

K251200 Vital Signs

Feb 2, 2026
290 days to decision

K251200 · Product code: **QME** · Cardiovascular
Source: <https://www.510kdatabase.net/k251200/>

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	Apr 18, 2025
Decision date	Feb 2, 2026
Days to decision	290 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
