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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

K961228

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.

OCT 10 1996

Applicant:

Karl Storz Endoscopy - America, Inc.
600 Corporate Pointe
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(310) 558-1500

Contact:

Marika Anderson
Senior Regulatory Affairs Specialist

Device Identification:

Common Name
Arthroscope
Trade Name
Karl Storz Magnifying Arthroscope

Indication: The KSEA magnifying arthroscopes and accessories are intended for use by qualified surgeons during arthroscopic procedures of the small and large joints. Specific arthroscope models are intended for arthroscopic procedures of the shoulder and knee; arthroscopic procedures of the elbow, ankle, wrist and jaw; and arthroscopic procedures for the shoulder, knee and illumination and visualization of the hip joint to diagnose disease and for the removal of loose bodies in the hip joint".

Device Description: The KSEA magnifying arthroscopes are manually operated, reusable surgical devices consisting of a rigid arthroscope with a ring for adjusting the magnification of the image The arthroscopes are long enough to gain access to the surgical site. The body contact materials are surgical grade stainless steel.

Substantial Equivalence: The KSEA magnifying arthroscopes and accessories 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 KSEA magnifying arthroscopes 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: Marika Anderson

Marika Anderson
Senior Regulatory Affairs Specialist