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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

K961605

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
Hysteroscope, Flexible
Fiber Optic Endoscope, Flexible
Fiberscope, Flexible
Hysterofiberscope
Trade Name
Karl Storz 10.5 Fr. Flexible Hysteroscope

Indication: The KSEA flexible hysteroscope is intended for hysteroscopy.

Device Description: The KSEA 10.5 Fr. flexible hysteroscope is a manually operated, reusable surgical device consisting of a flexible fiberscope with working channel. The instrument is long enough to gain access to the uterus.

Substantial Equivalence: The KSEA 10.5 Fr. flexible hysteroscope is 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 KSEA 10.5 Fr. flexible hysteroscope 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: Betty M. Johnson
Betty M. Johnson
Manager, Regulatory Affairs

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