

K970427



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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.
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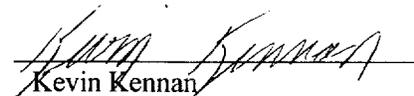
Device Identification: Common Name:
Flexible Urology Scopes

Trade Name: (optional)
Karl Storz Uretero-Reno-Fiberscope and Nephro-Fiberscope

Indication: The KSEA Uretero-Reno-Fiberscope and Nephro-Fiberscope is designed to be used by qualified surgeons and physicians for examination of the upper urinary tract including the ureter and kidney and, using additional accessories, to perform various diagnostic and therapeutic procedures.

Device Description: The KSEA Uretero-Reno-Fiberscope and Nephro-Fiberscope are manually operated surgical devices. The KSEA Uretero-Reno-Fiberscope and Nephro-Fiberscope are flexible fiberoptic telescopes which utilize fiber-optic technology. The body contact portions of the KSEA Intubation Laryngoscope are composed of medical grade polyurethane.

Substantial Equivalence: The KSEA Uretero-Reno-Fiberscope and Nephro-Fiberscope are substantially equivalent to the predicate devices since the basic features, design and intended uses are the same. The minor differences between the KSEA Uretero-Reno-Fiberscope and Nephro-Fiberscope and the predicate devices raise no new issues of safety and effectiveness, as these design differences have no affect on the performance, function or intended use of the devices.

Signed: 
Kevin Kennan
Regulatory Affairs Specialist