

**K090022 PARADIS VASO SHIELD**Apr 20, 2009  
105 days to decisionK090022 · Product code: **OMR** · CardiovascularSource: <https://www.510kdatabase.net/k090022/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent - U
Submission type	Traditional
Device classification	Vessel Guard Or Cover (OMR)
Date received	Jan 5, 2009
Decision date	Apr 20, 2009
Days to decision	105 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Spinemedica, LLC</b>
Location	Marietta, GA, US
Contact	SALLY THORSEN
510(k) history	2 submissions · 0 cleared · 2009-2009

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k090022/> 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 21, 2026