DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Karl Storz, Endoscopy-America, Inc.
Regulatory Affairs Department
Mr. Paul Lee
Senior Regulatory Affairs Specialist
600 Corporate Pointe, 5th Floor
Culver City, CA 90230-7600

JUL 27 2015

Re: K070716
Trade/Device Name: Image 1® Video Imaging System with Optional Insufflators Controls
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FET
Dated (Date on orig SE ltr): May 21, 2007
Received (Date on orig SE ltr): May 22, 2007

Dear Mr. Lee

This letter corrects our substantially equivalent letter of May 31, 2007.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K070716

INDICATIONS FOR USE

510(k) Number (if known): K070716

Device Name: Image 1® Video Imaging System with Optional Insufflators Controls

Indications for Use:

The Karl Storz Image 1® Video Imaging System with optional insufflators control allows remote control of Karl Storz insufflators by Image 1® camera head control buttons. The Karl Storz Image 1® Video Imaging System is a color video camera system which can be used as an endoscopic accessory with rigid or flexible endoscopes. The camera head is directly coupled to the endoscope. Any compatible Image 1® camera head may be used with the Image 1® Karl Storz Camera Control units (CCU). The endoscopic image can be displayed on any standard operating room video monitor and all standard endoscopic light sources may be used with the Image 1® camera head.

Prescription Use: ✓ (Per 21 CFR 801.Subpart D)

OR Over-The-Counter Use: _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K070716

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MAY 3 1 2007

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) 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. All data included in this document is accurate and complete to the best of KSEA's knowledge.

Applicant:

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Device Identification:

Common Name: Video Imaging System

Trade Name: Image 1® Video Imaging System with optional insufflators controls

Indication:

The Karl Storz Image 1® Video Imaging System with optional insufflators control allows remote control of Karl Storz insufflators by Image 1® camera head control buttons. The Karl Storz Image 1® Video Imaging System is a color video camera system which can be used as an endoscopic accessory with rigid or flexible endoscopes. The camera head is directly coupled to the endoscope. Any compatible Image 1® camera head may be used with the Image 1® Karl Storz Camera Control units (CCU). The endoscopic image can be displayed on any standard operating room video monitor and all standard endoscopic light sources may be used with the Image 1® camera head.

Device Description:

The Image 1® Video Imaging System with modification for insufflators control is a digital video imaging system used by qualified personnel in the operating room to view endoscopic images and to interface with Karl Storz devices such as selected insufflators through the Karl Storz Communication Bus (SCB). Karl Storz SCB technology, based on a modular design concept, provides centralized remote control over compatible medical equipment and peripheral system via touch screen or camera head buttons in the sterile environment. The modification for insufflators control is a software change only to the Image 1® Video Imaging System to allow the camera to exert control over Karl Storz insufflators functions through Karl Storz SCB

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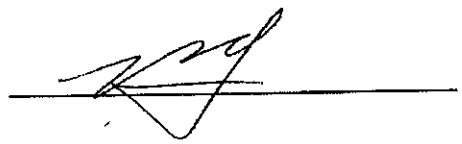
Substantial Equivalence: The Karl Storz Image 1® Video Imaging System is substantially equivalent to predicate devices since the basic technology and design are similar. The intended usage is similar to predicate devices and raises no new issues of safety and effectiveness. The minor differences between the Image 1® Video Imaging System and predicate devices have no effect on the performance, function or intended use of the devices.

Signature: 

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