FDA 510(k) Premarket Notification

K032298 MODIFICATION TO OUTBACK CATHETER

CLEARED

Aug 26, 2003
32 days to decision

K032298 · Product code: **DQY** · Cardiovascular
Source: https://www.510kdatabase.net/k032298/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Percutaneous (DQY)
Date received	Jul 25, 2003
Decision date	Aug 26, 2003
Days to decision	32 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