JUN 1 1999

K990154

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 Interface Camera Head Common Name -- Color Television Camera Head Classification Name -- Camera, Television, Endoscopic
Intended Use:	The Karl Storz Imaging (KSI) Direct Coupled Interface (DCI 5) Camera System combines a color, television camera head with an integrated light source cable and camera control unit (CCU). These units are designed for attachment to any Karl Storz Tuttlingen (KST) DCI compatible rigid or flexible endoscope, including, but not limited to sinoscopes, colonoscopes, sigmoidoscopes, bronchoscopes, gastroscopes, laparoscopes, choledochoscopes, ureteroscopes, hysteroscopes and arthroscopes. The DCI 5 camera head is coupled to the endoscope by directly pressing the endoscope onto the front of the camera head until it locks into place. An optional adapter allows DCI 5 camera head attachment to non-DCI rigid and flexible endoscopes. The endoscopic image can be displayed on any standard operating room video monitor. All commonly available endoscopic light sources may be used with the DCI 5 System.
Device Description:	The KSI DCI 5 incorporates two programmable function buttons (to select an accessory port(s) and to control the port output), a focus knob and a zoom in/zoom out control bar. The camera head also has an integrated light cable. The camera is designed to allow the user to axially rotate the camera head while maintaining proper image orientation on the monitor.

Substantial Equivalence:

The DCI 5 Camera System is a combination of features found in earlier KSI premarket notifications. The proposed camera head and its indications for use are based upon KSI's Direct Coupled Camera 510(k), K973252. Both devices feature direct connection to an endoscope, light guide camera connection, programmable buttons, camera head focus control, automatic image rotation, sealed aluminum camera housings, single CCD sensing and anti-fogging features.

The proposed camera IPM CCU board is based upon KSI's Digivideo 510(k), K950974. Both units feature contrast enhancement, use of standard video signal, and digital processing.

The proposed camera system's CCU is based upon KSI's Urocam/Hysterocam 510(k), K940283. Both units feature the same power supply, maximum signal amplification, electronic shutter control, composite video output and cable connection to a camera head. 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: 18 January 1999
Terry Fernandez

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 1999

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

Re: K990154
Trade Name: Karl Storz Imaging Direct Coupled Interface Camera Head
Regulatory Class: II
Product Code: FWF
Dated: April 28, 1999
Received: April 29, 1999

Dear Mr. Fernandez:

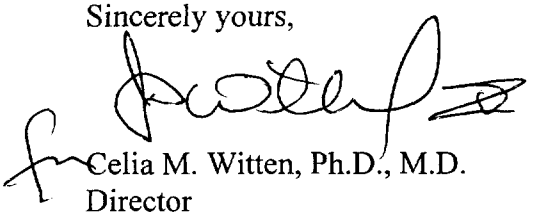
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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) 594-4595. 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,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K990154

Device Name: KSI DIRECT COUPLED CAMERA SYSTEM

Indication for Use:

The Karl Storz Imaging (KSI) Direct Coupled Interface (DCI 5) Camera System is a color, television camera head with integrated light source cable, and separate video processor.

The camera system is suitable for use with any KST DCI rigid or flexible endoscope, including, but not limited to sinoscopes, colonoscopes, sigmoidoscopes, bronchoscopes, gastroscopes, laparoscopes, choledochoscopes, ureteroscopes, hysteroscopes and arthroscopes. The camera head is coupled to the endoscope by directly pressing the endoscope onto the front of the DCI 5 camera head until it locks into place. The endoscopic image can be displayed on any standard operating room video monitor. >

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

510(k) Number K990154

Prescription Use X OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)