FDA 510(k) Premarket Notification

CLEARED

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, Gloucesterhsire, GB
Contact	Mark Drain
510(k) history	15 submissions · 15 cleared · 2007-2025