

**K013488 SOPHY PRESSURE ADJUSTABLE VALVE SYSTEM  
MODEL SM8**Mar 27, 2002  
159 days to decisionK013488 · Product code: **JXG** · Neurology  
Source: <https://www.510kdatabase.net/k013488/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Shunt, Central Nervous System And Components (JXG)
Date received	Oct 19, 2001
Decision date	Mar 27, 2002
Days to decision	159 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/k013488/> 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