FDA 510(k) Premarket Notification

K013593 CARDEON AEGIS CATHETER

CLEARED

Jun 24, 2002
237 days to decision

K013593 · Product code: **DWF** · Cardiovascular
Source: https://www.510kdatabase.net/k013593/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Cannula And Tubing, Vascular, Cardiopulmonary Bypass (DWF)
Date received	Oct 30, 2001
Decision date	Jun 24, 2002
Days to decision	237 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Cardeon Corp.**
Location	Cupertino, CA, US
Contact	JANE BEGGS
510(k) history	6 submissions · 6 cleared · 2000-2004