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K983536

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	October 3, 1998
Device	Name: PROXIMATE® Curved and Straight Intraluminal Staplers Classification Name: Endoscope and Accessories Common Name: Circular Stapler Trade Name /Proprietary Name: PROXIMATE® Curved and Straight Intraluminal Staplers
Legally marketed device	Modified ENDOPATH® ILS Circular Stapler (K940967).
Device description	All device functions, scientific concepts, significant physical and performance characteristics (i.e. device design, materials, physical properties, etc.) are identical to the design and manufacture described in 510 (k) #940967.
Intended use	The PROXIMATE® Curved and Straight Intraluminal Staplers have application throughout the alimentary tract for end to end, end to side and side to side anastomoses.

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

Indications statement	The PROXIMATE® Curved and Straight Intraluminal Staplers have application throughout the alimentary tract for end to end, end to side and side to side anastomoses, have application throughout the anal canal to perform surgical treatment for hemorrhoidal disease.
Technological characteristics	The PROXIMATE® Curved and Straight Intraluminal Staplers technological characteristics are identical to those described in 510(k) #940967.
Performance data	The PROXIMATE® Curved and Straight Intraluminal Staplers' performances are identical to that described in 510 (k) #940967.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 18 1998

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

Re: K983536
Trade Name: PROXIMATE® Curved and Straight Intraluminal Staplers
Regulatory Class: II
Product Code: GDW
Dated: October 8, 1998
Received: October 9, 1998

Dear Mr. Billips:

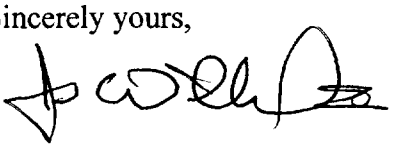
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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

K983536

Indications for Use Statement

Statement

Following is the Indications for Use Statement:

510(k) Number: K 983536
Device Name: PROXIMATE® Curved and Straight Intraluminal Staplers

Indications for Use:
The PROXIMATE® Curved and Straight Intraluminal Staplers have application throughout the alimentary tract for end to end, end to side and side to side anastomoses including application throughout the anal canal to perform surgical treatment for hemorrhoidal disease.

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K983536

Prescription Use X
(Per 21 CFR 801.109)