

**K900518 BLOM-SINGER(R) TRACHEOESOPHAGEAL  
PUNCTURE KIT**Jun 14, 1990  
132 days to decisionK900518 · Product code: **EWL** · Ear, Nose, Throat  
Source: <https://www.510kdatabase.net/k900518/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Laryngeal (taub) (EWL)
Date received	Feb 2, 1990
Decision date	Jun 14, 1990
Days to decision	132 days
Third-party review	No

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k900518/>; Data sourced from FDA 510(k) public records (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. - Generated May 26, 2026