K200612 R501 aortic root cannula without vent line, R502 aortic root cannula with vent line

CLEARED

Nov 17, 2020
253 days to decision

K200612 · Product code: **DWF** · Cardiovascular
Source: https://www.510kdatabase.net/k200612/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Cannula And Tubing, Vascular, Cardiopulmonary Bypass (DWF)
Date received	Mar 9, 2020
Decision date	Nov 17, 2020
Days to decision	253 days
Third-party review	No
Combination product	No
PCCP authorized	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