K033728

FEB 27 2004

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990 and 21 CFR 807.92. All data included in this document is accurate and complete to the best of KSEA's knowledge.

Applicant: Karl Storz Endoscopy - America, Inc.
600 Corporate Pointe Drive
Culver City, CA 90230
310-338-8100

Contact: Yvonne Fernandez
Senior Regulatory Affairs Specialist
310-348-4226

Device Identification: Common Name: Transvaginal Endoscope and Accessories

Indication: The Transvaginal Endoscope (TVE) and Accessories are indicated for use to provide video visual access for endoscopic examination of the vagina, cervix and uterus, and through transvaginal access, allow visualization of both fallopian tubes and the ovaries to perform diagnostic and operative procedures.

Specific Indications for Use

- Unexplained pelvic pain (acute, chronic)
- Menstrual abnormalities;
- Infertility and sterility;
- Indefinite pelvic mass;
- Ectopic pregnancy;
- Pelvic endometriosis;
- Polycystic ovaries;
- Pelvic inflammatory disease (PID);
- Pain mapping;
- Congenital abnormalities of the pelvic organs;
- Lysis of adhesions;
- Cytology mapping;
- Biopsy.

Device Description: The Transvaginal Endoscope Set is comprised of a rigid, panoramic telescope, which utilizes rod lens technology, and several tubular stainless steel components. The body contact portions of the components are manufactured from surgical grade stainless steel, which is commonly used in medical devices for a wide range of applications and has a long history of biocompatibility for human use.

Substantial Equivalence: The Transvaginal Endoscope Set is substantially equivalent to the predicate device since the basic features, design, and intended uses are the same. The minor differences between the Transvaginal Endoscope Set and the predicate device raise no new issues of safety and effectiveness, as these design differences have no affect on the performance, function or intended use of the devices.

Signed: _____
Yvonne Fernandez/Senior Regulatory Affairs Specialist

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 27 2004

Ms. Yvonne Fernandez
Senior Regulatory Affairs Specialist
Karl Storz, Endoscopy-America, Inc.
600 Corporate Pointe, 5th Floor
CULVER CITY CA 90230-7600

Re: K033728
Trade/Device Name: Transvaginal Endoscopy (TVE) Set
Regulation Number: 21 CFR 884.1640
Regulation Name: Culdoscope and accessories
Regulatory Class: II
Product Code: 85 HEW
Dated: November 18, 2003
Received: December 1, 2003

Dear Ms. Fernandez:

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 one of the following numbers, based on the regulation number at the top of the 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" (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,

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

510(k) Number (if known): K033728
Device Name: Transvaginal Endoscopy Set

Indications for Use: The TVE Set is indicated for use by qualified surgeons during outpatient or clinical endoscopic examination of the female genital tract. This examination method is designed to provide video visual access for endoscopic examination of the vagina, cervix and uterus, and through transvaginal access, allow visualization of both fallopian tubes and the ovaries to perform diagnostic and operative procedures. Indications for use are:

- Unexplained pelvic pain (acute, chronic)
- Menstrual abnormalities;
- Infertility and sterility;
- Indefinite pelvic mass;
- Ectopic pregnancy;
- Pelvic endometriosis;
- Polycystic ovaries;
- Pelvic inflammatory disease (PID);
- Pain mapping;
- Congenital abnormalities of the pelvic organs;
- Lysis of adhesions;
- Cytology mapping;
- Biopsy.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 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 K033728