

**K131947 PROVOX VEGA PUNCTURE SET**Oct 18, 2013  
113 days to decisionK131947 · Product code: **EWL** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k131947/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Laryngeal (taub) (EWL)
Date received	Jun 27, 2013
Decision date	Oct 18, 2013
Days to decision	113 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Atos Medical AB</b>
Location	Potomac, MD, US
Contact	FERENC DAHNER
510(k) history	15 submissions · 14 cleared · 1990-2016

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k131947/> 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 24, 2026