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K961244

MAY - 7 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 documents 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
arthroscopes
knives
dilators
sheaths
obturators
retractor with guiding tube

Indication: These devices are indicated for use in endoscopic carpal ligament release.

Device Description: The KSEA arthroscopes for use in endoscopic carpal ligament release are straight-shafted, rod-lens telescopes. Accessories are available for use with the arthroscopes include sheaths, obturators, knives, dilators, and a retractor with guiding tube. The body contact materials present in these devices are commonly used in medical devices for a wide range of applications, and have a long history of biocompatibility for human use.

Substantial Equivalence: The KSEA instruments for endoscopic carpal ligament release are substantially equivalent to the predicate devices, since the basic features, design and intended uses are the same. The minor differences between the KSEA instruments for the endoscopic treatment of carpal tunnel syndrome 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 the devices.

Signed:


Betty M. Johnson
Manager, Regulatory Affairs

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