DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 7 2001

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

Re: K003325
KSI's New Camera Architecture (NCA)
Video Imaging System
Dated: January 31, 2001
Received: February 1, 2001
Regulatory Class: II
21 CFR §876.1500/Procodes: 78 KOG 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 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). 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) 594-4639. 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" (21CFR 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/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known): K003325

Device Name: KSI NEW CAMERA ARCHITECTURE (NCA) VIDEO IMAGAING SYSTEM

Indication for Use:

The Karl Storz Imaging (KSI) New Camera Architecture (NCA) Video Imaging System is a color, television camera system which can be used with rigid or flexible endoscopes, such as sinoscopes, colonoscopes, sigmoidoscopes, bronchoscopes, gastroscopes, laparoscopes, choledochoscopes, ureteroscopes, hysteroscopes and arthroscopes. The camera head is coupled to the endoscope. Any compatible NCA camera head may be us with the NCA KSI Camera Control Unit (CCU). The endoscopic image can be displayed on any standard operating room video monitor.

All standard endoscopic light sources may be used with New Camera Architecture (NCA) camera heads. Both single chip and three chip camera heads will be available in NTSC and PAL configurations.

(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

Prescription Use ✓ OR Over-The-Counter Use

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K003325