

**K212688 Quantum PureFlow Standard Heat Exchanger,
Quantum PureFlow Cardioplegia Heat Exchanger**Jan 10, 2022
138 days to decisionK212688 · Product code: DTR · Cardiovascular
Source: <https://www.510kdatabase.net/k212688/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Heat-exchanger, Cardiopulmonary Bypass (DTR)
Date received	Aug 25, 2021
Decision date	Jan 10, 2022
Days to decision	138 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

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