

**K231982 Quantum Perfusion Blood Oxygenator VT75-E1,
Quantum Perfusion Blood Oxygenator VT75-E2**Sep 12, 2024
435 days to decisionK231982 · Product code: **DTZ** · Cardiovascular
Source: <https://www.510kdatabase.net/k231982/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	Jul 5, 2023
Decision date	Sep 12, 2024
Days to decision	435 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Qura S.R.L
Location	Mirandola, IT
Contact	Raffaella Tommasini
510(k) history	15 submissions · 15 cleared · 2020-2024

REGULATORY CONSULTANT

Consulting firm	Spectrum Medical S.R.L.
Contact	Raffaella Tommasini

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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