

K014117 MODIFICATION TO OUTBACK CATHETERJan 11, 2002
28 days to decisionK014117 · Product code: **DQY** · CardiovascularSource: <https://www.510kdatabase.net/k014117/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Percutaneous (DQY)
Date received	Dec 14, 2001
Decision date	Jan 11, 2002
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k014117/> Data sourced from FDA 510(k) public records (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. - Generated July 3, 2026