

**K992465 SOPHY SU8 PRESSURE ADJUSTABLE VALVE**Sep 21, 2000  
426 days to decisionK992465 · Product code: **JXG** · Neurology  
Source: <https://www.510kdatabase.net/k992465/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Shunt, Central Nervous System And Components (JXG)
Date received	Jul 23, 1999
Decision date	Sep 21, 2000
Days to decision	426 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Sophysa SA</b>
Location	Wellesley, MA, US
Contact	JACQUELINE 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/k992465/> 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 1, 2026