

K053262 KSEA UNIDRIVE ENT/NEURO/OMFS SYSTEM AND ACCESSORIESDec 19, 2005
27 days to decisionK053262 · Product code: ERL · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k053262/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Drill, Surgical, Ent (electric Or Pneumatic) Including Handpiece (ERL)
Date received	Nov 22, 2005
Decision date	Dec 19, 2005
Days to decision	27 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k053262/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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