MAY 15 2003

K030925

PROXIMATE® HCS Hemorrhoidal Circular Stapler and Accessories (PPH01)

510(k) Summary of Safety and Effectiveness

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

Date Prepared:
March 21, 2003

Contact:
Name: Carol Sprinkle
Title: Regulatory Affairs Specialist

Name of Device:
Trade Name: PROXIMATE® HCS Hemorrhoidal Circular Stapler and Accessories
Common Name: Intraluminal Stapler (ILS)
Classification Name: Implantable Staple, General & Plastic Surgery Surgical Device

Predicate Device:
PROXIMATE® HCS Hemorrhoidal Circular Stapler and Accessories (K991030).

Device Description:
The PROXIMATE HCS Hemorrhoidal Circular Stapler and Accessories are a set of instruments that facilitate delivery of a circumferential, staggered, double-row of staples while simultaneously resecting a segment of compressed soft tissue. The set is commonly used in the Procedure for Prolapse and Hemorrhoids (PPH). The set is also used for other applications where circular or semicircular stapling of anorectal tissue is desired.

Indications for Use:
The PROXIMATE® HCS Hemorrhoidal Circular Stapler and Accessories have application for general surgical treatment of anorectal wall defects by means of transanal stapling and resection of mucosal and musculomucosal tissue.

Technological Characteristics:
The PROXIMATE HCS Hemorrhoidal Circular Stapler is identical to the predicate device. The only changes are in the Indications for Use statement and Instructions for Use.

Clinical Evidence:
Published clinical data and other information demonstrate the general utility of the HCS device to staple and resect anorectal tissue in various procedures similar to the previously cleared Indications for Use for surgical treatment of hemorrhoidal disease, thus meeting all the requirements of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 15 2003

Ms. Carol Sprinkle
Regulatory Affairs Specialist
Ethicon Endo-Surgery, Inc.
4545 Creek Road
Cincinnati, Ohio 45242

Re: K030925
Trade/Device Name: PROXIMATE® HCS Hemorrhoidal Circular Stapler and Accessories
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: II
Product Code: GDW
Dated: March 21, 2003
Received: March 24, 2003

Dear Ms. Sprinkle :

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 (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. 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 may be obtained 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,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K030925

Device Name: PROXIMATE® HCS Hemorrhoidal Circular Stapler and Accessories

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Miriam C. Provost

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

510(k) Number K030925

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)