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 is accurate and complete to the best of KSEA's knowledge.

Applicant:

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K962396

Contact:

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Device Identification:

Common Name:
Bipolar Forceps

Trade Name: (optional)
KSEA Bipolar Coagulating Forceps

Indication: The KSEA Bipolar Coagulating Forceps for endoscopic and non-endoscopic ENT surgery are designed to be used with high frequency electrical current to coagulate tissue during endoscopic and non-endoscopic ENT surgical procedures.

Device Description: The KSEA Bipolar Coagulating Forceps are manual reusable surgical devices. The KSEA Bipolar Coagulating Forceps are long enough to gain access to the surgical area and are designed to be used as accessories to endoscopes. The body contact material is surgical grade stainless steel. The Bipolar Coagulating Forceps are insulated with commonly used materials.

Substantial Equivalence: The KSEA Bipolar Coagulating Forceps for endoscopic and non endoscopic ENT surgical 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 Bipolar Coagulating Forceps 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: Kevin Kennan

Kevin Kennan
Regulatory Affairs Specialist