

K190282 Quantum Smart Occluder LH (left-hand), Quantum Smart Occluder LH (right-hand)May 24, 2019
102 days to decisionK190282 · Product code: **DTQ** · Cardiovascular
Source: <https://www.510kdatabase.net/k190282/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Console, Heart-lung Machine, Cardiopulmonary Bypass (DTQ)
Date received	Feb 11, 2019
Decision date	May 24, 2019
Days to decision	102 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/k190282/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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