

K193626 Masimo Rad-97 Pulse CO-Oximeter and AccessoriesAug 10, 2020
228 days to decisionK193626 · Product code: **MWI** · Anesthesiology
Source: <https://www.510kdatabase.net/k193626/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient (without Arrhythmia Detection Or Alarms) (MWI)
Date received	Dec 26, 2019
Decision date	Aug 10, 2020
Days to decision	228 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Masimo Corporation
Location	Irvine, CA, US
Contact	Linus Park
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...
