

**K030016 TEOAE25**Mar 28, 2003  
85 days to decisionK030016 · Product code: **EWO** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k030016/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Audiometer (EWO)
Date received	Jan 2, 2003
Decision date	Mar 28, 2003
Days to decision	85 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

Company	<b>Interacoustics A/S, Assens</b>
Location	Eden Prairie, MN, US
Contact	DANIEL EGGAN
510(k) history	4 submissions · 4 cleared · 2002-2006

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k030016/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 30, 2026