FDA 510(k) Premarket Notification

K940638 PROVOX(TM) VOICE PROSTHESIS

CLEARED

Jun 22, 1994
128 days to decision

K940638 · Product code: **EWL** · Ear, Nose, Throat
Source: https://www.510kdatabase.net/k940638/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Laryngeal (taub) (EWL)
Date received	Feb 14, 1994
Decision date	Jun 22, 1994
Days to decision	128 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Atos Medical AB**
Location	Potomac, MD, US
Contact	KARL-ERIK KARLSSON
510(k) history	15 submissions · 14 cleared · 1990-2016

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k940638/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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