

**K904729 BLOM-SINGER SHOWER GUARD**Feb 28, 1991  
134 days to decisionK904729 · Product code: **EWL** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k904729/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Laryngeal (taub) (EWL)
Date received	Oct 17, 1990
Decision date	Feb 28, 1991
Days to decision	134 days
Third-party review	No

**APPLICANT**

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Company	<b>Helix Medical, Inc.</b>
Location	Santa Barbera, CA, US
Contact	ANN KORSAN
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/k904729/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 26, 2026