

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

1K955756

**510(k) SUMMARY OF SAFETY AND EFFECTIVENESS**

NOV 26 1996

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**  
Laparoscopic Thermocoagulator accessories

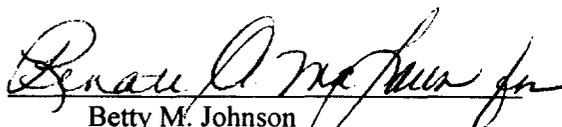
**Trade Name**  
Karl Storz Thermocoagulator accessories

**Indication:** The KSEA thermocoagulation accessories are designed to thermally coagulate tissue during laparoscopic surgical procedures in gynecology.

**Device Description:** The KSEA thermocoagulator accessories are manually operated, reusable surgical devices consisting of a point coagulator, crocodile forceps and a myoma enucleator. The instruments are long enough to gain access to the surgical area and are designed to be used as accessories to laparoscopes. The body contact materials are surgical grade stainless steel.

**Substantial Equivalence:** The KSEA thermocoagulator accessories are 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 thermocoagulator accessories 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  
Manager, Regulatory Affairs

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