FDA 510(k) Premarket Notification

K983791 PERIPHERAL RETROGRADE CARDIAPLEGIA CANNULA

CLEARED

Jun 11, 1999
227 days to decision

K983791 · Product code: **DWF** · Cardiovascular
Source: https://www.510kdatabase.net/k983791/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Cannula And Tubing, Vascular, Cardiopulmonary Bypass (DWF)
Date received	Oct 27, 1998
Decision date	Jun 11, 1999
Days to decision	227 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Edwards Lifesciences Research Medical**
Location	Midvale, UT, US
Contact	JOHN W SMITH
510(k) history	6 submissions · 6 cleared · 1998-2008