

**K212657 Quantum Heater-Cooler**May 6, 2022  
256 days to decisionK212657 · Product code: **DWC** · CardiovascularSource: <https://www.510kdatabase.net/k212657/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Controller, Temperature, Cardiopulmonary Bypass (DWC)
Date received	Aug 23, 2021
Decision date	May 6, 2022
Days to decision	256 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Spectrum Medical , Ltd.</b>
Location	Gloucester, Gloucestershire, GB
Contact	Colleen Powell
510(k) history	15 submissions · 15 cleared · 2007-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k212657/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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