FDA 510(k) Premarket Notification

# K091908 M3 MONITOR

**CLEARED**

Jul 10, 2009
15 days to decision

K091908 · 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, Gloucesterhsire, GB |
| Contact | STEVE TURNER |
| 510(k) history | 15 submissions · 15 cleared · 2007-2025 |