FDA 510(k) Premarket Notification

K131021 PULSE OXIMETER

CLEARED

Sep 11, 2013
152 days to decision

K131021 · Product code: **DQA** · Anesthesiology
Source: https://www.510kdatabase.net/k131021/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter (DQA)
Date received	Apr 12, 2013
Decision date	Sep 11, 2013
Days to decision	152 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Nonin Medical, Inc.**
Location	White Bear Lake, MN, US
Contact	BRODIE PEDERSEN
510(k) history	50 submissions · 50 cleared · 1986-2024