Karl Storz
Endoscopy-America, Inc.
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JUN 14 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
Laparoscopic bipolar accessories

Trade Name
Karl Storz Remorgida forceps

Indication: The Karl Storz Remorgida forceps are designed to grasp, coagulate and cut tissue during laparoscopic surgical procedures, including but not limited to laparoscopic separation of adhesions, laparoscopically assisted colon resection, laparoscopic appendectomy and Nissen fundoplication.

Device Description: The Karl Storz Remorgida forceps are a manually operated, reusable surgical device. The instrument features two pairs of forceps in a bipolar configuration and a retractable surgical knife. The device is long enough to gain access to the surgical area and is designed to be used as an accessory to a laparoscope. The body contact materials are surgical grade stainless steel and PEEK.

Substantial Equivalence: The Karl Storz Remorgida forceps 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 Karl Storz Remorgida forceps 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: Renate A. MacLaren

Renate A. MacLaren, Ph.D.
Regulatory Affairs Specialist

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