K962032

600 Corporate Pointe
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Phone 310-558-1500

JUL - 5 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:

Betty M. Johnson
Manager, Regulatory Affairs

Device Identification:

Common Name
Transilluminator

Trade Name
Karl Storz Universal Twin Transilluminator
Karl Storz Universal Fiber Optic Twin Transilluminator

Indication: The Karl Storz Universal Twin Transilluminator and Universal Fiber Optic Twin Transilluminator are designed to transilluminate sinus tissue during ENT procedures.

Device Description: The Karl Storz Universal Twin Transilluminator and Universal Fiber Optic Twin Transilluminator are manual, reusable, nonsterile medical devices. The body contact materials of these devices have a long history of biocompatibility with medical devices.

Substantial Equivalence: The Karl Storz Universal Twin Transilluminator and Universal Fiber Optic Twin Transilluminator are 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 Karl Storz Universal Twin Transilluminator and Universal Fiber Optic Twin Transilluminator 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
Regulatory Affairs Specialist