FDA 510(k) Premarket Notification

K014117 MODIFICATION TO OUTBACK CATHETER

CLEARED

Jan 11, 2002
28 days to decision

K014117 · Product code: **DQY** · Cardiovascular
Source: 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