

**K223879 Quantum PureFlow Standard Heat Exchangers  
(HX11W-S2, HX11W-S1M and HX11W-S2M)**Apr 13, 2023  
107 days to decisionK223879 · Product code: **DTR** · Cardiovascular  
Source: <https://www.510kdatabase.net/k223879/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Heat-exchanger, Cardiopulmonary Bypass (DTR)
Date received	Dec 27, 2022
Decision date	Apr 13, 2023
Days to decision	107 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Quara S.R.L.</b>
Location	Mirandola, IT
Contact	Raffaella Tommasini
510(k) history	1 submissions · 1 cleared · 2023-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k223879/>. Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 26, 2026