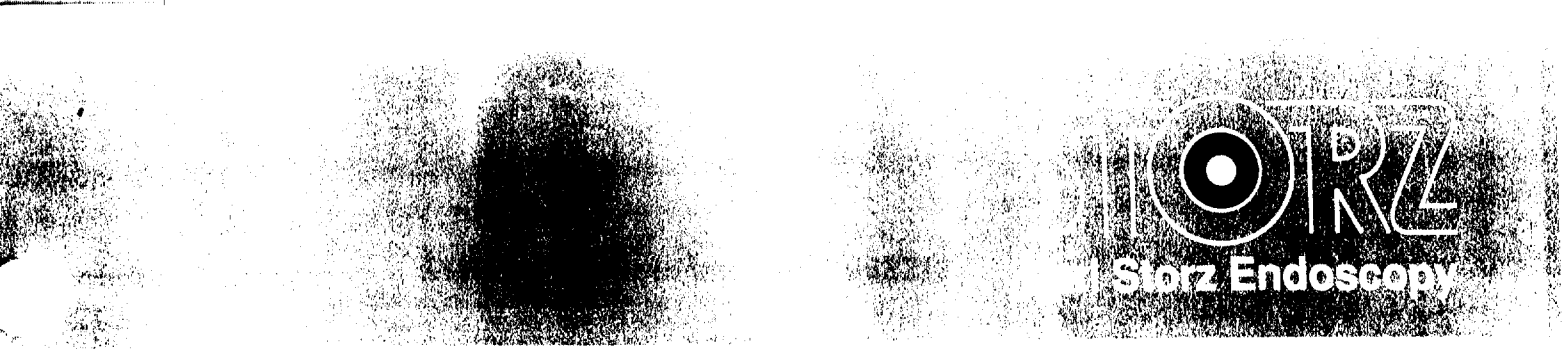

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K962212

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

DEC 13 1996

Applicant:

Karl Storz Endoscopy - America, Inc.
600 Corporate Pointe
Culver City, CA 90230
(310) 558-1500

Contact:

Betty M. Johnson
Manager, Regulatory Affairs

Device Identification:

Common Name
Wire Guide
Trade Name
KSEA Varioguide

Indication: The Karl Storz Frimberger Varioguide is a manually operated surgical designed for placing of bilioduodenal drains (endoprostheses) during endoscopic procedures.

Device Description: The KSEA Frimberger Varioguide is a manually operated, reusable surgical device consisting of a handle, guide, loader and Endo-pusher. The instruments are long enough to gain access to the surgical site. 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 Frimberger Varioguide is substantially equivalent to the predicate devices since the basic features, design and intended uses are the same. The minor differences in design and dimensions between KSEA Frimberger Varioguide 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: Marika Anderson

Marika Anderson
Senior Regulatory Affairs Specialist