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K961702

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

AUG 29 1998

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 documents 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
Endoscopic electrodes

Indications: The KSEA vaporization electrodes are intended to be used to cut prostate tissue, superficial bladder tumors, and to cauterize minor bleeding in the prostate and bladder (hemostasis).

Device Description: The KSEA vaporization electrodes are manually operated, single-use instruments which are provided sterile to the end-user. The instruments are long enough to gain access to the surgical area, and are designed to be used as accessories to resectoscopes. The body contact materials have a long history of use in medical devices, and do not pose any new issues of safety and effectiveness.

Substantial Equivalence: The KSEA vaporization electrodes are substantially equivalent to the predicate devices since the basic features, design and intended uses are similar. The minor differences in design and intended uses 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
Manager, Regulatory Affairs

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