

**K161986 SIDEKICK and USHER Support Catheters**Aug 4, 2016  
16 days to decisionK161986 · Product code: **DQY** · Cardiovascular  
Source: <https://www.510kdatabase.net/k161986/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Percutaneous (DQY)
Date received	Jul 19, 2016
Decision date	Aug 4, 2016
Days to decision	16 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Bard Peripheral Vascular, Inc.</b>
Location	Tempe, AZ, US
Contact	Melanie Hadlock
Website	<a href="https://www.bd.com">https://www.bd.com</a>
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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