

K97 1578

JUL 24 1997

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 are accurate and complete to the best of KSEA's knowledge.

Applicant: Karl Storz Endoscopy - America, Inc.  
600 Corporate Pointe  
Culver City, CA 90230  
(310) 558-1500

Contact: Marlana Allen Piercy, Ph.D.  
Senior Clinical Affairs Specialist

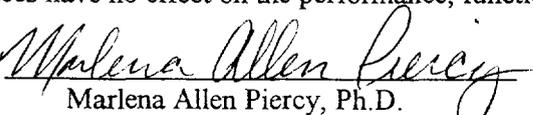
Device Identification: Common Name  
Semi-Rigid Hysteroscope and Accessories

Trade Name  
KSEA Semi-Rigid Hysteroscope  
KSEA Alken Motion Control Device

Indication: The KSEA Semi-Rigid Hysteroscope and Accessories are designed to view the uterus, and, using additional accessories, to perform various diagnostic and therapeutic procedures. The Alken Motion Control Device attaches to an instrument channel to precisely guide the introduction of small instrument into the patient.

Device Description: The KSEA Semi-Rigid Hysteroscope is a straight, graduated shaft endoscope with a remote eyepiece. The Alken Motion Control Device is an attachment to the instrument channel to control the introduction and movement of accessories. All devices are manually operated, reusable surgical devices. Body contact materials are stainless steel (chromium-plated Monel 400®).

Substantial Equivalence: The KSEA Semi-Rigid Hysteroscope and Accessories are substantially equivalent to the predicate devices since the basic features, design, and intended uses are the same or similar. The minor differences in dimensions between the KSEA Semi-Rigid Hysteroscope 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:   
Marlana Allen Piercy, Ph.D.  
Senior Clinical Affairs Specialist



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Marlena Allen Piercy, Ph.D.  
Senior Clinical Affairs Specialist  
Karl Storz Endoscopy-America, Inc.  
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Culver City, California 90230-7600

Re: K971518  
Semi-Rigid Hysteroscope and Alken Motion  
Control Device  
Dated: April 23, 1997  
Received: April 25, 1997  
Regulatory class: II  
21 CFR §884.1690/Product code: 85 HIH

JUL 24 1997

Dear Dr. Piercy:

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) 594-4613. 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/dsmmain.html>.

Sincerely yours,

Lillian Yin, Ph.D.  
Director, Division of Reproductive,  
Abdominal, Ear, Nose and Throat,  
and Radiological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

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Phone 310 558 1500

Toll Free 800 421 0937  
Fax 310 410 5527

510(k) Number (if known): Not yet assigned

Device Name: Semi-Rigid Hysteroscope with Accessories

Indications for Use: The Karl Storz Semi-Rigid Hysteroscope and Accessories are indicated in the following conditions:

Diagnostic

abnormal uterine bleeding      infertility and pregnancy wastage  
intrauterine foreign body      pelvic pain  
monitoring of IUD status  
evaluation of abnormal hysterosalpingogram  
evaluation of abnormalities of the endometrium

Operative

directed biopsy  
transection of intrauterine septa  
transection of intrauterine adhesions

Absolute Contraindications for Use:

acute PID

Relative Contraindications for Use:

inability to distend uterus      cervical/vaginal infection  
uterine bleeding or menses      known pregnancy  
invasive carcinoma of the cervix      recent uterine perforation  
medical contraindication      intolerance to anesthesia  
cervical stenosis

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

Robert A. Sathiyaj  
(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices

(Optional Format 1-2-96)

510(k) Number K971518

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