DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

KARL STORZ Endoscopy America Incorporated
Winkie Wong
Regulatory Affairs Specialist
2151 East Grand Avenue
El Segundo, California 90245

September 17, 2015

Re: K143640
Trade/Device Name: KSEA CMOS Camera System (C-cam)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: August 14, 2015
Received: August 18, 2015

Dear Ms. Wong:

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 Industry and Consumer Education 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 Industry and Consumer Education 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,

Joshua C. Nipper -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k143640

Device Name
KSEA CMOS Camera System (C-cam)

Indications for Use *(Describe)*
The C-cam camera head is designed for general endoscopic procedures in an operating room or a doctor's office. The camera head is suitable for attachment to all standard KARL STORZ Endoscopes and Fiberscopes and must be used with a C-MAC monitor or C-HUB for observation purposes in general endoscopic procedures.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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:	Karl Storz Endoscopy-America, Inc 2151 E. Grand Avenue EI Segundo, CA 90245
Contact:	Winkie Wong Regulatory Affairs Specialist 424-218-8379 [voice] 424-218-8519 [fax]
Date of Preparation:	September 10, 2015
Device Identification:	Trade Name: KSEA CMOS Camera System (C-CAM) Common Name: Endoscopic Camera System Classification Name: Endoscopic Camera System
Product Code:	GCJ
Regulation:	CFR 876.1500
Predicate Device(s):	Tricam (K950862)
Device Description:	The KSEA CMOS Camera System (C-CAM) consists of a camera head, a cable and a monitor. The camera head must be connected to the C-MAC monitor, 8403ZX. The KSEA CMOS Camera System is compatible for use with all standard KARL STORZ Endoscopes and Fiberscopes for endoscopic observation in general endoscopic procedures.
Indications For Use:	The KSEA CMOS Camera System is a camera system designed for use in the operating room for general endoscopic procedures. The camera head is suitable for attachment to all standard KARL STORZ Endoscopes and

	Fiberscopes and must be used with a C-MAC™ monitor or C-HUB for observation purposes in general endoscopic procedures.
Technological Characteristics:	The predicate and subject devices are both camera system that are used for observation purposes in general endoscopic surgery. However, in order to provide a lower cost alternative of the subject device to the end user compare to the current high cost camera in the market, they have minor differences in the technological characteristics. These differences are: • The subject device uses a CMOS sensor instead of a CCD sensor. • The resolution of the device is slightly lower than the predicate (350 TVL [H]). The bench test data for the KSEA CMOS Camera System (C-CAM) demonstrates that the design characteristics used as the basis for the comparison have been met. The results show that the subject device has met all its specifications. Combining the minor difference in specifications with the benefit of providing a lower cost device compared to the predicate device, Tricam, C-CAM does not raise new issues of safety and effectiveness and the devices are substantially equivalent for general endoscopic application.
Non-Clinical Performance Data:	C-CAM is tested according to the following standard: • IEC 60601-1 • IEC 60601-1-2 • IEC 60601-2-18 Additional bench testing for performance verification and validation purposes: • Resolution

	• Field Flatness • White Balance The bench testing performed verified and validated that the C-CAM has met all its design specification and is substantially equivalent to the predicate device, Tricam, for general endoscopic procedures.
Clinical Performance Data:	No clinical information is required for this submission
Conclusion:	The Karl Storz's CMOS Camera System (C-CAM) is substantially equivalent to its predicate devices. The non-clinical testing demonstrates that the device is as safe and effective as the legally marketed devices.