

JAN 30 1998

## 510(k) Summary of Safety and Effectiveness

K974 391

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 Endovision XL Endoscopic Camera System  
Common Name -- Color Television Camera System  
Classification Name -- Camera, Television, Endoscopic

**Intended Use:** The Karl Storz Imaging (KSI) Endovision XL System is a color, television camera head designed for use with any flexible or rigid endoscope.

The camera head may be attached to any rigid or flexible endoscope, such as sinoscopes, colonoscopes, sigmoidoscopes, bronchoscopes, gastroscopes, laparoscopes, choledoscopes, ureteroscopes, hysteroscopes and arthroscopes. The camera is connected to the video processor via a ten foot cable. The endoscopic image can be displayed on any standard operating room video monitor.

**Device Description:** The Endovision XL is a state-of-the-art endoscopic camera. The head of the camera is equipped with a V-mount thread, allowing the head to couple to Karl Storz V-mount optical adapters. Three adapters, 15 mm, 20 mm and 25 mm, are available with the system. These couplers allow easy attachment of the XL head to any standard endoscope. Microprocessor controlled automatic exposure adjusts image brightness. The image sensor is a 1/4" CCD-chip.

The processor weighs 1.77 pounds and the camera .6 pounds. Dimensions of the processor and camera in width, height and depth are: 8.29 x 2.16 x 6.07 inches and 1.96 x 2.4 x 3.9 inches respectively.

**Substantial Equivalence:**

**KSI believes that its proposed new device, the Endovision XL endoscopic camera system, is substantially equivalent to several other systems currently on the market including the KSI Tricam Color Endoscopic Television System (K950862) and the KSI Telecam Color Endoscopic Television System (K883943). The proposed new KSI Endovision XL is unique only in that it is a smaller, lighter, more portable camera system.**

Signed:   
Terry Fernandez

Date: 1/26/98



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JAN 30 1998

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

Re: K974391  
Trade Name: Karl Storz Endovision XL Endoscopic Camera System  
Regulatory Class: II  
Product Code: GCJ  
Dated: November 20, 1997  
Received: November 21, 1997

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.

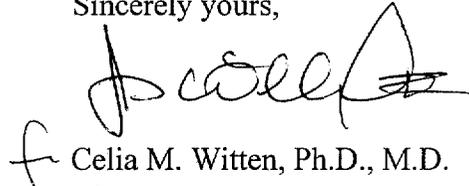
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, 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): \_\_\_\_\_

Device Name: KSI ENDOVISION XL CAMERA SYSTEM

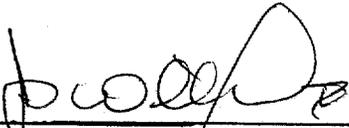
Indication for Use:

The Karl Storz Imaging (KSI) Endovision XL Camera System is a color, television camera system designed for attachment to endoscopic visioning systems.

The camera head is suitable for attachment to any rigid or flexible endoscope, including, such as sinoscopes, colonoscopes, sigmoidoscopes, bronchoscopes, gastroscopes, laparoscopes, choledoscopes, ureteroscopes, hysteroscopes and arthroscopes. The camera head is coupled to the endoscope with a V-mount adapter. The camera is connected to the video processor via cable. 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.)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
(Division Sign-Off)

510(k) Number K974391

Prescription Use  OR Over-The-Counter Use \_\_\_\_\_  
(Per 21 CFR 801.109)