SEP - 4 1996

K962595

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 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
300W Xenon Light Source

Trade Name
Karl Storz Xenon 300 Light Source for Non-Flash Applications

Indication:

This device is designed to supply light for endoscopic diagnostic and surgical procedures.

Device Description:

This light source is a 300W xenon light source with manually or automatically controlled brightness. This device is not for use with flash photography.

Substantial Equivalence:

The KSEA light source is substantially equivalent to the predicate device, since the basic features, design and intended uses are the same. The minor differences between the Xenon light source and the predicate device 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