K951343

APR 11 1996

SUMMARY OF SAFETY AND EFFECTIVENESS

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

K951343

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 CRF 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.
600 Corporate Pointe
Culver City, CA 90230
(310) 558-1500

Contact:

Betty M. Johnson
Manager, Regulatory Affairs

Device Identification:

Common Name:
fiberoptic endoscopes and accessories

Trade Name (optional):
Karl Storz Semi-Rigid Micro-Endoscopes and Accessories

Indication: The Karl Storz Semi-Rigid Micro-Endoscopes and Accessories are designed to allow viewing of, and access to, the surgical site during endoscopic gynecological surgical procedures.

Device Description: Karl Storz Semi-Rigid Micro-Endoscopes are straight-shafted, fiberoptic endoscopes. Accessories are available for use with the Micro-Endoscopes, including forceps, scissors, probes, trocars, cannulae, and needles. The body contact materials present in these devices are commonly used in medical devices for a wide range of applications, and have a long history of biocompatability for human use.

Substantial Equivalence: The Karl Storz Semi-Rigid Micro-Endoscopes and Accessories for endoscopic gynecological surgery are substantially equivalent to the predicate devices, since the basic features, design and intended uses are the same. The minor differences between the Karl Storz Semi-Rigid Micro-Endoscopes and Accessories for Endoscopic Gynecological Surgery 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 the devices.

Signed: Betty M. Johnson

Betty M. Johnson
Manager, Regulatory Affairs