

K082206 BLOM-SINGER DUAL VALVE INDWELLING VOICE PROSTHESIS, MODELS DV-1600 SERIES, DV-2000 SERIESSep 4, 2008
30 days to decisionK082206 · Product code: **EWL** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k082206/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Laryngeal (taub) (EWL)
Date received	Aug 5, 2008
Decision date	Sep 4, 2008
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Helix Medical, LLC
Location	Carpinteria, CA, US
Contact	CYNTHIA ANDERSON
510(k) history	4 submissions · 4 cleared · 2008-2013

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