

K932163 BLOM-SINGER VOICE PROSTHESIS FLUSHING PIPETDec 15, 1993
225 days to decisionK932163 · Product code: **EWL** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k932163/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Laryngeal (taub) (EWL)
Date received	May 4, 1993
Decision date	Dec 15, 1993
Days to decision	225 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Helix Medical, Inc.
Location	Santa Barbera, CA, US
Contact	CHRISTINE EMANUEL
510(k) history	14 submissions · 14 cleared · 1989-2002

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k932163/> 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 26, 2026