

K003994 KSEA UNIDRIVE II/II PLUS AND ENT ACCESSORIESApr 13, 2001
108 days to decisionK003994 · Product code: **ERL** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k003994/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Drill, Surgical, Ent (electric Or Pneumatic) Including Handpiece (ERL)
Date received	Dec 26, 2000
Decision date	Apr 13, 2001
Days to decision	108 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	KARL STORZ Endoscopy-America, Inc.
Location	Mchenry, IL, US
Contact	JAMES A LEE
510(k) history	361 submissions · 361 cleared · 1980-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k003994/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 15, 2026