

**K252541 Quantum PureFlow Standard Heat Exchanger Medium
Flow 1/4 W**Mar 12, 2026
212 days to decisionK252541 · Product code: **DTR** · Cardiovascular
Source: <https://www.510kdatabase.net/k252541/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Heat-exchanger, Cardiopulmonary Bypass (DTR)
Date received	Aug 12, 2025
Decision date	Mar 12, 2026
Days to decision	212 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/k252541/>. 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