K051594

SEP - 2 2005

McCartney Access Tube
510(k) Summary of Safety and Effectiveness Information

Company Gynetech Pty. Ltd.
P.O. Box 1227
Subiaco, Western Australia 6904, Australia

Contact Dennis Hahn, RAC
Director, Regulatory Affairs
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Date Prepared August 29, 2005

Device Name Trade Name: McCartney Access Tube
Classification Name: Culdoscope and Accessories

Predicate Device KOH Colpotomizer System (K954311)

Device Description
The McCartney Access Tube is a sterile, single use instrument consisting of a silicone rubber tube, a polypropylene body and a silicone rubber cap. The McCartney Access Tube is available in 35mm and 45mm diameters. The instrument is packaged with a stopcock that can be inserted on the cap in order to insufflate and desufflate the peritoneum along with minimizing gas leakage. The cap has two valves for 5mm and 10mm minimally invasive instrument access. The distal end of the silicone rubber tube is beveled and has a textured surface for internal identification.

Indications for Use
The McCartney Access Tube is intended to be inserted transvaginally to establish a path of entry for minimally invasive instruments and as a template for dissection, while maintaining pneumoperitoneum during laparoscopic hysterectomy. The instrument is indicated for use in laparoscopically assisted vaginal hysterectomies. The instrument is also a conduit for the extraction of specimens.

Contraindications:
The McCartney Access Tube is contraindicated when laparoscopic hysterectomy is contraindicated.

Comparison of Technological Characteristics
The McCartney Access Tube is similar to the predicate device in that it has a similar intended use. The McCartney Access Tube is different from the predicate device in that is a different design and constructed of different materials from the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Gynetech Pty. Ltd.
% Mr. Dennis Hahn, RAC
Director, Regulatory Affairs
Ethicon Endo-Surgery, Inc.
4545 Creek Road
CINCINNATI OH 45242-2839

Re: K051594
Trade/Device Name: McCartney Access Tube
Regulation Number: 21 CFR 884.1640
Regulation Name: Culdoscope and accessories
Regulatory Class: II
Product Code: HEW
Dated: August 15, 2005
Received: August 16, 2005

Dear Mr. Hahn:

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

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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/industry/support/index.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): K051594

Device Name: **McCartney Access Tube**

Indications for Use:

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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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K051594