

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

K961091

OCT - 3 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  
Fluid Monitoring System

Trade Name  
Karl Storz Model 203020 20 Equimat

**Indication:** The Karl Storz model 203020 20 Equimat system is designed to monitor the inflow and outflow of irrigation fluid from the uterus during endoscopic surgical procedures in gynecology.

**Device Description:** The Karl Storz model 203020 20 Equimat is a microprocessor controlled monitoring device designed to be used in conjunction with irrigation/aspiration systems to monitor the volume of irrigation fluid flowing into and out of the uterus during endoscopic surgical procedures in gynecology.

**Substantial Equivalence:** The Karl Storz model 203020 20 Equimat system for gynecology is substantially equivalent to the predicate devices since the basic features, design and intended uses are similar. The minor differences between the Karl Storz Equimat 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: \_\_\_\_\_

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

000005