

**K240934 Quantum Perfusion Blood Oxygenator ECC VT160-E3  
(VT160-E3)**Mar 12, 2026  
706 days to decisionK240934 · Product code: **DTZ** · Cardiovascular  
Source: <https://www.510kdatabase.net/k240934/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	Apr 5, 2024
Decision date	Mar 12, 2026
Days to decision	706 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Quantum Perfusion Blood Oxygenator ECC VT200-E3 (VT200-E3); Quantum Perfusion Blood Oxygenator VT75- E3 (VT75- E3);

**APPLICANT**

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Company	<b>Spectrum Medical S.R.L.</b>
Location	Mirandola, IT
Contact	Raffaella Tommasini
510(k) history	6 submissions · 6 cleared · 2024-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k240934/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated May 14, 2026