

K231773 Quantum Perfusion Blood Oxygenator with Integrated AF and Sensor VT75-C1U, Quantum Perfusion Blood Oxygenator with Integrated AF VT75-C2U, 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

Nov 8, 2023
145 days to decision

K231773 · Product code: DTZ · Cardiovascular
Source: <https://www.510kdatabase.net/k231773/>

SUBMISSION DETAILS

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Oxygenator, Cardiopulmonary Bypass (DTZ) |
| Date received | Jun 16, 2023 |
| Decision date | Nov 8, 2023 |
| Days to decision | 145 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 |

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k231773/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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