

K240908 Quantum Micro-Cardioplegia Delivery SystemJul 8, 2025
462 days to decisionK240908 · Product code: **DTR** · Cardiovascular
Source: <https://www.510kdatabase.net/k240908/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Heat-exchanger, Cardiopulmonary Bypass (DTR)
Date received	Apr 2, 2024
Decision date	Jul 8, 2025
Days to decision	462 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Quantum Micro-Cardioplegia Delivery Module (QMCDM)

APPLICANT

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

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