

**K121532 HERO GRAFT**Jun 22, 2012  
29 days to decisionK121532 · Product code: **DSY** · Cardiovascular  
Source: <https://www.510kdatabase.net/k121532/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Vascular Graft, Of 6mm And Greater Diameter (DSY)
Date received	May 24, 2012
Decision date	Jun 22, 2012
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Hemosphere, Inc.</b>
Location	Eden Prarie, MN, US
Contact	LAURIE LYNCH
510(k) history	3 submissions · 3 cleared · 2009-2012

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k121532/> 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 14, 2026