

**K220110 Quantum PureFlow Standard Heat Exchanger and
Quantum PureFlow Cardioplegia Heat Exchanger**May 6, 2022
113 days to decisionK220110 · Product code: **DTR** · Cardiovascular
Source: <https://www.510kdatabase.net/k220110/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Heat-exchanger, Cardiopulmonary Bypass (DTR)
Date received	Jan 13, 2022
Decision date	May 6, 2022
Days to decision	113 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.netDevice record: <https://www.510kdatabase.net/k220110/> 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 24, 2026