FDA 510(k) Premarket Notification

K172890 SedLine Sedation Monitor

CLEARED

Jan 26, 2018
126 days to decision

K172890 · Product code: **OLW** · Neurology
Source: https://www.510kdatabase.net/k172890/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Index-generating Electroencephalograph Software (OLW)
Date received	Sep 22, 2017
Decision date	Jan 26, 2018
Days to decision	126 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Masimo Corporation**
Location	Irvine, CA, US
Contact	Matthew Tiacharoen
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...