FDA 510(k) Premarket Notification

K071725 M2 MONITOR

CLEARED

Jul 11, 2007
16 days to decision

K071725 · Product code: **DRY** · Cardiovascular
Source: https://www.510kdatabase.net/k071725/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Blood-gas, On-line, Cardiopulmonary Bypass (DRY)
Date received	Jun 25, 2007
Decision date	Jul 11, 2007
Days to decision	16 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

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