

K162215 Aortic Arch Cannulae, Optiflow Aortic Arch CannulaeJun 16, 2017
312 days to decisionK162215 · Product code: **DWF** · Cardiovascular
Source: <https://www.510kdatabase.net/k162215/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Cannula And Tubing, Vascular, Cardiopulmonary Bypass (DWF)
Date received	Aug 8, 2016
Decision date	Jun 16, 2017
Days to decision	312 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sorin Group Italia S.R.L.
Location	Mirandola, IT
Contact	Luigi Vecchi
510(k) history	61 submissions · 61 cleared · 1995-2026

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