

K093258 BLOM-SINGER INDWELLING TEP OCCLUDERMar 3, 2010
135 days to decisionK093258 · Product code: **EWL** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k093258/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Laryngeal (taub) (EWL)
Date received	Oct 19, 2009
Decision date	Mar 3, 2010
Days to decision	135 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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