FDA 510(k) Premarket Notification

K211906 Vital Signs

CLEARED

Jul 20, 2021
29 days to decision

K211906 · Product code: **QME** · Cardiovascular
Source: https://www.510kdatabase.net/k211906/

SUBMISSION DETAILS

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

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