FDA 510(k) Premarket Notification

K023223 MODIFICATION TO LUMEND FRONTRUNNER CTO CATHETER

CLEARED

Oct 24, 2002
27 days to decision

K023223 · Product code: **DQY** · Cardiovascular
Source: https://www.510kdatabase.net/k023223/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Percutaneous (DQY)
Date received	Sep 27, 2002
Decision date	Oct 24, 2002
Days to decision	27 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