

**K001577 OUTBACK CATHETER**Jan 11, 2001  
234 days to decisionK001577 · Product code: **DQY** · Cardiovascular  
Source: <https://www.510kdatabase.net/k001577/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	May 22, 2000
Decision date	Jan 11, 2001
Days to decision	234 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Lumend, Inc.</b>
Location	Redwood City, CA, US
Contact	PHIL HOPPER
510(k) history	11 submissions · 11 cleared · 2001-2005

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k001577/> 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 July 3, 2026