

Karl Storz
Endoscopy, Inc.
600 Corporate Pointe
Culver City, California 90230-7600
Phone 310 558-1500

Toll Free 800 421 0837
Fax 310 558-1527

K961713

MAY 3 | 1996

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

The 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
Arthroscope, Arthroscopic forceps, cannulae, sheaths, dilation rods, dilation sheaths, Trephine, Spinal Needles, Curettes

Trade Name
Karl Storz Arthroscopes, Karl Storz Arthroscopic forceps, Karl Storz cannulae and sheaths, Karl Storz dilation rods and dilation sheaths, Karl Storz puncture needles, Karl Storz trephines, Karl Storz curettes

Indication: The KSEA instrument set for arthroscopic percutaneous discectomy is designed to be used to visualize and treat vertebral disc herniations in the lumbar region of the spine using a posterolateral approach and fluoroscopic control.

Device Description: The KSEA instrument set for arthroscopic percutaneous discectomy are manually operated, reusable surgical devices consisting of arthroscopes, forceps, cannulae, sheaths, dilation rods, dilation sheaths, trephines, puncture needles and curettes. The instruments are long enough to gain access to the surgical area and are designed to be used as accessories to arthroscopes. The body contact materials are surgical grade stainless steel or chrome plated brass.

Substantial Equivalence: The KSEA instrument set for arthroscopic percutaneous discectomy procedures are substantially equivalent to the predicate devices since the basic features, design and intended uses are similar. The minor differences in design and dimensions between the KSEA instruments 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