

K960791

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.
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Contact: Betty M. Johnson
Manager, Regulatory Affairs

Device Identification: Common Name
Bronchoscopic cutting loop

Trade Name
Karl Storz Huzly high-frequency cutting loops

Indication: The KSEA Huzly high-frequency cutting loops are designed to remove various pathologies of the bronchi and/or esophagus using high-frequency electrical current during ENT endoscopic surgical procedures.

Device Description: The KSEA Huzly high-frequency cutting loops are manually operated, reusable surgical devices consisting of a bronchoscope tube with a cutting loop and connection for a high-frequency cord. The Huzly high-frequency cutting loops are available in both adult and pediatric sizes, which are long enough to gain access to the surgical area. The body contact materials are surgical grade stainless steel and tungsten.

Substantial Equivalence: The KSEA Huzly high-frequency cutting loops are substantially equivalent to the predicate devices since the basic features, design and intended uses are the same or similar. The differences in features and dimensions between the KSEA Huzly high-frequency cutting loops 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 these devices.

Signed: Betty M. Johnson
Betty M. Johnson
Manager, Regulatory Affairs

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