

**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) 558-1500

**Contact:** Kevin Kennan  
Regulatory Affairs Specialist

**Device Identification:** **Common Name:**  
Culdoscope

**Trade Name:** (optional)  
KSEA Culdoscope

**Indication:** The KSEA Rigid Culdoscope and Accessories is intended for use by qualified surgeons for viewing the organs within the peritoneal cavity, via a posterior vaginal fornix entry, using CO<sub>2</sub> gas insufflation. This Culdoscope is not intended for transvaginal hydrolaparoscopy (transflotation). This Culdoscope has the following diagnostic indications:

- Unexplained pelvic pain (acute, chronic)
- Menstrual abnormalities
- Infertility and sterility
- Indefinite pelvic mass
- Ectopic pregnancy
- Pelvic endometriosis
- Polycystic ovaries
- Pelvic inflammatory disease
- Pain mapping
- Congenital anomalies of the pelvic organs

**Device Description:** The KSEA Culdoscope and Accessories are manual reusable surgical devices. The KSEA Culdoscope and Accessories are composed of a Forward-Oblique 30° Telescopes, Culdoscope Sheath and a sharp obturator. The body contact portions of the KSEA Culdoscope and Accessories are composed of 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 KSEA Culdoscope and Accessories is substantially equivalent to the predicate devices since the basic features and intended uses are similar. The minor differences between the Karl Storz Culdoscope and Accessories and the predicate devices raise no new issues of safety and effectiveness, as these differences have no effect on the performance, function or intended use of these devices.

Signed: \_\_\_\_\_

Kevin Kennan  
Senior Regulatory Affairs Specialist



FEB 7 2000

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Kevin Kennan  
Senior Regulatory Affairs Specialist  
Karl Storz Endoscopy – America, Inc.  
600 Corporate Pointe  
Culver City, CA 90230-7600

Re: K993804  
KSEA Rigid Culoscope and Accessories, Series G27  
Dated: November 5, 1999  
Received: November 9, 1999  
Regulatory Class: II  
21 CFR §884.1640/Procode: 85 HEW

Dear Mr. Kennan:

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 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). 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 requirements, 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) 594-4613. 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/dsma/dsmamain.html>".

Sincerely yours,

CAPT Daniel G. Schultz, M.D.  
Acting Director, Division of Reproductive,  
Abdominal, Ear, Nose and Throat,  
and Radiological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known): 993804

Device Name: Rigid Culdoscope and Accessories

Indications for Use: The KSEA Rigid Culdoscope and Accessories is intended for use by qualified surgeons for viewing the organs within the peritoneal cavity, via a posterior vaginal fornix entry, using CO<sub>2</sub> gas insufflation. This Culdoscope is not intended for transvaginal hydrolaparoscopy (transflotation). This Culdoscope has the following diagnostic indications:

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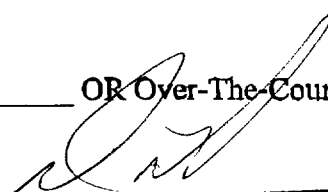
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IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use:  OR Over-The-Counter Use:   
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

  
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(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices  
510(k) Number K993804