

Karl Storz
Endoscopy, Inc.

600 Corporate Pointe
Culver City, California 90230-7600
Phone 310 558 1500

Toll Free 800 421 0837
Fax 310 410 1527

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

JUL 17 1995

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

K 954982

Contact: Betty M. Johnson
Manager, Regulatory Affairs

Device Identification: Common Name
Fetal Blood Sampler

Trade Name
Karl Storz Scalp Blood Collection Set

Indication: The KSEA Scalp Blood Collection Set is intended to draw blood from the fetal scalp during obstetric endoscopic procedures.

Device Description: The KSEA Scalp Blood Collection Set is a manually operated, reusable surgical device consisting of handle, blade holder and tubing. The instrument is long enough to gain access to the surgical area and is designed to be used as an accessory to an endoscope. The body contact materials are surgical grade stainless steel and medical grade PVC.

Substantial Equivalence: The KSEA Scalp Blood Collection Set is 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 KSEA Scalp Blood Collection 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: _____

Betty M. Johnson
Betty M. Johnson
Manager, Regulatory Affairs

000027