K131953

DEC 2 0 2013

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 Ave
El Segundo, CA 90245
(424) 218-8379

Contact: Winkie Wong
Regulatory Affairs Specialist

Date of Preparation: Nov. 25, 2013

Device Identification:

Common Name: Endoscopic Video Imaging System/Component

Trade Name: (optional) Image1 SPIES

Device Classification: Endoscopes and accessories
21 CFR 876.1500
Class II

Indications: The Image1 SPIES is a camera control unit (CCU) for use with camera heads or video endoscopes for visualization, image recording and documentation during general endoscopic and microscopic procedures.

Contraindications: No contraindications relating directly to the medical device are currently known. The responsible physician must decide whether the foreseen application is admissible based on the general condition of the patient.

Device Description: The Image1 SPIES (Storz Professional Image Enhancement System) camera control unit is a medical device which consists of an Image1 Connect display module (TC200), and a combination of a minimum of one to a maximum of three camera head input modules that is intended and designed for use during endoscopic procedures. Image1 H3-Link (TC300) and Image1 X-Link (TC301) are available as head input modules. The device's modularity enables customers to customize their Image1 SPIES system to their specific current and future video needs. Descriptions of these three modular devices are provided below.

Image1 Connect (TC200):
The Image1 Connect display module is connected to the head module(s) via an inter-module link cable. The Image1 Connect accepts video from the head module(s) and offers additional functionality such as image capture, image printing, picture-in-picture representation and generation of a digital video output for monitor viewing purposes.

Image1 H3-Link (TC300):
The Image1 H3-Link head module processes raw video signals from the H3 family of camera heads.

Image1 X-Link (TC301)
The Image1 X-Link head module also processes raw video signal from a certain set of imagers housed in a camera head. Visually, the card edge connector receptacle of the X-Link is wider than the receptacle of the H3-Link.

Summary of Technological Characteristics: The Image1 SPIES is a modification of the already cleared Image1 Video Imaging System (K070716). The underlying fundamental technology and intended use remains unchanged. All the changes were made to enhance image quality and to allow printing of an image via the USB printer or storing an image to a USB storage device for documentation purposes. Internal safety and performance testing are performed to ensure the safety and efficacy of the device.

The Image1 SPIES is also substantially equivalent to Fujinon EPX-4440HD Video Processor and Light Source (K102466). Both devices consist of a video processor (CCU) and a keyboard. They also share the same indications for use and fundamental technologies, providing external image storage capability and similar features such as: Brightness Control, Enhancement Control, Light Source Control, White Balance, Zoom and HD Capability. The differences between the subject and predicate devices are the subject device incorporates the KARL STORZ Communication Bus (SCB) system for ease of use and Insufflator Control for user convenience.

Non-Clinical Performance Tests:

The bench testing performed for the subject device demonstrates the continued electrical safety of the device (IEC 60601-1 and IEC 60601-1-2), optical performance which includes white balance, brightness, image enhancement, video output format, zoom, image quality, image capture, latency and interface control as well as the reliability of the software.

Conclusion:
The Karl Storz Image 1 SPIES is substantially equivalent to its predicate devices. The non-clinical testing demonstrates that the device is as safe, as effective and performs as well as or better than the legally marketed devices.

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

December 20, 2013

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

Re: K131953
Trade/Device Name: Image1 SPIES
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscopes and accessories
Regulatory Class: Class II
Product Code: FET
Dated: November 27, 2013
Received: November 29, 2013

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 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,

Elaine Blyskun

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

KARL STORZ—ENDOSKOPE

Indication for Use

510(k) Number (if known): ~~Not yet assigned~~ K131953

Device Name: Image1 SPIES

Indication for use:

The Image1 SPIES is a camera control unit (CCU) for use with camera heads or video endoscopes for visualization, image recording and documentation during general endoscopic and microscopic procedures.

Contraindication:

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Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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)

Elaine Blyskun
for Benjamin Fisher