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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
Surgical Arthroscopic Blade

Trade Name
Karl Storz Slotted Whisker Arthroscopic Blade

Indication: The KSEA Slotted Whisker Arthroscopic Blade is designed to provide controlled shaving, abrading, debridement or cutting of tissue during arthroscopic surgical procedures in both large joints (shoulder, hip, and knee) and small joints (elbow, wrist, ankle and TMJ), including debridement in patellar chondromalacia and smoothing of meniscal edges, the glenoid labrum, or rotator cuff.

Device Description: The KSEA Slotted Whisker Arthroscopic Blade is sold as a sterile, single use device. The blade is long enough to gain access to the surgical area and is designed to be used as an accessory to arthroscopes. The body contact materials of the blades are surgical grade stainless steel.

Substantial Equivalence: The KSEA Slotted Whisker Arthroscopic Blade 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 Slotted Whisker Arthroscopic Blade 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

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