K962881

# 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 is accurate and complete to the best of KSEA's knowledge.

**Applicant:**

Karl Storz Endoscopy - America, Inc.
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(310) 558-1500

OCT 22 1996

**Contact:**

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Regulatory Affairs Specialist

**Device Identification:**

Common Name:
Culdocentesis Set

Trade Name: (optional)
KSEA Culdocentesis Set

**Indication:** The KSEA Culdocentesis Set are intended for use by qualified surgeons or physicians in the collection of peritoneal fluid.

**Device Description:** The KSEA Culdocentesis Set are manual reusable surgical devices (with two single-use disposable components). The KSEA Culdocentesis Set provides a high success rate in the collection of peritoneal fluid, while minimizing the problems of conventional culdocentesis. The body contact materials are surgical grade stainless steel, PTFE, and polyurethane. The non-body contact materials of the Culdocentesis Set are silicone, polyolefin, and PVC.

**Substantial Equivalence:** The KSEA Culdocentesis for collection of peritoneal fluid are substantially equivalent to the predicate devices since the basic features, design and intended uses are similar. The minor differences in design and dimensions between the KSEA Culdocentesis Set 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: _____

Kevin Kennan
Regulatory Affairs Specialist