

K242001 Philips VSC-MEDlibApr 4, 2025
269 days to decisionK242001 · Product code: **BZQ** · Anesthesiology
Source: <https://www.510kdatabase.net/k242001/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Breathing Frequency (BZQ)
Date received	Jul 9, 2024
Decision date	Apr 4, 2025
Days to decision	269 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Philips Medical Systems Nederland B.V.
Location	Best, NL
Contact	David Boser
510(k) history	103 submissions · 102 cleared · 2005-2026

CLINICAL EVIDENCE - NCT06140433**Vital Signs Camera Study**

Status	Completed - <i>No results published to ClinicalTrials.gov</i>
Enrollment	94 patients (actual)
Study sites	1 site
Condition studied	Respiration Rate; Heart Rate
Primary purpose	Screening
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Mar 15, 2024
Sponsor	Philips Clinical & Medical Affairs Global (Industry)

Primary outcome

Clinical safety and effectiveness VSC-MEDlib according to IFU

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT06140433