

K120006 HERO GRAFTFeb 2, 2012
30 days to decisionK120006 · Product code: **DSY** · Cardiovascular
Source: <https://www.510kdatabase.net/k120006/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Vascular Graft, Of 6mm And Greater Diameter (DSY)
Date received	Jan 3, 2012
Decision date	Feb 2, 2012
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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