

**K110957 M4 MONITOR**May 31, 2011  
56 days to decisionK110957 · Product code: **DRY** · Cardiovascular  
Source: <https://www.510kdatabase.net/k110957/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Blood-gas, On-line, Cardiopulmonary Bypass (DRY)
Date received	Apr 5, 2011
Decision date	May 31, 2011
Days to decision	56 days
Third-party review	Yes
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Spectrum Medical, Llp</b>
Location	Cheltenham, GB
Contact	STEVE TURNER
510(k) history	2 submissions · 2 cleared · 2006-2011

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k110957/> 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 June 19, 2026