Karl Storz
Endoscopy-America, Inc.

600 Corporate Pointe
Culver City, California 90230-7600
Phone 310 558 1500

Toll Free 800 421 0837
Fax 310 410 5527

K971977

AUG 12 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: Marlena Allen Piercy, Ph.D.
Senior Clinical Affairs Specialist

Device Identification:: Common Name:
Flexible Choledochoscope and Accessories

Trade Name (optional):
KSEA 15.5 Fr. Flexible Choledocho-Fiberscope and Accessories

Indication: The KSEA 15.5 Fr. Flexible Choledocho-Fiberscope is designed to be used by qualified surgeons and physicians for examination of the gall bladder and bile duct, and, using additional instruments, to perform various diagnostic and therapeutic procedures.

Device Description: The KSEA 15.5 Fr. Flexible Choledocho-Fiberscope is a manually operated surgical device. The Flexible Choledocho-Fiberscope is a flexible fiber-optic telescope which utilizes fiber-optic technology. The body contact portions of the Flexible Choledocho-Fiberscope are composed of medical-grade polyurethane. The Accessories are double-action flexible forceps (grasping and biopsy), which are constructed of surgical-grade stainless steel (AISI series 303 and 304 for the shafts, AISI series 420 for jaws and handles).

Substantial Equivalence: The KSEA 15.5 Fr. Flexible Choledocho-Fiberscope is substantially equivalent to the predicate devices since the basic features, design, and intended uses are the same. The minor differences between the KSEA 15.5 Fr. Flexible Choledocho-Fiberscope and Accessories and the predicates devices raise no new issues of safety and effectiveness, as these design differences have no effect on the performance, function, or intended use of the devices.

Signed: Marlena Allen Piercy
Marlena Allen Piercy, Ph.D.
Senior Clinical Affairs Specialist

000073

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 2 1997

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

Re: K971977
15.5 Fr. Flexible Choledocho-Fiberscope
Dated: May 28, 1997
Received: May 29, 1997
Regulatory class: II
21 CFR §876.1500/Product code: 78 FBN

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 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/dsmamain.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

510(k) Number (if known): ~~Not yet assigned~~. K971977

Device Name: 15.5 Fr. Flexible Choledocho-Fiberscope

Indications for Use:

The 15.5 Fr. Flexible Choledocho-Fiberscope is indicated for examination of the gall bladder and bile duct, and, using additional accessories, to perform diagnostic and therapeutic procedures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, E[illegible]
and Radiological Devices
510(k) Number K971977

Prescription Use: X OR Over-the-Counter Use: _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)