

K091491 HERO VASCULAR ACCESS DEVICEJul 31, 2009
72 days to decisionK091491 · Product code: **DSY** · Cardiovascular
Source: <https://www.510kdatabase.net/k091491/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Vascular Graft, Of 6mm And Greater Diameter (DSY)
Date received	May 20, 2009
Decision date	Jul 31, 2009
Days to decision	72 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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