

**K181923 Quantum Workstation 12.1**Aug 17, 2018  
30 days to decisionK181923 · Product code: **DRY** · CardiovascularSource: <https://www.510kdatabase.net/k181923/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Monitor, Blood-gas, On-line, Cardiopulmonary Bypass (DRY)
Date received	Jul 18, 2018
Decision date	Aug 17, 2018
Days to decision	30 days
Third-party review	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/k181923/> 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