

K192838 Quantumn Centrifugal Drive- High Pressure, Quantum Centrifugal Drive- Medium PressureApr 13, 2020
193 days to decisionK192838 · Product code: **DWA** · Cardiovascular
Source: <https://www.510kdatabase.net/k192838/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Control, Pump Speed, Cardiopulmonary Bypass (DWA)
Date received	Oct 3, 2019
Decision date	Apr 13, 2020
Days to decision	193 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k192838/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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