

**K093286 POWERCROSS .018 OTW PTA DILATION CATHETER**Nov 13, 2009  
24 days to decisionK093286 · Product code: LIT · Cardiovascular  
Source: <https://www.510kdatabase.net/k093286/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Angioplasty, Peripheral, Transluminal (LIT)
Date received	Oct 20, 2009
Decision date	Nov 13, 2009
Days to decision	24 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ev3, Inc.</b>
Location	Plymouth, MN, US
Contact	SARA BAKKER
510(k) history	35 submissions · 26 cleared · 2003-2014

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k093286/> 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 6, 2026