

K214072 Masimo O3 Regional Oximeter SystemMay 6, 2022
130 days to decisionK214072 · Product code: **MUD** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k214072/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter, Tissue Saturation (MUD)
Date received	Dec 27, 2021
Decision date	May 6, 2022
Days to decision	130 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Masimo Corporation
Location	Irvine, CA, US
Contact	Kertana Shankar
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...

CLINICAL EVIDENCE - NCT04584788**Validation of the O3 Regional Somatic Tissue Oxygenation Monitor**

Status	Completed
Enrollment	37 patients (actual)
Study sites	1 site
Condition studied	Oxygen Deficiency
Primary purpose	Other
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Jun 2, 2021
Sponsor	Masimo Corporation (Industry)

Primary outcome**Accuracy of O3 Sensor by ARMS Calculation of Percent rSO2**Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT04584788