

**K212341 Quantum Perfusion Blood Oxygenator with Integrated AF and Sensor VT200-C1U, Quantum Perfusion Blood Oxygenator with Integrated AF VT200-C2U, Quantum Perfusion Blood Oxygenator with Integrated AF and Sensor VT160-C1U, Quantum Perfusion Blood Oxygenator with Integrated AF VT160-C2U**

Jan 28, 2022  
184 days to decision

K212341 · Product code: DTZ · Cardiovascular  
Source: <https://www.510kdatabase.net/k212341/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	Jul 28, 2021
Decision date	Jan 28, 2022
Days to decision	184 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

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