

**K945287 INHEALTH BLOM-SINGER INDWELLING VALVED
INSERT ACCESSORY DEVICE**Dec 9, 1994
39 days to decisionK945287 · Product code: **EWL** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k945287/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Laryngeal (taub) (EWL)
Date received	Oct 31, 1994
Decision date	Dec 9, 1994
Days to decision	39 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k945287/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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