

**K181942 Quantum Ventilation Module**Oct 18, 2018  
90 days to decisionK181942 · Product code: **DTX** · CardiovascularSource: <https://www.510kdatabase.net/k181942/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gas Control Unit, Cardiopulmonary Bypass (DTX)
Date received	Jul 20, 2018
Decision date	Oct 18, 2018
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Spectrum Medical , Ltd.</b>
Location	Gloucester, Gloucestershire, GB
Contact	Mark Drain
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/k181942/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 26, 2026