FDA 510(k) Premarket Notification

K132402 SENSMART MODEL X-100 UNIVERAL OXIMETRY SYSTEM

CLEARED

Feb 21, 2014
204 days to decision

K132402 · Product code: **DQA** · Anesthesiology
Source: https://www.510kdatabase.net/k132402/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter (DQA)
Date received	Aug 1, 2013
Decision date	Feb 21, 2014
Days to decision	204 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