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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

MAY - 1 1996

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 are accurate and complete to the best of KSEA's knowledge.

Applicant: Karl Storz Endoscopy - America, Inc.
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K960757

Contact: Betty M. Johnson
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Device Identification: Common Name
Resectoscope
Trade Name
Karl Storz Ureter Resectoscope

Indication: The KSEA ureter resectoscope is designed to be used for diagnostic and therapeutic procedures in the transurethral resection of tissue in the ureters and renal pelvis.

Device Description: The KSEA ureter resectoscope is a manually operated, reusable surgical device consisting of a straight forward view telescope (0°), a working element, a sheath, cutting loops, electrodes, a cold knife and high frequency cables. The instrument is long enough to gain access to the surgical area and is designed to be used as an urological endoscope. The body contact materials are surgical grade stainless steel.

Substantial Equivalence: The KSEA ureter resectoscope is substantially equivalent to the predicate devices since the basic features, design and intended uses are similar. The minor differences in dimensions between the KSEA ureter resectoscope and the predicate devices raise no new issues of safety and effectiveness, as these design differences have no effect on the performance, function or intended use of these devices.

Signed: Betty M. Johnson
Betty M. Johnson
Manager, Regulatory Affairs