

**K043138 PROVOX NID VOICE REHABILITATION SYSTEM,  
MODEL REF 7101 TO 7134**

Nov 22, 2004  
10 days to decision

K043138 · Product code: **EWL** · Ear, Nose, Throat  
Source: <https://www.510kdatabase.net/k043138/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Laryngeal (taub) (EWL)
Date received	Nov 12, 2004
Decision date	Nov 22, 2004
Days to decision	10 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Atos Medical AB</b>
Location	Potomac, MD, US
Contact	EDDY ABERG
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/k043138/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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