

KAS1458

MAY 20 1998

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) 410-2769

Contact: Kevin Kennan
Senior Regulatory Affairs Specialist

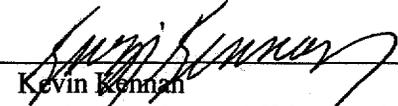
Device Identification: **Common Name:**
Flexible ENT Scopes

Trade Name: (optional)
Karl Storz Rhino-Laryngo-Broncho-Fiberscope, Pediatric Broncho-Fiberscope, and Broncho-Fiberscope, 11001 RK, 11002 BC and 11004 B

Indication: The KSEA Rhino-Laryngo-Broncho-Fiberscope, Pediatric Broncho-Fiberscope, and Broncho-Fiberscope are designed to be used by qualified surgeons and physicians for examination of the nasal sinuses, larynx, pharynx and, using additional accessories, to perform various diagnostic and therapeutic procedures.

Device Description: The KSEA Rhino-Laryngo-Broncho-Fiberscope, Pediatric Broncho-Fiberscope, and Broncho-Fiberscope are manually operated surgical devices. The KSEA Rhino-Laryngo-Broncho-Fiberscope, Pediatric Broncho-Fiberscope, and Broncho-Fiberscope are flexible fiberoptic telescopes which utilize fiber-optic technology. The body contact portions of the KSEA Intubation Laryngoscope are composed of medical grade polyurethane.

Substantial Equivalence: The KSEA Rhino-Laryngo-Broncho-Fiberscope, Pediatric Broncho-Fiberscope, and Broncho-Fiberscope are substantially equivalent to the predicate devices since the basic features, design and intended uses are the same. The minor differences between the KSEA Rhino-Laryngo-Broncho-Fiberscope, Pediatric Broncho-Fiberscope, and Broncho-Fiberscope and the predicate devices raise no new issues of safety and effectiveness, as these design differences have no affect on the performance, function or intended use of the devices.

Signed: 
Kevin Kennan
Senior Regulatory Affairs Specialist



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850Kevin Kennan
Senior Regulatory Affairs Specialist
Karl Storz Endoscopy
600 Corporate Pointe
Culver City, California 90230-7600Re: K981458
Rhino-Laryngo-Broncho-Fiberscope
Dated: April 20, 1998
Received: April 23, 1998
Regulatory Class: II
21 CFR 874.4760/Procode: 77 EOB
21 CFR 874.4680/Procode: 77 EOQ

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 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 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/dsma/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

K981458

Device Name: Rhino-Laryngo-Broncho-Fiberscope, Pediatric Broncho-Fiberscope, and Broncho-Fiberscope

Indications for Use:

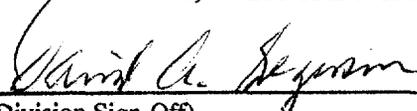
The Rhino-Laryngo-Broncho-Fiberscope is indicated for examination of the nasal sinuses, larynx and bronchi and, using additional accessories, to perform various diagnostic and therapeutic procedures.

The Pediatric Broncho-Fiberscope is indicated for examination of the larynx and bronchi in pediatric patients and, using additional accessories, to perform various diagnostic and therapeutic procedures.

The Broncho-Fiberscope is indicated for examination of the larynx and bronchi in adult patients and, using additional accessories, to perform various 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, ENT,
and Radiological Devices

510(k) Number K981458

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

(Optional Format 1-2-96)

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