



Food and Drug Administration
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February 1, 2016

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

Re: K160044
Trade/Device Name: Image1 SPIES System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: FET
Dated: January 6, 2016
Received: January 8, 2016

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

Indications for Use

510(k) Number (if known)

K160044

Device Name

Image1 SPIES System

Indications for Use (Describe)

The IMAGE1 SPIES is a camera control unit (CCU) for use with camera heads or video endoscopes for the visualization, image recording and documentation during general 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.

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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 1, 2016
Device Identification:	Trade Name: Image1 SPIES System Common Name: Endoscopic Camera System Classification Name: Endoscope and accessories
Product Code:	FET
Regulation:	CFR 876.1500
Predicate Device:	Image1 SPIES (K131953)
Device Description:	The modified Image1 SPIES (Storz Professional Image Enhancement System) camera control unit includes an additional camera head that can be connected to the X-link module and software updates for improvement of existing features and bug fixes. The SPIES Camera System is intended and designed for use during endoscopic and microscopic procedures.
Indications For Use:	The IMAGE1 SPIES is a camera control unit (CCU) for use with camera heads or video endoscopes for the visualization, image recording and documentation during general endoscopic and microscopic procedures.

<p>Technological Characteristics:</p>	<p>The predicate and subject devices are both camera systems that are used for the visualization and documentation of endoscopic and microscopic procedures. There are some minor differences in the technological characteristics. These differences are:</p> <ul style="list-style-type: none"> • The subject device uses a CMOS sensor instead of a CCD sensor. • The subject device has a smaller telescope size attachment than the predicate device. <p>The bench test data for the Image1 SPIES 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 can be provided upon request.</p> <p>The minor difference in specifications when compared to the predicate device, Image1 SPIES System, does not raise new issues of safety and effectiveness and the devices are substantially equivalent for the visualization and documentation of endoscopic and microscopic procedures.</p>
<p>Non-Clinical Performance Data:</p>	<p>Image1 SPIES System undergone bench testing for performance verification and validation purposes:</p> <ul style="list-style-type: none"> • Resolution • Brightness • White Balance • Color Performance • Latency • Temporal Noise • Residual Spatial Noise • Step Response of Automated Exposure System • Software Verification Tests <p>The bench testing performed verified and validated that the Image1 SPIES System has met all its design specification and is substantially equivalent to the predicate device, Image1 SPIES, for use in all endoscopic procedures within</p>

	the peritoneal and thoracic cavity, including gynecological and urological anatomy.
Clinical Performance Data:	No clinical information is required for this submission
Conclusion:	The Image1 SPIES 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.