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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) 558-1500

Contact:

Susie Chen
Director, Regulatory and Legal Affairs
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Device Identification:

Common Name: Video Lower G.I. Endoscope System

Trade Name: Karl Storz Video Lower G.I. Endoscope System

Indication: The Karl Storz Video Lower G.I. Endoscope System is intended to be used by physican / endoscopist in the visual examination and treatment of the lower digestive tract including the anus, rectum, colon and ileocecal valve. The Video Lower G.I. Endoscope System is intended to provide optical visualization via a video monitor and therapeutic access to the lower digestive tract.

KARL STORZ ENDOSCOPY

Device Description: The Karl Storz Video Lower G.I. Endoscope System includes flexible endoscopes with distal-CCD chip technology which connects to the Karl Storz Camera Control Processor treatment of the lower digestive tract. The flexible video endoscopes contain an image module, air/water insufflation, jet nozzle, suction, and illumination light and biopsy channels. The Karl Storz Video Lower G.I. Endoscope System is a Class II device under 21CFR876.1500, Endoscope and accessories.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Ms. Susie Chen
Director, Regulatory and Legal Affairs
Karl Storz Endoscopy-America, Inc.
600 Corporate Pointe, 5th Floor
CULVER CITY CA 90230-7600

JAN 31 2007

Re: K063585
Trade/Device Name: Karl Storz Video Lower G.I. Endoscope System
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Codes: FDF, FAM and KOG
Dated: November 30, 2006
Received: December 1, 2006

Dear Ms. Chen:

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

KARL STORZ ENDOSCOPY

Indication for Use

510(k) Number (if known): K063585

Device Name: Karl Storz Video Lower G.I. Endoscope System

Indications for Use: The Karl Storz Video Lower G.I. Endoscope System is intended to be used by physician / endoscopist in the visual examination and treatment of the lower digestive tract including the anus, rectum, colon and ileocecal valve. The Karl Storz Video Lower G.I. Endoscope System is intended to provide optical visualization via a video monitor and therapeutic access to the lower 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: X 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 K063585