

KEB 3949

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

DEC 19 1996

Contact: Kevin Kennan
Regulatory Affairs Specialist

Device Identification: **Common Name:**
Suction/irrigation Pump

Trade Name: (optional)
Karl Storz Unimat Plus

Indication: The Karl Storz Unimat Plus system is designed to provide irrigation and aspiration of the surgical site during gynecologic laparoscopic surgical procedures.

Device Description: The Karl Storz Unimat Plus and accessories is a membrane type irrigation/aspiration pump with fixed irrigation/aspiration flow rate of 3.5 liters/min. and a maximum irrigation pressure of 400 mm Hg.

Substantial Equivalence: The Karl Storz Unimat Plus system is substantially equivalent to the predicate devices since the basic features and intended uses are similar. The minor differences between the Karl Storz Unimat Plus 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:



Kevin Kennan
Regulatory Affairs Specialist