Karl Storz
Endoscopy-America, Inc.

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

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, California 90230
(310) 558-1500

Contact:

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

Device Identification:

Common Name
Irrigation Pump System

Trade Name (optional)
KSEA Hydromat 263110-20, Pressure Chambers and Accessories

Indication: The KSEA Hydromat 263110-20 and Pressure Chambers are indicated for use by qualified surgeons and physicians to provide low-pressure irrigation to the peritoneal cavity and operative sites during laparoscopic and pelviscopic surgical and diagnostic procedures.

Device Description: The KSEA Hydromat 263110-20 is a low-pressure infusion pump designed to deliver sterile irrigating fluid to the operative site. The KSEA Pressure Chambers are metal chambers designed to hold and pressurize bags of irrigation fluid for infusion into the peritoneal cavity; a pressure chamber is available which heats the irrigation fluid to body temperature or to slightly above body temperature. The Accessories (Tubing Sets) are designed to convey the sterile irrigation solution into the peritoneal cavity.

Substantial Equivalence: The KSEA Hydromat 263110-20 and Pressure Chambers are substantially equivalent to the predicate devices since the basic features and intended uses are similar. The minor differences between the Karl Storz Hydromat 263110-20 and Pressure Chambers 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: Marlena Allen Piercy
Marlena Allen Piercy, Ph.D.
Senior Clinical Affairs Specialist

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 22 1998

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

Re: K972488
KSEA Hydromat 263110-20
pressure chambers and accessories
Dated: October 23, 1997
Received: October 24, 1997
Regulatory Class: II
21 CFR 884.1720/Procode: 85 HET

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): K972488

Device Name: KSEA Hydromat 263110-20; Pressure Chambers and Accessories

Indications for Use: These instruments are indicated for use by qualified surgeons and physicians to provide pressurized fluid, with a heating option, for irrigation to the surgical site or hydro-dissection during laparoscopic surgical and diagnostic procedures.

Contraindications for Use: These instruments are contraindicated for hysteroscopic procedures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Peter D Sotling

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K972488

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

(Optional Format 1-2-96)