FDA 510(k) Premarket Notification

K141542 NELLCOR PORTABLE SPO2 PATIENT MONITORING SYSTEM (NPSPMS)

CLEARED

Oct 2, 2014
114 days to decision

K141542 · Product code: **DQA** · Anesthesiology
Source: https://www.510kdatabase.net/k141542/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter (DQA)
Date received	Jun 10, 2014
Decision date	Oct 2, 2014
Days to decision	114 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Covidien, LLC**
Location	Mansfield, MA, US
Contact	MIA M WARE
510(k) history	88 submissions · 85 cleared · 2010-2026

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k141542/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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