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 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 Insufflator

Trade Name
Karl Storz Model 264305 20 Electronic Endoflator

Indication: The Karl Storz Model 264305 20 Electronic Endoflator is designed to facilitate the use of laparoscopes by distending the abdomen with CO_2 gas during laparoscopic surgical and diagnostic procedures.

Device Description: The Karl Storz Model 264305 20 Electronic Endoflator for laparoscopy is a microprocessor controlled insufflator system with a maximum gas flow rate of 20 liters per minute. The insufflation pressure is user adjustable between 0 and 30 mmHg. The safety features include acoustic and visual alarms for overpressure, negative pressure and low gas supply.

Substantial Equivalence: The Karl Storz Model 264305 20 Electronic Endoflator for laparoscopy is substantially equivalent to the predicate devices since the basic features, design and intended uses are the same. The minor differences between the KSEA Endoflator 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

Betty M. Johnson
Manager, Regulatory Affairs