K955972

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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:

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DEC - 6 1996

Contact:

Betty M. Johnson
Manager, Regulatory Affairs

Device Identification:

Common Name
Laparoscopic Insufflator

Trade Name (optional)
KSEA Thermoflator (model 26 4320 20)

Indication:
This device is designed to carefully deliver large flow rates for rapid insufflation, and monitor the amounts of CO_2 gas needed to establish and maintain proper distention of the peritoneal cavity during Ob/Gyn laparoscopic surgical and diagnostic procedures

Device Description:
The KSEA Thermoflator (model 26 4320 20) is a microprocessor-based system, with gas output that is user adjustable from 0-30 liters/minute, and pressure that is user adjustable from 0-30 mmHg. The unit uses contemporary technology in pressure and flow-sensing, and incorporates a wide variety of safety features.

Substantial Equivalence:
The KSEA Thermoflator (model 26 4320 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 Thermoflator (model 26 4320 20) and the predicate device raise no new issues of safety and effectiveness, as these design differences have no effect on the performance, function or intended use of the devices.

Signed: Betty M. Johnson

Betty M. Johnson
Manager, Regulatory Affairs