



Karl Storz
Endoscopy-America, Inc.

600 Corporate Pointe
Culver City, California 90230-7600
Phone 310 558 1500

Toll Free 800 421 0837
Fax 310 410 5527

K963426

NOV - 7 1996

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.

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

Contact: Marika Anderson
Senior Regulatory Affairs Specialist

Device Identification: **Common Name**
Micro-Laryngoscope
Trade Name
Karl Storz Contact Micro-Laryngoscopes

Indication: The KSEA Contact Micro-Laryngoscopes are intended to visualize the larynx during ENT diagnostic and surgical procedures, utilizing both panoramic vision and tissue contact vision at high magnification.

Device Description: The KSEA Contact Micro-Laryngoscope is a manually operated, reusable surgical device with an assortment of magnifying powers. The Micro-Laryngoscope is long enough to gain access to the surgical site. The body contact materials are surgical grade stainless steel.

Substantial Equivalence: The KSEA Contact Micro-Laryngoscope 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 the KSEA Contact Micro-Laryngoscope 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