

K141380 PROVOX FREEHANDS FLEXIVOICESep 26, 2014
122 days to decisionK141380 · Product code: **EWL** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k141380/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Laryngeal (taub) (EWL)
Date received	May 27, 2014
Decision date	Sep 26, 2014
Days to decision	122 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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