

K202557 Quantum Workstation 12 EliteOct 2, 2020
29 days to decisionK202557 · Product code: **DRY** · Cardiovascular
Source: <https://www.510kdatabase.net/k202557/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Monitor, Blood-gas, On-line, Cardiopulmonary Bypass (DRY)
Date received	Sep 3, 2020
Decision date	Oct 2, 2020
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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