JAN - 2 2014

510(K) Summary of Safety and Effectiveness

Submitter: KARL STORZ Endoscopy America Inc.			Date of Preparation: **May 8, 2013**
Sponsor Company Name: KARL STORZ Endoscopy America Inc. (KSEA)			**Phone Number:** (424) 218 8322
Street Address: 2151 East Grand Avenue			**Fax Number:** (424) 218 8519
City: El Segundo	**State:** California	**Country:** USA	**Zip Code:** 90245

Prepared By: Shiven Gandhi			
Contact Tittle: Regulatory Submission Specialist			
Email Address: shiven.gandhi@karlstorz.com			
Manufacturing Company Name: Karl Storz Endovision, Inc.			**Establishment Registration Number:** 1221826
Street Address: 91 Carpenter Hill Rd			
City: Charlton	**State/Province:** MA	**Country:** USA	**Zip Code:** 01507
Manufacturing Company Name: Karl Storz Video Endoscopy Estonia			**Establishment Registration Number:** 3004644065
Street Address: Akadeemia Tee 21 A			
City: Tallinn	**State/Province:** Estonia	**Country:** Europe	**Zip Code:** 12618

Classification Name: Cysto Urethroscope

Information about devices to which Substantial Equivalence is claimed:

510 (K) Number	Trade/ Proprietary Name/Model Number	Manufacturer/
K062918	Flexible Video-Urethro-Cystoscope System	Karl Storz GmbH & Co. KG
K945185	Flexible Fiber Optic Cystoscope	Karl Storz GmbH & Co. KG

Introduction:

Device Trade Name:	Flexible CMOS-Video-Cysto-Urethroscope
Classification Name:	Cysto Urethroscope
Regulation Number:	21 CFR 876.1500
Product Code:	FBO

Device Description:

The Flexible CMOS-Video-Cysto-Urethroscope system consists of an endoscope and a monitor. The endoscope is a single device and can be said to be made up of an instrument handle, a shaft and a video connector cable. The handle has three camera control buttons, a deflection control lever and a luer connector to the working channel. An LED located in the handle and is use to provide the illumination for visualization of the anatomy under examination. The light is transmitted from the LED to the distal tip via glass fiber light bundles, where it is used to illuminate the body cavity under examination. The CMOS imaging sensor is located at the distal-tip of the endoscope shaft captures the reflected light and converts it to a standard NTSC video signal. The luer connector and working channel are used as an introduction port for irrigation fluid and endoscopic instruments. The 8402ZX monitor provides visualization of the image being captured by the CMOS chip in the endoscope. During the procedure, the physician can use the control buttons on the monitor to perform functions, such as video and single image capture.

Indication for Use

The flexible CMOS Video-Cysto-Urethroscope is used to provide visualization and operative access during diagnostic and therapeutic endoscopic procedures of the lower urinary tract including the bladder and urethra.

Summary of Substantial Equivalence:

The Flexible CMOS-Video-Cysto-Urethroscope system is substantially equivalent to the existing 510(k) cleared devices on the market i.e. Karl Storz's Video-Urethro-Cystoscope System (K945185 cleared January 17, 2007) and Karl Storz's Flexible Fiber Optic Cystoscope (K062918 cleared May 3, 1995). The indication for use of the Flexible CMOS-Video-Cysto-Urethroscope is identical to the predicate devices. The Flexible CMOS-Video-Cysto-Urethroscope does not incorporate any special technology or characteristics when compared to its predicate devices.

Technological Characteristics:

Parameter	Flexible CMOS-Video-Cysto-Urethroscope (Subject Device)	Flexible Video-Urethro-Cystoscope (Predicate Device)	Flexible Fiber Optic Cystoscope (Predicate Device)
Applicant	KARL STORZ Endoscopy America Inc.	KARL STORZ Endoscopy America Inc.	KARL STORZ Endoscopy America Inc.
510(k) number	Not yet assigned	K062918	K945185
Intended Use	The flexible CMOS Video-Cysto-Urethroscope is used to provide visualization and operative access during diagnostic and therapeutic endoscopic procedures of the lower urinary tract including the bladder and urethra	The Karl Storz Video-Urethro-Cystoscope System is intended for use by physicians in the visual examination and treatment of a variety of urological endoscopic procedures. The Video-Urethro-Cystoscope is intended to provide optical visualization via a video monitor and therapeutic access	Provide visual and operative access during examination, diagnosis and treatment of disorders in the interior of the bladder and urethra.
Imaging technology	CMOS chip at distal tip	CCD chip at distal tip	Fiber optic
Illumination Source	LED	External Light Source	External Light Source
Distal Tip (mm) [Outer Diameter]	5.5	5.5	5.2
Shaft Diameter (mm)	5.3	5.3	5.25
Working Channel Diameter (mm)	2.2	2.2	2.33
Working Length (mm)	370	370	370
Deflection (°)	210 up°/ 140° down	210 up°/ 140° down	210 up°/ 140° down

Performing Testing

Bench testing (non-clinical) were conducted to verify the performance of the Flexible CMOS-Video-Cysto-Urethroscope. Design verification testing was conducted to evaluate the mechanical, optical and illumination performance. Basic safety and performance testing was performed in accordance with IEC 60601-1, IEC 60601-1-2 and IEC 60601-2-18. The Karl Storz flexible CMOS Video-Cysto-Urethroscope was validated for the cleaning instructions provided in the Instruction for Use manual. The Flexible CMOS-Video-Cysto-Urethroscope has been validated for high level disinfection (HLD) with Resert XL and sterilization with STERRAD 100NX to provide a sterility assurance level of 10^{-6}. The device is provided non-sterile. The patient contacting part of the device was evaluated for biocompatibility per ISO 10993-1:2009. The risk analysis was carried out in accordance with established in-house acceptance criteria based on ISO 14971. The software in the monitor of the device was validated as per the Software verification Testing.

Performance standards under section 514 of the Code of Federal Regulations Title 21 have not been developed for this device however the manufacturer complies with the following voluntary standards:

- IEC 60601-1
- IEC 60601-1-2
- IEC 60601-2-18
- ISO 8600-1
- ISO 8600-3
- ISO 8600-4

Testing demonstrated that the device is as safe & effective and performs as well as or better than the predicate devices

Conclusion:

The Karl Storz Flexible CMOS-Video-Cysto-Urethroscope is substantially equivalent to the predicate device mentioned above and the non-clinical performance testing demonstrates that the device is as safe and 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

January 2, 2014

KARL STORZ Endoscopy-America, Inc.
Shiven Gandhi
Regulatory Submission Specialist
2151 E. Grand Avenue
El Segundo, CA 90245

Re: K131364
Trade/Device Name: Flexible CMOS-Video-Cysto-Urethroscope
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FBO
Dated: November 22, 2013
Received: November 25, 2013

Dear Shiven Gandhi,

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,

Benjamin R. Fisher -S

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

Indication for Use

510(k) Number (if known): Not yet assigned K131364

Device Name: Flexible CMOS-Video-Cysto-Urethroscope

Indication for use: The Flexible CMOS Video-Cysto-Urethroscope is used to provide visualization and operative access during diagnostic and therapeutic endoscopic procedures of the lower urinary tract including the bladder and urethra.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801.109 i.e. Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Benjamin R. Fisher -S
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