K973252
Nov. 24, 1997

510(k) Summary of Safety and Effectiveness

This summary of premarket notification 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.

Application:	Karl Storz Imaging, Incorporated 175 Cremona Drive Goleta, California 93117
Contact:	Mr. Terry Fernandez
Registration:	2027009
Device Name:	Proprietary Name -- Karl Storz Imaging Direct Coupled Camera Head Common Name -- Color Television Camera Head Classification Name -- Camera, Television, Endoscopic
Intended Use:	The Karl Storz Imaging (KSI) Direct Coupled (DCC) Camera Head is a color, television camera head designed for attachment to a Karl Storz Tuttlingen (KST) DCC endoscopic visioning system. The KSI DCC camera head is compatible with the currently marketed KSI Telecam SL (Super Luxury) video processor and the KSI Telecam SL with IPM (Image Processing Module) video processor. The camera head is suitable for attachment to any KST DCC rigid or flexible endoscope, including, but not limited to sinoscopes, colonoscopes, sigmoidoscopes, bronchoscopes, gastroscopes, laparoscopes, choledoscopes, ureteroscopes, hysteroscopes and arthroscopes. The camera head is coupled to the endoscope by directly pressing the endoscope onto the front of the DCC camera head until it locks into place. An optional adapter allows DCC camera head attachment to non-DCC rigid and flexible endoscopes. The endoscopic image can be displayed on any standard operating room video monitor.
Device Description:	The KSI DCC incorporates two programmable function buttons (to select an accessory port(s) and to control the port output) and two focus buttons. The light cable is connected directly to the back of the camera head. The camera is designed to allow the user to directionally rotate the camera head to maintain proper image orientation on the monitor.

Substantial Equivalence:

KSI believes that its proposed new device, the Direct Coupled Camera Head, is substantially equivalent to several other camera heads currently in commercial distribution including the camera head in the KSI Tricam Color Endoscopic Television Camera System (K950862) and the camera head in the KSI Telecam Color Endoscopic Television Camera System (K883943). The proposed new KSI camera head is unique only in that it incorporates into one camera head variations of several features found in similar, earlier camera head models.

Signed: _____ Date: 08/27/97

Terry Fernandez

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 24 1997

Terry Fernández
Director, Regulatory and Standards Compliance
Karl Storz Imaging, Inc.
175 Cremona Drive
Goleta, California 93117

Re: K973252
Karl Stortz Direct Coupled Camera Head
Dated: August 27, 1997
Received: August 29, 1997
Regulatory class: II
21 CFR §876.1500/Product code: 78KOG and GCJ

Dear Mr. Fernandez:

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 requirement, 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/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): K973250

Device Name: KSI DIRECT COUPLED CAMERA SYSTEM

Indication for Use:

The Karl Storz Imaging (KSI) Direct Coupled (DCC) Camera Head is a color, television camera head designed for attachment to a Karl Storz Tuttlingen (KST) DCC endoscopic visioning system. The KSI DCC camera head is compatible with the currently marketed KSI Telecam SL (Super Luxury) and the KSI Telecam SL with IPM (Image Processing Module) video processors.

The camera head is suitable for attachment to any KST DCC rigid or flexible endoscope, including, but not limited to sinoscopes, colonoscopes, sigmoidoscopes, bronchoscopes, gastroscopes, laparoscopes, choledoscopes, ureteroscopes, hysteroscopes and arthroscopes. The camera head is coupled to the endoscope by directly pressing the endoscope onto the front of the DCC camera head until it locks into place. The endoscopic image can be displayed on any standard operating room video monitor.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K973252

(Division Sign-Off)

510(k) Number _____

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

(Optional Format 1-2-96)