FDA 510(k) Premarket Notification

K990396 T-ANASTAFLO

CLEARED

Oct 1, 1999
234 days to decision

K990396 · Product code: **DWF** · Cardiovascular
Source: https://www.510kdatabase.net/k990396/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Cannula And Tubing, Vascular, Cardiopulmonary Bypass (DWF)
Date received	Feb 9, 1999
Decision date	Oct 1, 1999
Days to decision	234 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