K212161 Radical-7 Pulse CO-Oximeter and Accessories, Rad-97 and Accessories

CLEARED

Mar 6, 2023
602 days to decision

K212161 · Product code: **MWI** · Anesthesiology
Source: https://www.510kdatabase.net/k212161/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient (without Arrhythmia Detection Or Alarms) (MWI)
Date received	Jul 12, 2021
Decision date	Mar 6, 2023
Days to decision	602 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Masimo Corporation**
Location	Irvine, CA, US
Contact	Katelynn Kirby
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...

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k212161/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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