

K971244 PROVOX 2 VOICE PROSTHESIS SYSTEMJun 6, 1997
64 days to decisionK971244 · Product code: **EWL** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k971244/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Laryngeal (taub) (EWL)
Date received	Apr 3, 1997
Decision date	Jun 6, 1997
Days to decision	64 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Atos Medical AB
Location	Potomac, MD, US
Contact	EDDY ABERG
510(k) history	15 submissions · 14 cleared · 1990-2016

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