

**K083597 SONOWAND INVITE**Sep 25, 2009  
294 days to decisionK083597 · Product code: **HAW** · Neurology  
Source: <https://www.510kdatabase.net/k083597/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Neurological Stereotaxic Instrument (HAW)
Date received	Dec 5, 2008
Decision date	Sep 25, 2009
Days to decision	294 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Sonowand AS</b>
Location	Ne, MN, US
Contact	CONSTANCE G BUNDY
510(k) history	2 submissions · 2 cleared · 2009-2012

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k083597/> 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 15, 2026