K051972

AUG 15 2005

Karl Storz
Endoscopy-America, Inc.

600 Corporate Pointe 5th Floor
Culver City, California 90230-7600
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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: Yvonne Fernandez
Senior Regulatory Affairs Specialist

Device Identification: Common Name - Flexible Esophagoscopes
Trade Name - Karl Storz Trans-Nasal Esophagoscopes
(11301BN1, 11302BD1)

Indication: The Karl Storz Trans-Nasal Esophagoscopes are designed to be used by qualified surgeons and physicians and are indicated for endoscopic access and examination of the nasal sinuses, larynx, esophagus and gastro-esophageal junction and, using additional accessories, to perform various diagnostic and therapeutic procedures.

Device Description: The Karl Storz Trans-Nasal Esophagoscopes are manually operated surgical devices, flexible fiberoptic telescopes that utilize fiber-optic technology. The body contact portions of the Karl Storz Trans-Nasal Esophagoscopes are manufactured using medical grade polyurethane.

Substantial Equivalence: The Karl Storz Trans-Nasal Esophagoscopes are substantially equivalent to the predicate devices since the basic features, design and intended uses are the same. The minor differences between the Karl Storz Trans-Nasal Esophagoscopes and the KSEA Rhino-Laryngo-Broncho-Fiberscope and Broncho-Fiberscope (K981458), and the TNE-2000 marketed by Vision Sciences, Inc. (K031786) 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Karl Storz Endoscopy-America, Inc.
c/o Yvonne Fernandez
Senior Regulatory Affairs Specialist
600 Corporate Pointe, 5th Floor
Culver City, CA 90230-7600

Re: K051972
Trade/Device Name: Trans-Nasal Esophagoscope
Regulation Number: 21 CFR 874.4710
Regulation Name: Esophagoscopes and accessories
Regulatory Class: Class II
Product Code: EOX
Dated: July 20, 2005
Received: July 21, 2005

Dear Ms. Fernandez:

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), please contact the Office of Compliance at (301) 827-8910. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

David M. Whipple
Acting Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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

Device Name: Karl Storz Trans-Nasal Esophagoscopes

Indications for Use:

The Karl Storz Trans-Nasal Esophagoscopes are designed to be used by qualified surgeons and physicians and are indicated for endoscopic access and examination of the nasal sinuses, larynx, esophagus and gastro-esophageal junction 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)

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

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K051972