

**K090342 POLARIS PRESSURE ADJUSTABLE VALVE, MODELS
SPV, SPVA, SPVB, SPV-140, SPV-300, SPV-400**Aug 11, 2009
182 days to decisionK090342 · Product code: **JXG** · Neurology
Source: <https://www.510kdatabase.net/k090342/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Shunt, Central Nervous System And Components (JXG)
Date received	Feb 10, 2009
Decision date	Aug 11, 2009
Days to decision	182 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sophysa SA
Location	Wellesley, MA, US
Contact	ESTHER SALTZ
510(k) history	9 submissions · 9 cleared · 2000-2017

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k090342/> Data sourced from FDA 510(k) public records (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. - Generated June 1, 2026