K060907

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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

NOV - 9 2006

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.
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(310) 558-1500

Contact: Paul S. Lee
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Device Identification: Common Name: Gastro Intestinal Videoscope

Trade Name: Karl Storz Video Gastroscope System

Indication: The Karl Storz Video Gastroscope System is intended to be used by physician / endoscopist in the visual examination and treatment of the upper digestive tract including the esophagus, stomach, and duodenum. The Video Gastroscope System is intended to provide optical visualization via a video monitor and therapeutic access to the upper digestive tract.

Device Description: The Karl Storz Video Gastroscope System is a flexible endoscope with a distal-CCD chip technology which connects to the Karl Storz Camera Control Processor (CCU) to provide clear images on the video monitor during the examination and treatment of the upper digestive tract. The flexible video gastroscope contains image module, air/water insufflation, jet nozzle, suction, and illumination light and biopsy channels. The Karl Storz Video Gastroscope is a Class II device under 21CFR876.1500, Endoscope and accessories.

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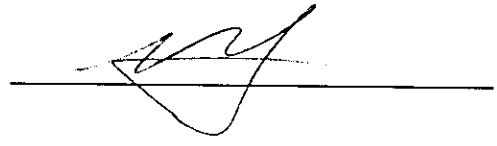
Substantial Equivalence: The Karl Storz Video Gastroscope System is substantially equivalent to predicate devices since the basic technology and design are similar. The intended usage is similar to predicate devices and raise no new issues of safety and effectiveness. The minor differences between the Karl Storz Video Gastroscope System and predicate devices have no effect on the performance, function or intended use of the devices.

Signature: 

Paul Lee
Senior Regulatory Affairs Specialist

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Paul S. Lee, Ph.D.
Senior Regulatory Affairs Specialist
Karl Storz Endoscopy – America, Inc.
600 Corporate Pointe Drive
CULVER CITY CA 90230

NOV - 9 2006

Re: K060907
Trade/Device Name: Karl Storz Video Gastroscope System
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Product Codes: FDS, GCT and FWF
Regulatory Class: II
Dated: October 11, 2006
Received: October 12 2006

Dear Dr. 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 (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 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 one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

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 (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K060907

Device Name: Karl Storz Video Gastroscope System

Indications for Use: The Karl Storz Video Gastroscope System is intended to be used by physician / endoscopist in the visual examination and treatment of the upper digestive tract including the esophagus, stomach, and duodenum. The Video-Gastroscope System is intended to provide optical visualization via a video monitor and therapeutic access to the upper digestive tract.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: ✓ ~~AND~~/OR Over-The-Counter Use: _____
(Per 21 CFR 801.Subpart D) (21 CFR 801 Subpart C)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K060907