

K163657 Quantum WorkstationJan 18, 2017
26 days to decisionK163657 · Product code: **DRY** · Cardiovascular
Source: <https://www.510kdatabase.net/k163657/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Monitor, Blood-gas, On-line, Cardiopulmonary Bypass (DRY)
Date received	Dec 23, 2016
Decision date	Jan 18, 2017
Days to decision	26 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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