

K211498 Nonin OTC Pulse Oximeter Model 3250Nov 13, 2024
1279 days to decisionK211498 · Product code: **OLK** · Anesthesiology
Source: <https://www.510kdatabase.net/k211498/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pulse Oximeter For Over-the-counter Use (OLK)
Date received	May 14, 2021
Decision date	Nov 13, 2024
Days to decision	1279 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Covance by Labcorp
Contact	Sheila Mena

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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