

12062918

**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.  
600 Corporate Pointe Drive  
Culver City, CA 90230  
(310) 338-8100

JAN 17 2007

**Contact:** Monika Campbell  
Senior Regulatory Affairs Specialist

**Device Identification:** Common Name: Video-Urethro-Cystoscope System  
  
Trade Name: Karl Storz Flexible Video-Urethro  
-Cystoscope System

**Indication:** 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.

**Device Description:** The KARL STORZ Flexible Video-Urethro-Cystoscope System is use of the Video-Urethro-Cystoscope with Karl Storz CCU and Karl Storz Light source. The body contact portions of the Video-Urethro-Cystoscope are composed of materials used in other Karl Storz devices which have a long history of biocompatibility for human use and are commonly used in medical devices for a wide range of applications.

**Substantial Equivalence:** The Karl Storz Video-Urethro-Cystoscope System is substantially equivalent to the predicate devices since the basic features and intended uses are similar. The minor differences between the Karl Storz Video-Urethro-Cystoscope System and the predicate devices raise no new issues of safety and effectiveness, as these differences have no effect on the performance, function or intended use of these devices.

Signature: 

Monika Campbell  
Senior Regulatory Affairs Specialist

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
9200 Corporate Blvd.  
Rockville MD 20850

Ms. Susie Chen  
Director, Regulatory and Legal Affairs  
Karl Storz Endoscopy-America, Inc.  
600 Corporate Point, 5<sup>th</sup> Floor  
CULVER CITY CA 90230

JAN 17 2007

Re: K062918  
Trade/Device Name: Video Urethro-Cystoscope  
Regulation Number: 21 CFR §876.1500  
Regulation Name: Endoscope and accessories  
Regulatory Class: II  
Product Code: FBO  
Dated: January 3, 2007  
Received: January 5, 2007

Dear Ms. Chen:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such 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.



*Protecting and Promoting Public Health*

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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150

or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indication for Use

510(k) Number (if known): K062918

Device Name: Karl Storz Flexible Video-Urethro-Cystoscope System

Indications for Use: 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.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use:  AND/OR Over-The-Counter Use:   
(Per 21 CFR 801.Subpart D) (21 CFR 801 Subpart C)

Nancy Brogdon  
(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices  
510(k) Number K062918