SEP 27 2002

K021266

510(k) Summary of Safety and Effectiveness Information

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

Contact Ken Charak, MBA, RAC
Manager Regulatory Affairs
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Date Prepared April 18, 2002

Device Name Trade Name: EndoWindow™ High Frequency Electrocautery Device
Classification Name: Electrosurgical Device

Predicate Device Microvasive Gold Probe

Device Description

EndoWindow™ is a sterile, single-use, disposable bipolar device that is intended to cauterize tissue in the esophagus. EndoWindow fits around a flexible endoscope and contains electrodes located distally on the exterior surface of the device. When positioned and activated, the electrodes deliver electrical current to cauterize tissue. Cauterization of tissue manifests as a white coagulum and occurs in full view of the user in the narrow rectangular window located between the electrodes. The inner diameter of EndoWindow is designed to accommodate an endoscope having a maximum diameter of 8.7mm.

Indications for Use

EndoWindow High Frequency Electrocautery Device is indicated for the transendoscopic electrocautery of tissue in the upper gastrointestinal tract such as Barrett's esophagus.

Technological Characteristics

While the basic design of EndoWindow is different than Gold Probe, a comprehensive assessment of the differences versus Gold Probe does not raise any new issues relating to safety and effectiveness.

Performance Data

Laboratory and animal testing was performed to verify performance and safety. A biocompatibility assessment was conducted in accordance with ISO 10993-1 with satisfactory results.

Conclusion

EndoWindow is substantially equivalent to Gold Probe. The information provided in this submission provides assurance that EndoWindow will meet the requirements for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 27 2002

Mr. Ken Charak
Manager of Regulatory Affairs
Ethicon Endo-Surgery, Inc.
4545 Creek Road
CINCINNATI OH 45242-2839

Re: K021266
Trade/Device Name: EndoWindow™ High-Frequency Electrocautery Device
Regulation Number: 21 CFR §876.4300
Regulation Name: Endoscopic electrosurgical unit and accessories
Regulatory Class: II
Product Code: 78 KNS
Dated: July 31, 2002
Received: August 1, 2002

Dear Mr. Charak:

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 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 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 one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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 Part 807.97). 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,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510 (k) Number (if known): K021266

Device Name: EndoWindow™ High Frequency Electrocautery Device

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K021266

(Optional Format 3-10-98)