

**K945288 INHEALTH BLOM-SINGER INDWELLING PLUG INSERT
ACCESSORY DEVICE**Dec 2, 1994
32 days to decisionK945288 · Product code: **EWL** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k945288/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Laryngeal (taub) (EWL)
Date received	Oct 31, 1994
Decision date	Dec 2, 1994
Days to decision	32 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/k945288/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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