K102632

510(k) Summary

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

Contact Renee Rowe
Staff QS/RA Project Manager
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OCT - 7 2010

Date Prepared: September 10, 2010

New Device Name:

Trade Name: Ethicon Endo-Surgery® 5mm Laparoscopic Multi-feed Stapler
Common or Usual Name: Surgical Stapler with Implantable Staples
Classification Name: Implantable staple (21 CFR 878.4750, Product Code GDW
Endoscope and Accessories, (21 CFR 876.1500, Product Code GCJ

Predicate Device:

Ethicon, Inc. ENDOPATH Disposable Endoscopic Multifeed (EMS) Stapler (K913469)

Device Description The Ethicon Endo-Surgery® 5mm Laparoscopic Multi-feed Stapler is a sterile, single patient use instrument designed for use with a 5mm diameter trocar. The device places rectangular titanium staples. The staple opens to a tip to tip width of about 6.1mm (0.240 inches). Closed staple dimensions are approximately 5.5 mm x 6.1 mm (0.215 inches x 0.242 inches). The instrument shaft is 5.5mm (0.218 inches) in diameter and 457mm (18 inches) long and contains about 40 staples.

Indications for Use The Ethicon Endo-Surgery® 5mm Laparoscopic Multi-feed Stapler has application for use in a variety of minimally invasive procedures for approximation of tissue.

Contraindications: This instrument is not intended for use in vascular or neural tissue or in solid organs such as liver or spleen. The staples in this instrument are not hemostatic and therefore should not be used to achieve hemostasis.

Technological Characteristics: Like the predicate, the ENDOPATH Disposable Endoscopic Multifeed (EMS) Stapler, the new Ethicon Endo-Surgery® 5mm Laparoscopic Multi-feed Stapler is a sterile single patient use instrument. The new device is designed for use in a 5mm diameter or larger port, while the EMS predicate is compatible with a 10/11mm port. Like the EMS predicate, the new device utilizes a titanium box staple and a pistol grip handle with a single trigger configuration. The

staple of the EMS predicate device is formed and released with one activation of the trigger, while staples in the new device requires two activations - one to advance and open the staple, and a second to form the staple and release it. The shaft of the new device is 18 inches (457mm) long and contains about 40 staples, while the shaft of the predicate is 375mm long and contains 15-30 staples. The new and the predicate device both offer a 360° shaft rotation feature.

A comprehensive assessment of the Ethicon Endo-Surgery® 5mm Laparoscopic Multi-feed Stapler versus the predicate device indicates the new features do not raise any new issues relating to safety and effectiveness.

Performance Data: Design and development were predicated on use of technology currently used in Ethicon Endo-Surgery manual stapler devices. Bench testing and preclinical laboratory evaluations were performed to demonstrate that the device performs as intended. Device materials have been evaluated for biocompatibility and comply with the requirements of ISO 10993-1. This data indicates the Ethicon Endo-Surgery® 5mm Laparoscopic Multi-feed Stapler is substantially equivalent to the predicate device.

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

OCT 7 2010

Ethicon Endo-Surgery, Inc.
% Ms. Renee Rowe
Staff QS/RA Project Manager
4545 Creek Road
Cincinnati, Ohio 45242

Re: K102632
Trade/Device Name: Ethicon Endo-Surgery® 5mm Laparoscopic Multi-feed Stapler
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: Class II
Product Code: GDW
Dated: September 10, 2010
Received: September 13, 2010

Dear Ms. Rowe:

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,

for

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): K102632

Device Name: **Ethicon Endo-Surgery® 5mm Laparoscopic Multi-feed Stapler**

Indications for Use:

The Ethicon Endo-Surgery® 5mm Laparoscopic Multi-Feed Stapler has application for use in a variety of minimally invasive procedures for approximation of tissue.

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 Kwan for MXM

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

510(k) Number K102632