FDA 510(k) Premarket Notification

CLEARED

K203113 Masimo SedLine Sedation Monitor and Accessories

Feb 25, 2022
498 days to decision

K203113 · Product code: **OLW** · Anesthesiology
Source: https://www.510kdatabase.net/k203113/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Index-generating Electroencephalograph Software (OLW)
Date received	Oct 15, 2020
Decision date	Feb 25, 2022
Days to decision	498 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Masimo Corporation**
Location	Irvine, CA, US
Contact	Sindura Penubarthi
Website	http://www.masimo.com/
510(k) history	84 submissions · 82 cleared · 2004-2025

Masimo Corporation is an American health technology and consumer electronics company headquartered in Irvine, California. The company develops patient monitoring devices, non-invasive sensors, and related software platforms for hospital and home settings. Masimo has received FDA 510(k) clearances from total submissions since its first clearance in 2004. The company's regulatory focus centers on Anesthesiology devices, which represent 74% of submissions. Latest clearance activity in 2025 demonstrates continued regulatory engagement. Recent cleared devices span Anesthesiolo...