

K240193 R501 - R502 aortic root cannulae with and without vent line (R501-15: R501-20: R501-26. R502-15

Feb 22, 2024
29 days to decision

K240193 · Product code: **DWF** · Cardiovascular
Source: <https://www.510kdatabase.net/k240193/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Cannula And Tubing, Vascular, Cardiopulmonary Bypass (DWF)
Date received	Jan 24, 2024
Decision date	Feb 22, 2024
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	R502-20: R502-26)

APPLICANT

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