

**K090406 EP15 SOFTWARE MODULE, EP25 SOFTWARE MODULE**

Jul 22, 2009  
155 days to decision

K090406 · Product code: **EWO** · Ear, Nose, Throat  
Source: <https://www.510kdatabase.net/k090406/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Audiometer (EWO)
Date received	Feb 17, 2009
Decision date	Jul 22, 2009
Days to decision	155 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Interacoustics AS</b>
Location	Minnesota, MN, US
Contact	HANNE NIELSEN
510(k) history	4 submissions · 4 cleared · 2005-2009

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k090406/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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