

K964548 APEX UNIVERSAL DRIVE SYSTEMJan 17, 1997
65 days to decisionK964548 · Product code: **ERL** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k964548/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Drill, Surgical, Ent (electric Or Pneumatic) Including Handpiece (ERL)
Date received	Nov 13, 1996
Decision date	Jan 17, 1997
Days to decision	65 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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