

K173976 Masimo Acoustic Respiration Sensors, infant and neonateSep 5, 2018
250 days to decisionK173976 · Product code: **BZQ** · Anesthesiology
Source: <https://www.510kdatabase.net/k173976/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Monitor, Breathing Frequency (BZQ)
Date received	Dec 29, 2017
Decision date	Sep 5, 2018
Days to decision	250 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Masimo Corporation
Location	Irvine, CA, US
Contact	Karina Simpson
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...

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Device record: <https://www.510kdatabase.net/k173976/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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