FDA 510(k) Premarket Notification

K001577 OUTBACK CATHETER

CLEARED

Jan 11, 2001
234 days to decision

K001577 · Product code: **DQY** · Cardiovascular
Source: https://www.510kdatabase.net/k001577/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	May 22, 2000
Decision date	Jan 11, 2001
Days to decision	234 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