Karl Storz
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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:

Betty M. Johnson
Manager, Regulatory Affairs

Device Identification:

Common Name
Fiberscope

Trade Name
Karl Storz intubation fiberscope

Indication: The Karl Storz intubation fiberscope is designed to provide visual access to the larynx and tracheobronchial tree during ENT endoscopic procedures.

Device Description: The Karl Storz intubation fiberscope consists of a focusing ocular lens, a moveable eyepiece, a rigid curved stainless steel shaft that houses the fiber optic imaging and illumination system, a distal objective lens, a channel for insufflation of oxygen, a sliding cap to accommodate endotracheal catheters of various sizes and a connection for a fiber optic light cable.

Substantial Equivalence: The Karl Storz intubation fiberscope is 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 Karl Storz intubation fiberscope 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