

**K031097 POLARIS PRESSURE ADJUSTABLE VALVE SYSTEM  
MODES SPV, SPVA, SPVB**Feb 26, 2004  
325 days to decisionK031097 · Product code: **JXG** · Neurology  
Source: <https://www.510kdatabase.net/k031097/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Shunt, Central Nervous System And Components (JXG)
Date received	Apr 7, 2003
Decision date	Feb 26, 2004
Days to decision	325 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Sophysa SA</b>
Location	Wellesley, MA, US
Contact	JACQUELINE E MASSE
510(k) history	9 submissions · 9 cleared · 2000-2017

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k031097/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated June 1, 2026