

**K250150 VANGUARD Blood cardioplegia Systems (Vanguard 4:1 Blood cardioplegia set)**May 30, 2025  
129 days to decisionK250150 · Product code: DTR · Cardiovascular  
Source: <https://www.510kdatabase.net/k250150/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Heat-exchanger, Cardiopulmonary Bypass (DTR)
Date received	Jan 21, 2025
Decision date	May 30, 2025
Days to decision	129 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	VANGUARD Blood cardioplegia Systems (Vanguard 4:1 Blood cardioplegia set with shunt); VANGUARD Blood cardioplegia Systems (Vanguard 4:1 Blood Cardioplegia Set Mini)

**APPLICANT**

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Company	<b>Sorin Group Italia S.R.L.</b>
Location	Mirandola, IT
Contact	Martina Carlini
510(k) history	61 submissions · 61 cleared · 1995-2026

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