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K960323

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

APR 22 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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Contact:

Betty M. Johnson
Manager, Regulatory Affairs

Device Identification:

Common Name
Semi-rigid ureteroscope and accessory

Trade Name
Karl Storz 'Gelet' Uretero-Renoscopes
Karl Storz Alken motion control device

Indication: The KSEA 'Gelet' uretero-renoscopes are designed to view the ureter, and, using additional accessories, to perform various diagnostic and therapeutic procedures. The Alken motion control device attaches to an instrument channel to precisely guide the introduction of a laser fiber, electrode or small instrument into the patient.

Device Description: The KSEA 'Gelet' uretero-renoscopes are semi-rigid endoscopes with graduated shafts and a remote eyepiece. The Alken motion control device is an attachment to the irrigation/instrument channel to control the introduction and movement of accessories. Both devices are manually operated, reusable surgical devices. The body contact materials are chromium plated Monel 400®.

Substantial Equivalence: The KSEA 'Gelet' uretero-renoscopes and the Alken motion control device are substantially equivalent to the predicate devices since the basic features, design and intended uses are the same or similar. The minor differences in dimensions between the KSEA 'Gelet' uretero-renoscopes, the Alken motion control device 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.

Signed: Betty M. Johnson

Betty M. Johnson
Manager, Regulatory Affairs