MAY 17

K991030

510(k) Summary of Safety and Effectiveness (App. A)

Contact

Edwin O. Billips, Senior Associate Regulatory Affairs
Ethicon Endo-Surgery, Inc.
4545 Creek Road
Cincinnati, Ohio 45242
Telephone (513) 786-7162
Fax (513) 786-7134

Date

March 26, 1999

Device

Name: Circular Stapler and accessories
Classification Name: Endoscope and Accessories
Common Name: Circular Stapler
Trade Name /Proprietary Name: PROXIMATE® HCS Hemorrhoidal Circular Stapler and accessories

Legally marketed device

PROXIMATE® Curved and Straight Intraluminal Staplers (K983536).

Device description

PROXIMATE® HCS Hemorrhoidal Circular Stapler and accessories is available in a 33 mm diameter size only. The instruments allow the surgeon to control tissue compression by varying the height of the closed staple. The instrument has been designed to facilitate insertion, operation and removal..

Intended use

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

510(k) Summary of Safety and Effectiveness (App. A)

Indications statement	The PROXIMATE® HCS Hemorrhoidal Circular Stapler and Accessories have application throughout the anal canal to perform surgical treatment for hemorrhoidal disease.
Technological characteristics	The PROXIMATE® HCS Hemorrhoidal Circular Stapler and Accessories technological characteristics are identical to those described in the Predicate Device.
Performance data	Pre-clinical laboratory evaluations were performed to ensure that the device can be used as designed. The studies demonstrated acceptable performance to the Predicate Device in pressure holding capability, staple form and height as well as other stapling parameters.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 17 1999

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

Re: K991030
Trade Name: PROXIMATE® HCS Hemorrhoidal Circular Stapler and Accessories
Regulatory Class: II
Product Code: GDW
Dated: March 26, 1999
Received: March 29, 1999

Dear Mr. Billips:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

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

Enclosure

K991030

Indications for Use Statement (App. C)

Statement

Following is the Indications for Use Statement:

510(k) Number: K_____
Device Name: PROXIMATE® HCS Hemorrhoidal Circular Stapler and Accessories

Indications for Use:
The PROXIMATE® HCS Hemorrhoidal Circular Stapler and accessories has application throughout the anal canal to perform surgical treatment of hemorrhoidal disease.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use____
(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K991030