

K243687 Vital SignsAug 27, 2025
271 days to decisionK243687 · Product code: **QME** · CardiovascularSource: <https://www.510kdatabase.net/k243687/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Software For Optical Camera-based Measurement Of Pulse Rate, Heart Rate, Breathing Rate, And/or Respiratory Rate (QME)
Date received	Nov 29, 2024
Decision date	Aug 27, 2025
Days to decision	271 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Oxehealth Limited
Location	Abingdon, GB
Contact	John Kemeny
510(k) history	6 submissions · 5 cleared · 2021-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k243687/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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