DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Karl Storz Endoscopy-America, Inc.
Ms. Suzie Chen
Director of Regulatory Affairs
600 Corporate Pointe, 5th Floor
Culver City, CA 90230-7600

JUL 27 2003

Re: K031895
Trade/Device Name: The KSEA OPserver LAP
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FET, GCT
Dated (Date on orig SE ltr): July 5, 2003
Received (Date on orig SE ltr): July 22, 2003

Dear Ms. Chen,

This letter corrects our substantially equivalent letter of September 23, 2003.

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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

Device Name: Opserver LAP

Indications for Use: The OPserver LAP is an integral combination unit comprised of the following legally marketed Karl Storz equipment intended for use in laparoscopic surgeries: XENON 300, Video Camera, THERMOFLATOR®, UNIDRIVE® II, AUTOCON® II 400, LAPAROMAT®, and QUADRO SWITCH.

The XENON 300 is a 300 watt short arc Xenon lamp light source designed to supply light for endoscopic diagnostic and surgical procedures.

The Video Camera is a camera system designed for use in laparoscopic surgeries. The TRICAM®/TELECAM® camera head is suitable for attachment to any rigid or flexible endoscope.

The THERMOFLATOR® is a gas insufflator designed for laparoscopic surgical and diagnostic procedures. The device is designed to carefully deliver large flow rates for rapid insufflation, and to monitor the amounts of CO_2 gas needed to establish and maintain proper distention of the peritoneal cavity.

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(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)

(Optional Format 1-2-96)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

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The UNIDRIVE® II is the control unit that operates the motorized handles during endoscopic surgical procedures.

The AUTOCON® II 400 is an electrosurgical generator that is intended for use by qualified surgeons to provide a high frequency (HF) electrical current for cutting and coagulating tissue during endoscopic surgeries.

The LAPAROMAT® is a high-capacity suction/irrigation device for use by qualified surgeons to infuse and aspirate sterile irrigation solutions into the peritoneal cavity to rinse or remove carbon deposits, blood clots, or excised tissue during laparoscopic and pelviscopic surgical procedures.

The QUADRO SWITCH, in conjunction with its associated handpiece or footswitch, functions as a suction/irrigation control switch device that controls the rinsing and removal of carbon deposits, blood clots, or excised tissue from operative sites during surgical procedures.

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

(Optional Format 1-2-96)

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and Neurological Devices

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SEP 2 3 2003

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: Susie Chen

Device Identification:

Common Name:
Multi-component surgical equipment console

Trade Name: (optional)
The KSEA OPserver LAP

Indication: The OPserver LAP is an integral combination unit comprised of the legally marketed Karl Storz equipment intended for use in laparoscopic surgeries.

Device Description: The OPserver LAP is comprised of XENON 300, Video Camera, THERMOFLATOR®, UNIDRIVE® II, AUTOCON® II 400, LAPAROMAT®, and QUADRO SWITCH. It is controlled via the Karl Storz SCB either by touch screen or by voice activation.

Substantial Equivalence: The KSEA OPserver LAP is substantially equivalent to the predicate devices since the performance specifications, safety features, and intended uses are identical. The minor differences between the KSEA OPserver LAP 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: _____

Susie Chen
Director of Regulatory Affairs