

**K211906 Vital Signs**Jul 20, 2021  
29 days to decisionK211906 · Product code: **QME** · Cardiovascular  
Source: <https://www.510kdatabase.net/k211906/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Software For Optical Camera-based Measurement Of Pulse Rate, Heart Rate, Breathing Rate, And/or Respiratory Rate (QME)
Date received	Jun 21, 2021
Decision date	Jul 20, 2021
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Oxehealth Limited</b>
Location	Abingdon, GB
Contact	Hugh Lloyd-Jukes
510(k) history	6 submissions · 5 cleared · 2021-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k211906/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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