

**K002007 SULZER VASCUTEK GELSOFT ERS VASCULAR PROSTHESIS**Jan 25, 2001  
206 days to decisionK002007 · Product code: **DSY** · Cardiovascular  
Source: <https://www.510kdatabase.net/k002007/>**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	Jul 3, 2000
Decision date	Jan 25, 2001
Days to decision	206 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 O'CONNOR
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/k002007/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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