

K902112 BLOM-SINGER(R) TRACHEOESOPHAGEAL FISTULA STENTAug 1, 1990
84 days to decisionK902112 · Product code: **EWL** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k902112/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Laryngeal (taub) (EWL)
Date received	May 9, 1990
Decision date	Aug 1, 1990
Days to decision	84 days
Third-party review	No

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k902112/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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