

**K991587 BLOM-SINGER INDWELLING 2000 VOICE
PROSTHESIS**Jun 25, 1999
49 days to decisionK991587 · Product code: **EWL** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k991587/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Laryngeal (taub) (EWL)
Date received	May 7, 1999
Decision date	Jun 25, 1999
Days to decision	49 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k991587/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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