

K091908 M3 MONITORJul 10, 2009
15 days to decisionK091908 · Product code: **DRY** · Cardiovascular
Source: <https://www.510kdatabase.net/k091908/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Blood-gas, On-line, Cardiopulmonary Bypass (DRY)
Date received	Jun 25, 2009
Decision date	Jul 10, 2009
Days to decision	15 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	Spectrum Medical , Ltd.
Location	Gloucester, Gloucestershire, GB
Contact	STEVE TURNER
510(k) history	15 submissions · 15 cleared · 2007-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k091908/> Data sourced from FDA 510(k) public records (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. - Generated May 26, 2026