FDA 510(k) Premarket Notification

CLEARED

K260880 SedLine Sedation Monitor

Jul 10, 2026
115 days to decision

K260880 · Product code: **OLW** · Anesthesiology
Source: https://www.510kdatabase.net/k260880/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Index-generating Electroencephalograph Software (OLW)
Date received	Mar 17, 2026
Decision date	Jul 10, 2026
Days to decision	115 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Masimo Corporation**
Location	Irvine, CA, US
Contact	Monish Patel
Website	http://www.masimo.com/
510(k) history	86 submissions · 84 cleared · 2004-2026

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...