

**K100984 XYLOS VESSEL GUARD**Jul 7, 2010  
90 days to decisionK100984 · Product code: **OMR** · Cardiovascular  
Source: <https://www.510kdatabase.net/k100984/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent - U
Submission type	Traditional
Device classification	Vessel Guard Or Cover (OMR)
Date received	Apr 8, 2010
Decision date	Jul 7, 2010
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Xylos Corporation</b>
Location	Washington, DC, US
Contact	JOYCE ELKINS
510(k) history	9 submissions · 8 cleared · 1998-2011

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k100984/> 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 18, 2026