August 27, 2025

Oxehealth Limited
John Kemeny
Head of Compliance
Bee House, 140 Eastern Ave
Milton Park
Abingdon, OX14 4SB
United Kingdom

Re: K243687
Trade/Device Name: Vital Signs
Regulation Number: 21 CFR 870.2785
Regulation Name: Software For Optical Camera-Based Measurement Of Pulse Rate, Heart Rate, Breathing Rate, And/Or Respiratory Rate
Regulatory Class: Class II
Product Code: QME
Dated: July 23, 2025
Received: July 28, 2025

Dear John Kemeny:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

JENNIFER W. SHIH -S

Jennifer Kozen
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics, and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K243687

Please provide the device trade name(s).

Vital Signs

Please provide your Indications for Use below.

The Vital Signs device is intended for noninvasive spot measurement of pulse rate and breathing rate when the subject is still. It is software assessing video footage from a fixed-installation solution for use within single occupancy rooms within hospitals, general care and secured environments with professional healthcare oversight and where a framework exists which mandates periodic checks by a trained professional to ensure subject safety.
The system is intended for use by appropriately trained staff and should not be used by untrained users.
The Vital Signs device is indicated for use on subjects 12 years of age or older who do not require critical care or continuous vital signs monitoring.
The device is not intended to be the sole method of checking the physical health of a subject.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

Vital Signs

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR 807.92.

General information

Submitter's Name:	John Kemeny
Address:	Oxehealth Limited Bee House 140 Eastern Avenue, Milton Park Oxfordshire OX14 4SB, UK
Phone:	+44 (0) 1865 900 599
Contact Person:	John Kemeny
Email:	john.kemeny@oxehealth.com

Date Prepared:	22 August 2025

Device Information

Trade name:	Vital Signs
Common Name:	Vital Signs
Address of Sponsor:	Oxehealth Limited Bee House 140 Eastern Avenue, Milton Park Oxfordshire OX14 4SB, UK
Classification Name:	QME, Biofeedback device, 21 CFR 870.2785
Predicate Device:	Vital Signs - K211906

Indication for Use: The Vital Signs device is intended for noninvasive spot measurement of pulse rate and breathing rate when the subject is still. It is software assessing video footage from a fixed-installation solution for use within single occupancy rooms within hospitals, general care, and secured environments with professional healthcare oversight and where a framework exists which mandates periodic checks by a trained professional to ensure subject safety.

The system is intended for use by appropriately trained staff and should not be used by untrained users.

The Vital Signs device is indicated for use on subjects 12 years of age or older, who do not require critical care or continuous vital signs monitoring.

The device is not intended to be the sole method of checking the physical health of a subject.

Device Description: The subject device is the next generation device of the predicate (K211906). Vital Signs is a software-only medical device (SaMD) that provides retrospective monitoring of non-contact pulse rate and respiratory rate data derived from video, without the need for contact devices to be attached to the patient or bed.

The device consists of custom-designed software assessing video footage collected using off-the-shelf cameras installed within single occupancy rooms within hospitals, general care and secured environments. Proprietary software-controlled algorithms are used to derive patient spot heart rate and respiratory rate data from the analysis of this video data, once the user has followed a workflow to initiate the system's data analysis.

Improvements to the device compared to the predicate are as follows:

- 24 hour trends
- Expansion of intended population from 18 years and older → 12 years and older
- Widened respiratory rate range from 8-31 bpm → 8-39 bpm

Technological Characteristics and Comparison:

The subject device algorithm is identical to the predicate device. It uses the same methods of Vital sign detection and the same Machine Learning techniques as the predicate device (K211906). It also uses the same processing, pipeline, storage, management and display/interface components, and image processing as the predicate device. The subject device is substantially equivalent to the Vital signs device (K211906).

Non Clinical Performance

Since the device is SaMD using off-the-shelf image acquisition and data processing equipment, no EMC or electrical safety testing has been performed.

Since the device has no patient contacting parts, no biocompatibility or mechanical safety testing has been performed.

Oxehealth have reviewed the FDA's database of recognized consensus standards and has consequently applied the following standards to the development of the device:

- ISO 14971:2019 + A11:2021 - Application of risk management to medical devices
- AAMI BS 34971:2022 - Application of risk management to Artificial Intelligence and Machine Learning Devices
- IEC 62304:2006 + A1:2015 - Software life cycle processes
- IEC 82304-1:2016 - Health software
- IEC 80001-1:2021 - Application of risk management for IT-networks incorporating medical devices — Part 1: Safety, effectiveness and security in the implementation and use of connected medical devices or connected health software
- IEC 81001-5-1:2021 - Health software and health IT systems safety, effectiveness and security — Part 5-1: Security — Activities in the product life cycle
- IEC/TR 80002-1:2009 - Medical device software — Part 1: Guidance on the application of ISO 14971 to medical device software
- IEC 62366-1:2015 +A1:2020 - Application of risk management to medical devices
- ISO 15223-1:2021 - Medical devices — Symbols to be used with information to be supplied by the manufacturer
- ISO 20417:2021 Symbols to be used with information to be supplied by the manufacturer

The firm has also performed penetration and vulnerability testing in line with FDA's guidance on cybersecurity.

