FDA 510(k) Premarket Notification

K965247 ENVOY GUIDING CATHETER

CLEARED

Jul 23, 1997
211 days to decision

K965247 · Product code: **DQY** · Cardiovascular
Source: https://www.510kdatabase.net/k965247/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Dec 24, 1996
Decision date	Jul 23, 1997
Days to decision	211 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Cordis Neurovascular, Inc.**
Location	Miami Lakes, FL, US
Contact	JODI FRASIER
510(k) history	37 submissions · 37 cleared · 1994-2008