

**K930105 BLOM-SINGER LOW PRESSURE VOICE  
PROSTHESIS,P.I.D.S.**May 17, 1993  
126 days to decisionK930105 · Product code: **EWL** · Ear, Nose, Throat  
Source: <https://www.510kdatabase.net/k930105/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Laryngeal (taub) (EWL)
Date received	Jan 11, 1993
Decision date	May 17, 1993
Days to decision	126 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k930105/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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