

K944476 APEX UNIVERSAL DRIVE SYSTEMNov 18, 1994
67 days to decisionK944476 · Product code: **ERL** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k944476/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Drill, Surgical, Ent (electric Or Pneumatic) Including Handpiece (ERL)
Date received	Sep 12, 1994
Decision date	Nov 18, 1994
Days to decision	67 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Linvatec Corp.
Location	Research Triangle Pa, NC, US
Contact	CAROL A WEIDEMAN
510(k) history	93 submissions · 87 cleared · 1992-2009

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k944476/> 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 14, 2026