FDA 510(k) Premarket Notification

K033535 LUMEND FRONTRUNNER CTO CATHETER AND ACCESSORIES

CLEARED

Jan 7, 2004
58 days to decision

K033535 · Product code: **PDU** · Cardiovascular
Source: https://www.510kdatabase.net/k033535/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter For Crossing Total Occlusions (PDU)
Date received	Nov 10, 2003
Decision date	Jan 7, 2004
Days to decision	58 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