KARL STORZ—ENDOSKOP

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 El Segundo, CA 90245
Contact:	Leigh Spotten Regulatory Affairs Manager Phone: 424-218-8738
Device Identification:	Trade Name: Karl Storz Flexible Video-Uretero-Renoscope System Common Name: Ureteroscope and Accessories, Flexible Rigid Classification Name: Endoscope and Accessories
Date of Preparation	April 22, 2013
Regulation:	21 CFR 876.1500
Product Code:	FGB
Predicate Devices:	The Karl Storz Flexible Video-Uretero-Renoscope System is substantially equivalent to the ACMI Dur-Digital Ureteroscope and Choledochoscope System (K060269, including the Invisio Digital Controller) and the Karl Storz Imaging , New Camera Architecture (NCA) Video Imaging System (K003325)
Indications For Use:	The Karl Storz Flexible Video-Uretero-Renoscope System is indicated for endoscopic examination in the urinary tract and can be used to examine the interior of the kidney, and using additional accessories, to perform various diagnostic and therapeutic procedures.
Device Description:	The Flexible Video-Uretero-Renoscope System is used for visualization purposes during diagnostic and therapeutic procedures. The crucial components of the system are the Flexible Video-Uretero-Renoscope and the Image 1 HD Camera Control Unit. The Flexible Video-Uretero-Renoscope uses an LED light integrated in the handle and fiber light guides to illuminate the cavity under examination. The video image is produced by a complementary metal–oxide–semiconductor (CMOS) imaging sensor is located at the tip of the insertion shaft. The imaging sensor transfers the video signal to the Image1 HD CCU via electronics in the handle. The Image1 HD CCU processes the sensor images and displays them on a standard SD or HD monitor. The Karl Storz Flexible Video-Uretero-Renoscope System is a Class II device under 21 CFR 876.1500.

Technological Characteristics:

Device Name	Karl Storz Flexible Video-Uretero-Renoscope System (Subject Device)	ACMI DUR-Digital Ureteroscope and Choledochosope System (Predicate) K060269
Digital video technology	CMOS	CMOS
Illumination Source	LED	LED
Field of View (Diagonal)	90	80
Outer Shaft Diameter (mm)	2.9	3.1
Working Length (mm)	700	650
Working Channel Diameter (mm)	1.2	1.2
Up/Down Deflection (°)	Up: 270 Down: 270	Up: 250 Down: 250
Field of View	90^0	80^0
Direction of View	0^0	9^0

Device Name	Image1 HD HUB CCU (Subject Device)	Invisio Digital Controller (Predicate Device) K060269
Brightness Control	Yes	Yes
Enhancement Control (contrast and definition)	Yes	Yes
Shutter Speed	1/60 - 1/17000 sec	1/60 - 1/10000 sec
White Balance	Yes	Yes
Zoom	Yes	Yes
Output Formats	NTSC/PAL/VGA/DVI/SDI	NTSC/PAL/VGA/DVI
Image/Video Capture	Yes	No

Device Name	Image1 HD HUB CCU (Subject Device)	Karl Storz New Camera Architecture CCU (Predicate Device), K003325
Video Format Inputs (Cameras)	SD and HD	SD
Video Format Outputs	SD and HD	SD
Brightness Control	Yes	Yes
Enhancement Control (contrast and definition)	Yes	Yes
Shutter Speed	1/60 - 1/17000 sec	1/60 - 1/17000 sec
White Balance	Yes	Yes
Zoom	Yes	Yes
Output Formats	Analog and Digital NTSC/PAL/VGA/DVI/SDI	Analog - NTSC/PAL/VGA/
Image/Video Capture	Yes (with ICM)	No
Camera Head Configurable	Yes	Yes

Technological Comparison Summary

The Karl Storz Flexible Video-Uretero-Renoscope System is has the same indications for use, methods of operation, design and materials used are either identical or substantially equivalent to existing legally marketed predicate devices.

Non-Clinical Performance Data:

The Karl Storz Flexible Video-Uretero-Renoscope System has been successfully tested for its functions and performance, including verification of optical characteristics per ISO 8600 (image quality,

illumination) and mechanical characteristics (bend, deflection, articulation), leak testing, and insertion testing). Safety testing was performed including electrical safety IEC 60601-1 and IEC 60601-2-18, electromagnetic compatibility per IEC 60601-1-2 and biocompatibility of the patient contacting materials per ISO 10993. Additional validations were conducted for the system software, the manual cleaning method, sterilization process, and sterilant rinsing efficacy.

Conclusion:

The Karl Storz Flexible Video-Uretero-Renoscope System 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

November 26, 2013

Karl Storz Endoscopy America, Inc.
Leigh Spotten
Regulatory Affairs Manager
2151 E. Grand Avenue
El Segunado, CA 90245

Re: K131369
Trade/Device Name: Flexible Video-Uretero-Renoscope System
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FGB
Dated: October 23, 2013
Received: October 25, 2013

Dear Leigh Spotten,

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

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): K131369

Device Name: Flexible Video-Uretero-Renoscope System

Indications for Use:

The Karl Storz Flexible Video-Uretero-Renoscope System is indicated for endoscopic examination in the urinary tract and can be used to examine the interior of the kidney, and using additional accessories, to perform various diagnostic and therapeutic procedures.

Prescription Use X 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)

Herbert P. Lerner -S
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