

K043534 MODIFICATION TO OUTBACK CATHETERJan 21, 2005
30 days to decisionK043534 · Product code: **DQY** · CardiovascularSource: <https://www.510kdatabase.net/k043534/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Percutaneous (DQY)
Date received	Dec 22, 2004
Decision date	Jan 21, 2005
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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