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510(k) SMMARY OF SAFETY AND EFFECTIVENESS

K012527

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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:

James A. Lee
Regulatory Affairs Specialist

Device Identification:

Common Name:
Miniature Telescope and Accessories

Trade Name: (optional)
KSEA Sialoendoscopes and accessories

Indication: The KSEA Sialoendoscopes and Accessories are used by qualified surgeons in the diagnosis and treatment of salivary gland diseases.

Device Description: The KSEA Sialoendoscope is a fiber optic micro-endoscope. The body contact portions of the KSEA Sialoendoscopes and Accessories are composed of chromium plated Monel 400® and surgical grade stainless steel, which are 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 Sialoendoscopes and Accessories are substantially equivalent to the predicate devices since the design, materials and intended uses are identical or similar. The minor differences between the subject 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: _____

James A. Lee, Ph.D.
Regulatory Affairs Specialist

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 01 2001

Mr. James A. Lee
Regulatory Affairs Specialist
Karl Storz Endoscopy - America, Inc.
600 Corporate Pointe Drive
Culver City, California 90230

Re: K012527
Trade/Device Name: KSEA Sialoendoscopes and Accessories
Regulation Number: 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: August 3, 2001
Received: August 6, 2001

Dear Mr. Lee:

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.

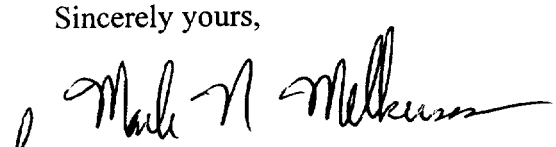
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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); 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.

This letter will allow you to begin marketing your device as described in your Section 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 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,



for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K012527

NOV 01 2001

Device Name: KSEA Sialoendoscopes and accessories.

Indications for Use: The KSEA Sialoendoscopes and Accessories are for use by qualified surgeons in the diagnosis and treatment of salivary gland diseases. The Sialoendoscope is used to visualize the surgical site in salivary gland diagnostic and therapeutic procedures. The sheath is to protect the telescope. The obturator allows the surgeon to gain access to the surgical site without damaging other tissue layers. The grasping forceps are used to hold, grasp and remove stone fragments. The stone basket is used to entrap and remove stone fragments in salivary gland endoscopic therapeutic procedures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhouse

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K012527

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

(Optional Format 1-2-96)