

**K092593 PROVOX ACTIVALVE (SIZE 4.5MM, 6MM, 8MM, 10MM, 12.5MM)**Oct 14, 2010  
416 days to decisionK092593 · Product code: **EWL** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k092593/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent - K
Submission type	Traditional
Device classification	Prosthesis, Laryngeal (taub) (EWL)
Date received	Aug 24, 2009
Decision date	Oct 14, 2010
Days to decision	416 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/k092593/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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