

**K203424 Quantum Perfusion Blood Oxygenator ECC VT200-E1, Quantum Perfusion Blood Oxygenator ECC VT200-E2, Quantum Perfusion Blood Oxygenator ECC VT160-E1, Quantum Perfusion Blood Oxygenator ECC VT160-E2**Dec 17, 2021  
392 days to decisionK203424 · Product code: DTZ · Cardiovascular  
Source: <https://www.510kdatabase.net/k203424/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	Nov 20, 2020
Decision date	Dec 17, 2021
Days to decision	392 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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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k203424/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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