FDA 510(k) Premarket Notification

K140569 ANTEGRADE CARDIOPLEGIA CANNULA(N-TYPE)

CLEARED

Nov 19, 2014
258 days to decision

K140569 · Product code: **DWF** · Cardiovascular
Source: https://www.510kdatabase.net/k140569/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Cannula And Tubing, Vascular, Cardiopulmonary Bypass (DWF)
Date received	Mar 6, 2014
Decision date	Nov 19, 2014
Days to decision	258 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Maquet Cardiopulmonary, AG**
Location	Fairfield, IA, US
Contact	SARAH BETZ
510(k) history	44 submissions · 44 cleared · 2005-2015