FDA 510(k) Premarket Notification

CLEARED

K223498 Radius VSM and Accessories

Jun 1, 2023
192 days to decision

K223498 · Product code: **MHX** · Cardiovascular
Source: https://www.510kdatabase.net/k223498/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Nov 21, 2022
Decision date	Jun 1, 2023
Days to decision	192 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 - NCT04676152

Validation of Noninvasive Blood Pressure Device

Status	Completed
Enrollment	106 patients (actual)
Study sites	2 sites
Condition studied	Healthy; Hypertension; Hypotension
Primary purpose	Other
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Nov 2, 2020
Sponsor	Masimo Corporation (Industry)

Primary outcome

Mean and Standard Deviation of Differences Between Masimo NIBP Device and Manual Sphygmomanometer Measurements.

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT04676152