instruments have application in multiple open or minimally invasive general, gynecologic, urologic (including radical prostatectomy), thoracic, and pediatric surgical procedures. They can be used with staple line or tissue buttressing material such as bovine pericardium.

The ENDOPATH® ETS Flex45 No-Knife Articulating Linear Staplers and ETS Compact-Flex45 No-Knife Articulating Linear Staplers are intended for transection, resection, and/or creation of anastomoses. The instruments have application in multiple open or minimally invasive general, gynecologic, urologic (including radical prostatectomy), thoracic, and pediatric procedures. They can be used with staple line or tissue buttressing material such as bovine pericardium.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N. Melhorn
(Division Sign-Off)

Division of General Restorative Devices

510(k) Number

K002398

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)

NOV - 3 2000

Ethicon Endo-Surgery, Inc
ENDOPATH® ETS45 Linear Cutters, Staplers, and Reloads**Section L****510(k) Summary of Safety and Effectiveness (2 copies)****Company:**

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

Contact:

Edwin O. Billips
Senior Regulatory Associate
Telephone: 513- 337-7162
Fax: 513- 337-7134

Date Prepared:

August 3, 2000

Modified Devices:

ENDOPATH® ETS45 Linear Cutters, Linear Staplers and Reloads

Marketed Devices:

ENDOPATH® ETS45 Linear Cutters, Linear Staplers and Reloads

Device Description:

The ENDOPATH® ETS45 Linear Cutters, Linear Staplers and Reloads are sterile, single patient use instruments that deliver two or three double-staggered rows of staples.

Indication For Use:

The ENDOPATH® ETS45 Endoscopic Linear Cutters, the ETS-Flex45 Endoscopic Articulating Linear Cutters, and the ETS Compact- Flex45 Articulating Linear Cutter are intended for transection, resection, and/or creation of anastomoses. The instruments have application in multiple open or minimally invasive general, gynecologic, urologic (including radical prostatectomy), thoracic, and pediatric surgical procedures. They can be used with staple line or tissue buttressing material such as bovine pericardium.

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pediatric procedures. They can be used with staple line or tissue buttressing material such as bovine pericardium.

Technological characteristics:

The technological characteristics of the modified devices are the similar to the marketed products. The modified devices are linear cutters/staplers that are used for transection, resection, and/or creation of anastomoses.

Performance Data:

Preclinical testing was performed to ensure that the devices performed as intended. Testing demonstrated satisfactory performance in transection, resection, and/or creation of anastomoses. The modified device will provide increased clamping force when the anvil and channel (which holds the cartridge) is clamped down across tissue, resulting in more consistent staple formation.

Conclusion:

Based on 21CFR § 807, we conclude that the modified products are as safe and effective as the marketed devices.