FDA 510(k) Premarket Notification

CLEARED

K201432 Masimo O3 Regional Oximeter System

Aug 29, 2020
89 days to decision

K201432 · Product code: **MUD** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k201432/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter, Tissue Saturation (MUD)
Date received	Jun 1, 2020
Decision date	Aug 29, 2020
Days to decision	89 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Masimo Corporation**
Location	Irvine, CA, US
Contact	Sindura Penubarthi
Website	http://www.masimo.com/
510(k) history	85 submissions · 83 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...

CLINICAL EVIDENCE - NCT04002960

Desaturation Validation of INVSENSOR00036

Status	Completed
Enrollment	23 patients (actual)
Study sites	1 site
Condition studied	Healthy
Primary purpose	Other
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Jul 5, 2019
Sponsor	Masimo Corporation (Industry)

Primary outcome

Trending Accuracy of INVSENSOR00036

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT04002960