

**K010388 SONDREX P.A.L. SYSTEM**Dec 11, 2001  
306 days to decisionK010388 · Product code: **HCC** · Neurology  
Source: <https://www.510kdatabase.net/k010388/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Biofeedback (HCC)
Date received	Feb 8, 2001
Decision date	Dec 11, 2001
Days to decision	306 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Ohmeda Medical</b>
Location	Madison, WI, US
Contact	ALBERTO F PROFUMO
510(k) history	120 submissions · 118 cleared · 1984-2013

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k010388/> 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 May 14, 2026