FDA 510(k) Premarket Notification

K133151 SARNS HIGH FLOW AORTIC ARCH CANNULA

CLEARED

Feb 3, 2014
109 days to decision

K133151 · Product code: **DWF** · Cardiovascular
Source: https://www.510kdatabase.net/k133151/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Cannula And Tubing, Vascular, Cardiopulmonary Bypass (DWF)
Date received	Oct 17, 2013
Decision date	Feb 3, 2014
Days to decision	109 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Terumo Cardiovascular Systems Corp.**
Location	Elkton, MD, US
Contact	GARRY A COURTNEY
510(k) history	43 submissions · 43 cleared · 2000-2015