FDA 510(k) Premarket Notification

K232389 Carescape SpO2 - Masimo

CLEARED

Sep 7, 2023
29 days to decision

K232389 · Product code: **DQA** · Anesthesiology
Source: https://www.510kdatabase.net/k232389/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Oximeter (DQA)
Date received	Aug 9, 2023
Decision date	Sep 7, 2023
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Masimo rainbow SET IntelliVue

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...