510(k) Summary

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

Contact Kimberly McCoy, RAC
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Date Prepared May 18, 2005

Device Name: PROXIMATE® PPH Hemorrhoidal Circular Stapler and accessories
Classification Name: Implantable Staples [21 CFR 878.4750 (GDW)]

Predicate Device PROXIMATE® PPH Hemorrhoidal Circular Stapler and accessories

Device Description The PROXIMATE PPH Hemorrhoidal Circular Stapler (PPH03) is available in a 33mm diameter size only . The instruments allow surgeon to control tissue compression by varying the height of the closed staple. The instrument has been designed for the procedure for prolapse and hemorrhoids (PPH).

Indications for Use The PROXIMATE PPH Hemorrhoidal Circular Stapler and accessories have application throughout the anal canal to perform surgical treatment of hemorrhoidal disease.

Contraindications The following contraindications for PROXIMATE PPH Hemorrhoidal Circular Stapler have been added to the labeling (package insert):

- **Do not use the instrument for full rectal wall resection.**
- **Do not use the instrument for the Stapled Transanal Rectal Resection (STARR) procedure.**

Technological and Performance Characteristics The technological and performance characteristics of the device remain unchanged..

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 3 0 2005

Ms. Kimberly McCoy, RAC
Regulatory Affairs Associate I
Ethicon Endo-Surgery, Inc.
4545 Creek Road
Cincinnati, Ohio 45242

Re: K051301
Trade/Device Name: PROXIMATE® PPH Hemorrhoidal Circular Stapler and Accessories
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: II
Product Code: GDW
Dated: August 8, 2005
Received: August 9, 2005

Dear Ms. McCoy:

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.

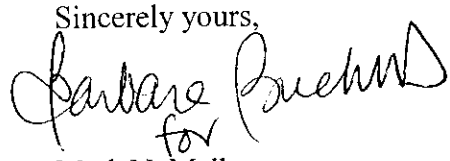
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K051301

Device Name:
PROXIMATE® PPH Hemorrhoidal Circular Stapler and Accessories

Indications for Use:

The PROXIMATE® PPH Hemorrhoidal Circular Stapler and accessories have application throughout the anal canal to perform surgical treatment of hemorrhoidal disease.

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)

(Posted November 13, 2003)

Barbara Buehrd for MKM

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K051301