

K241206 Quantum Perfusion Hybrid SystemJul 18, 2024
79 days to decisionK241206 · Product code: **DTN** · CardiovascularSource: <https://www.510kdatabase.net/k241206/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reservoir, Blood, Cardiopulmonary Bypass (DTN)
Date received	Apr 30, 2024
Decision date	Jul 18, 2024
Days to decision	79 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k241206/> Data sourced from FDA 510(k) public records (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. - Generated May 14, 2026