

**K932120 BLOM-SINGER INDWELLING LOW PRESSURE VOICE  
PROSTHES**Apr 15, 1994  
347 days to decisionK932120 · Product code: **EWL** · Ear, Nose, Throat  
Source: <https://www.510kdatabase.net/k932120/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Prosthesis, Laryngeal (taub) (EWL) |
| Date received         | May 3, 1993                        |
| Decision date         | Apr 15, 1994                       |
| Days to decision      | 347 days                           |
| Third-party review    | No                                 |
| Summary / Statement   | Statement                          |

**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/k932120/> 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