K013838

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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS JAN 1 6 2002

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.

Application:

Karl Storz Endoscopy – America, Inc.
600 Corporate Pointe Drive
Culver City, CA 90230
(310) 338-8100

Contact:

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

Device Identification:

Common Name:
Suction/Irrigation Pump

Trade Name: (optional)
KSEA Clearvision®

Indication: The KSEA Clearvision® is a lens irrigation system for cleaning the lens and maintaining clear visualization without removing the scope from the surgical site during sinus surgery.

Device Description: The KSEA Clearvision® is a microprocessor-controlled pump device. The device provides irrigation to clean the objective lens of scope, and removes residual solution on the lens. It is used in conjunction with an irrigation sheath.

Substantial Equivalence: The KSEA Clearvision® is substantially equivalent to the predicate device since the basic features and intended uses are the same. The minor differences between the KSEA Clearvision® and the predicate device raise no new questions of safety or effectiveness, as these differences have no effect on the performance, function, or intended use of the devices.

Signed: _____

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

COMPARISON CHART FOR THE KSEA CLEARVISION

FEATURES	KSEA Clearvision®	Xomed Endo-Scrub/ Endo-Scrub 2 (K98254)
Type of Pump	Microprocessor controlled	Same
Function	Irrigation and reverse flow with adjustable flow intervals	Irrigation and reverse flow with adjustable cycles
Controls	Foot pedal	Same
Pump Console Dimensions (w x h x d)	203 mm x 101 mm x 130 mm	Not available from marketing info
Pump Console Weight	1.5 Kg	Not available from marketing info
Accessories	Reusable 2.7 or 4.0 mm irrigation Sheath and Disposable Tubing Set	Disposable 2.7 or 4.0 mm irrigation Sheath and Disposable Tubing Set
Safety Features	IEC 601-1; IEC 60601-1-2; self diagnostics during power up; temperature and current monitoring during operation	IEC 60601-1-1; IEC 60601-1-2
Intended Use	Lens cleaning during sinus surgery	Same

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Karl Storz Endoscopy – America, Inc
c/o James A. Lee, Ph.D.
600 Corporate Pointe 5th Floor
Culver City, California 90230

JAN 1 6 2002

Re: K013838
Trade/Device Name: KSEA Clearvision® Lens Irrigation System
Regulation Number: 21 CFR 874.4760
Regulation Name: Nasopharyngoscope and accessory
Regulatory Class: Class II
Product Code: EOB
Dated: November 16, 2001
Received: November 19, 2001

Dear Mr. Lee:

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 requirements, 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 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) 594-4613. 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" (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,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number (if known):

Device Name: KSEA Clearvision® Lens Irrigation System

Indication for Use: The KSEA Clearvision® is a lens irrigation system for cleaning the lens and maintaining clear visualization without removing the scope from the surgical site during sinus surgery.

(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)

Karen A Baker 1/4/02
(Division Sign-Off)
Division of Ophthalmic Ear, Nose and Throat Devises

510(k) Number K013838

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