

**K013022 SULZER VASCUTEK GELWEAVE VALSALVA  
VASCULAR PROSTHESIS**Jun 13, 2002  
279 days to decisionK013022 · Product code: **DSY** · Cardiovascular  
Source: <https://www.510kdatabase.net/k013022/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Vascular Graft, Of 6mm And Greater Diameter (DSY)
Date received	Sep 7, 2001
Decision date	Jun 13, 2002
Days to decision	279 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Sulzer Carbomedics, Inc.</b>
Location	Austin, TX, US
Contact	LISA PETERSON
510(k) history	8 submissions · 8 cleared · 1998-2002

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k013022/> 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 July 3, 2026