FDA 510(k) Premarket Notification

K181923 Quantum Workstation 12.1

CLEARED

Aug 17, 2018
30 days to decision

K181923 · Product code: **DRY** · Cardiovascular
Source: https://www.510kdatabase.net/k181923/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Monitor, Blood-gas, On-line, Cardiopulmonary Bypass (DRY)
Date received	Jul 18, 2018
Decision date	Aug 17, 2018
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Spectrum Medical , Ltd.**
Location	Gloucester, Gloucesterhsire, GB
Contact	Colleen Powell
510(k) history	15 submissions · 15 cleared · 2007-2025