

K173591 Quantum Diagnostic Module, Quantum Diagnostic Module - No Gas

Mar 28, 2018
127 days to decision

K173591 · Product code: **DRY** · Cardiovascular
Source: <https://www.510kdatabase.net/k173591/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Blood-gas, On-line, Cardiopulmonary Bypass (DRY)
Date received	Nov 21, 2017
Decision date	Mar 28, 2018
Days to decision	127 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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k173591/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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