Karl Storz
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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 CRF 807.92. All data included in this documents 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
gynecologic electrocautery generator

Trade Name (optional)
KSEA Thermocoagulator (model 265100 20)

Indication: The KSEA Thermocoagulator is intended to be used for the laparoscopic treatment of endometriosis, coagulation of biopsy sites, hemostasis, coagulation of blood vessels and separation of adhesions.

Device Description: The KSEA Thermocoagulator is composed of a generator unit, a footswitch, a cord to connect the unit to a power supply, and a cord to connect the unit to the thermocoagulation probes. The Thermocoagulator contains no are no patient contact materials. Coagulation time can be set by the end user for 10-70 seconds, and the instrument temperature can be set by the end user for 70-130°C. The safety features include a number of audio signals and alarms.

Substantial Equivalence: The KSEA Thermocoagulator (model 265100 20) is substantially equivalent to the predicate devices since the basic features, design and intended uses are the same. The minor differences between the KSEA Thermocoagulator 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 this device.

Signed: _____

Betty M. Johnson
Manager, Regulatory Affairs