

**K210669 Quantum Mini Ventilation Module**May 4, 2021  
60 days to decisionK210669 · Product code: **DTX** · CardiovascularSource: <https://www.510kdatabase.net/k210669/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gas Control Unit, Cardiopulmonary Bypass (DTX)
Date received	Mar 5, 2021
Decision date	May 4, 2021
Days to decision	60 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/k210669/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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