

K031005 LUMEND FRONTRUNNER GW CTO CATHETERJun 18, 2003
79 days to decisionK031005 · Product code: **PDU** · CardiovascularSource: <https://www.510kdatabase.net/k031005/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter For Crossing Total Occlusions (PDU)
Date received	Mar 31, 2003
Decision date	Jun 18, 2003
Days to decision	79 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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