Karl Storz
Endoscopy-America, Inc.

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

Toll Free 800 421 0837
Fax 310 410 5527

K960486

OCT 25 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
Infusion Pump

Trade Name
KSEA Model 383320 20 Angiomat

Indication: The KSEA model 383320 20 Angiomat pump is designed to provide a clear field of view during percutaneous and intra-operative endoscopy of the peripheral vascular system. Please consult your angioscope manual for specific indications and contraindications for use.

Device Description: The KSEA model 383320 20 Angiomat for endoscopy of the peripheral vascular system is a microprocessor-based infusion pump, with user adjustable flow rates and pressure adjustment. The unit incorporates a wide variety of safety features including: bubble detection, pressure monitoring, volume monitoring and flow control. The Angiomat has two operating modes and also incorporates a bolus infusion function.

Substantial Equivalence: The KSEA model 383320 20 Angiomat for endoscopy of the peripheral vascular system is substantially equivalent to the predicate devices since the basic features, design and intended uses are similar. The minor differences between the KSEA Angiomat 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: Renate A. MacLaren

Renate A. MacLaren, Ph.D.
Regulatory Affairs Specialist