DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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November 20, 2015

Karl Storz Endoscopy-America, Inc.
Winkie Wong
Regulatory Affairs Specialist
2151 E. Grand Ave
El Segundo, California 90245

Re: K150525
Trade/Device Name: SPIES 3D System
Regulation Number: 21 CFR 884.1720
Regulation Name: Gynecologic Laparoscope And Accessories
Regulatory Class: Class II
Product Code: HET, GCJ, FGB
Dated: October 16, 2015
Received: October 19, 2015

Dear Winkie 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" (21 CFR 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,

Herbert P. Lerner -S

for 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

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)*
K150525

Device Name
SPIES 3D System

Indications for Use *(Describe)*
3D TIPCAM®1: The Rigid Videoendoscope is intended to be used together with the camera control unit is for use during diagnostic and/or surgical procedures when endoscopic video assistance is required. For use in all endoscopy and endoscopic surgery within the peritoneal and thoracic cavity, including gynecological and urological anatomy.

IMAGE1 SPIES is a camera control unit (CCU) for use with camera heads or videoendoscopes for the visualization and documentation of endoscopic and microscopic 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 424-218-8519
Date of Preparation:	February 25, 2015
Device Identification:	Trade Name: SPIES 3D System Common Name: Endoscopic Camera System Classification Name: Gynecologic Laparoscope And Accessories
Product Code:	HET, GCJ, FGB
Regulation:	21 CFR 884.1720
Predicate Device(s):	ENDOEYE FLEX 3D DEFLECTABLE VIDEOSCOPE SYSTEM (K123365)
Device Description:	The SPIES 3D System is intended for use during diagnostic and/or surgical procedures when endoscopic video assistance is required within the peritoneal and thoracic cavity, including gynecological and urological anatomy. The SPIES 3D System is a medical device system which consists of the camera control unit (CCU) – a combination of the previously 510k cleared device (K131953) – Image1 Connect module (TC200) and the D3-Link module, and 3D Tipcam®1.

Indications For Use:	3D TIPCAM®1: The Rigid Videoendoscope is intended to be used together with the camera control unit is for use during diagnostic and/or surgical procedures when endoscopic video assistance is required. For use in all endoscopy and endoscopic surgery within the peritoneal and thoracic cavity, including gynecological and urological anatomy. IMAGE1 SPIES is a camera control unit (CCU) for use with camera heads or videoendoscopes for the visualization and documentation of endoscopic and microscopic procedures.
Technological Characteristics:	The predicate and subject devices are both camera systems that are used for observation purposes in general endoscopic surgery within the thoracic and peritoneal cavity, including gynecological and urological anatomy. There are some minor differences in the technological characteristics. These differences are: • The subject device uses a CMOS sensor instead of a CCD sensor. • The subject device has a more limited specification on field of view (82° vs. 90°) due to the deflectable tip in the predicate device. • The subject device includes different patient contacting materials The bench test data for the SPIES 3D System 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. The performance validation test report is provided in section 021_Performance Testing of this submission. The minor difference in specifications when compared to the predicate device, ENDOEYE FLEX 3D DEFLECTABLE Videoscope System, is that the SPIES 3D System does not raise new issues of safety and effectiveness and the devices are substantially equivalent for general endoscopic application within the thoracic and peritoneal cavity.

Non-Clinical Performance Data:	Software validation was completed for a moderate level of concern per the FDA guidance document: "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" dated May 11, 2005. Reprocessing validation as completed per the FDA guidance document: "Reprocessing Medical Devices in Heath Care Settings: Validation Methods and Labeling" dated March 2, 2015. SPIES 3D System is tested according to the following standard: • IEC 60601-1 • IEC 60601-1-2 • IEC 60601-2-18 • ISO 10993-5, 2009 (Cytotoxicity) • ISO 10993-11, 2010 (Systemic Toxicity) • ISO 10993-10, 2010 (Sensitization and Irritation) Additional bench testing for performance verification and validation purposes: • Resolution • Brightness • White Balance • 3D-2D Mode • Color Performance • Latency • Electrosurgical Unit Susceptibility • Minimum Illumination • Auto Exposure Setp Response • Auto Light Source Control • Zero Degree Parallax The bench testing performed verified and validated that the SPIES 3D System has met all its design specification and is substantially equivalent to the predicate device, ENDOEYE FLEX 3D DEFLECTABLE VIDEOSCOPE SYSTEM, for use in all endoscopic procedures within the peritoneal and thoracic cavity, including gynecological and urological

	anatomy.
Clinical Performance Data:	No clinical information is required for this submission
Conclusion:	The SPIES 3D System 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.