

K183697 Masimo Rad-97 and AccessoriesMay 15, 2019
135 days to decisionK183697 · Product code: **MWI** · Anesthesiology
Source: <https://www.510kdatabase.net/k183697/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient (without Arrhythmia Detection Or Alarms) (MWI)
Date received	Dec 31, 2018
Decision date	May 15, 2019
Days to decision	135 days
Third-party review	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...
