FEB 4 2000

K994090

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 Autoclavable Camera Head
Common Name -- Color Television Camera Head
Classification Name -- Camera, Television, Endoscopic

Intended Use: The Karl Storz Imaging (KSI) Autoclavable camera head is a color, television camera. suitable for use with any 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. The camera head may be used with any current, compatible KSI camera control unit (CCU). The endoscopic image can then be displayed on any standard operating room video monitor.

Device Description: The new autoclavable camera heads are identical to previous single chip and three chip models with the exception that these units are hermetically sealed and use a magnetic switch for operating the integral hand-held camera controls.

Substantial Equivalence:
KSI Autoclavable Camera Heads are substantially equivalent to previously reviewed KSI single CCD (charge coupled device) and triple CCD camera heads and, in pressurized steam sterilization capability, to M.P. Video Autoclaveable Camera Heads. KSI's proposed new camera heads and their indications for use are based upon KSI's premarket notification numbers, K883943 (single chip) and K950862 (three chip), and its autoclavability based upon M.P. Video's "Autoclaveable Medicam 900 Digicon Camera", premarket notification number K942358.

Signed: _____ Date: 1/31/00
Terry Fernandez

1/31/00

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 4 2000

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

Re: K994090
KSI Autoclavable Camera Head
Dated: December 2, 1999
Received: December 3, 1999
Regulatory Class: II
21 CFR §876.1500/Procode: 78 KOG

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) 594-4613. 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/dsma/dsmamain.html".

Sincerely yours,

CAPT Daniel G. Schultz, M.D.
Acting 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): K994090

Device Name: KSI AUTOCLAVABLE CAMERA HEAD

Indication for Use:

The Karl Storz Imaging (KSI) Autoclavable camera head is a color, television camera. suitable for use with any 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. The camera head may be used with any current, compatible KSI camera control unit (CCU). The endoscopic image can then 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 _____

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 K994090

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