

K050049 DYNAFLO BYPASS GRAFTJan 31, 2005
21 days to decisionK050049 · Product code: **DSY** · Cardiovascular
Source: <https://www.510kdatabase.net/k050049/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Vascular Graft, Of 6mm And Greater Diameter (DSY)
Date received	Jan 10, 2005
Decision date	Jan 31, 2005
Days to decision	21 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bard Peripheral Vascular, Inc.
Location	Tempe, AZ, US
Contact	GLENN NORTON
Website	https://www.bd.com
510(k) history	34 submissions · 30 cleared · 2004-2026

Bard Peripheral Vascular, Inc. is a medical device manufacturer based in Tempe, Arizona. The company specializes in cardiovascular and surgical devices for minimally invasive procedures. FDA 510(k) regulatory activity spans from 2004 to 2026. The company has received FDA 510(k) clearances from total submissions. Cardiovascular devices represent a dominant category, including PTA balloons, atherectomy systems, and vascular access solutions. The company remains actively engaged in device development, with the latest clearance in 2026. Recent cleared devices reflect expertis...

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