Substantial equivalence

	Subject device	Predicate	Equivalence
Trade Name	Vital Signs	Vital Signs	
Submission reference	K243687	K211906	
Sponsor	Oxehealth Limited	Oxehealth Limited	*Identical*
Intended Use	Vital Sign monitoring	Vital Sign monitoring	*Identical*
Primary Product Code	QME	QME	*Identical*
Primary Regulation	21 CFR 870.2785	21 CFR 870.2785	*Identical*

Intended Use	The Vital Signs device is intended for noninvasive spot measurement of pulse rate and breathing rate when the subject is still. It is software assessing video footage from a fixed-installation solution for use within single occupancy rooms within hospitals, general care and secured environments with professional healthcare oversight and where a framework exists which mandates periodic checks by a trained professional to ensure subject safety. The system is intended for use by appropriately trained staff, and should not be used by untrained users. The device is not intended to be the sole method of checking the physical health of a subject.	The Oxehealth Vital Signs device is intended for noninvasive spot measurement of pulse rate and estimated breathing rate (chest wall movements) when the subject is still. It is software assessing video footage from a fixed-installation solution for use within single occupancy rooms within hospitals, general care and secured environments with professional healthcare oversight and where a framework exists which mandates periodic checks by a trained professional to ensure subject safety. The Oxehealth system is intended for use by appropriately trained staff with a duty of care, and should not be used by untrained users. The device is not intended to be the sole method of checking the physical health of a subject.	*Substantially equivalent to the predicate device*
Intended use population	Subjects 12 years of age or older.	Adults 18 years of age and over.	*Substantially equivalent; no new questions of safety and effectiveness based on clinical validation testing in the intended population*
Intended use environment	Single occupancy rooms within hospitals, general care and secured environments.	Single occupancy rooms within hospitals, general care and secured environments.	*Identical*
Patient Worn Device	No	No	*Identical*
Device outputs	Spot measurement of heart rate and respiratory rate	Spot measurement of heart rate and breathing rate (chest wall movements)	*Substantially equivalent; respiratory rate output validated against gold standard*
Reporting	User operates User Interface to view and/or export reports of vital sign trends in electronic form (.PDF).	None	*Substantially equivalent*
Design/Principle of operation	SaMD device using OTS hardware. Measures movement, and physiological sign data using an optical sensor (camera - contactless).	SaMD device using OTS hardware. Measures movement, and physiological sign data using an optical sensor (camera - contactless).	*Identical*

Clinical Validation	Accuracy Pulse rate measurement 50 to 130 ± 3 beats per minute Respiratory rate measurement 8 to 39 ± 2 breaths per minute	Accuracy Pulse rate measurement 50 to 130 ± 3 beats per minute Breathing rate measurement 8 to 31 ± 2 breaths per minute	*Substantially equivalent; widened respiratory rate range was clinically validated against the gold standard in the intended population.*
Commercial distribution	Prescription use.	Prescription use.	*Identical*
Technological Characteristics			
Software Components	The Vital Signs Device is installed in standard, off-the-shelf computers to retrieve collected data from the off-the-shelf video and generate reports based on collected data.	The Vital Signs Device is installed in standard, off-the-shelf computers to retrieve collected data from the off-the-shelf video and generate reports based on collected data.	*Substantially Equivalent. Subject device Vital Signs Trends not available in the predicate device. No new questions of safety and effectiveness.*
Hardware components	The Vital Signs Device is a software-only medical device (SaMD) supported by off-the-shelf hardware.	The Vital Signs Device is a software-only medical device (SaMD) supported by off-the-shelf hardware.	*Identical*
Data Collection method	Data collection is from an off-the shelf video camera, collecting continuously.	Data collection is from an off-the shelf video camera, collecting continuously.	*Identical*
Recording Time	24 hours	N/A	*The Vital sign trends feature has a record time of 24 hours*
Data Recording Unit to PC Interface	The software is connected directly to the camera over structured network cabling	The software is connected directly to the camera over structured network cabling	*Identical*
User Interface	Application developed by the manufacturer, installed on OTS computer or mobile device. Installed by the manufacturer with no other applications in the operating environment.	Application developed by the manufacturer, installed on OTS computer or mobile device. Installed by Oxehealth with no other applications in the operating environment.	*Identical*

Table 1: Summary substantial equivalence summary between the subject device and the predicate

Clinical Performance 30 subjects representative of the intended population were dually monitored with both the subject device and reference devices for pulse rate and respiratory rate validation (FDA-cleared finger pulse oximeter and

capnogram respectively). Subjects performed a variety of activities reflecting real-world behavior, under a variety of environmental conditions similar to those expected in the intended environment. The subjects validated the entire claimed RR range using metronome breathing.

The capnogram output was manually-annotated by a physician blinded to both device outputs, which is the accepted gold standard for respiratory rate validation.

The study results demonstrated acceptable accuracy in all subgroups based on age, sex, Fitzpatrick skin tone, and BMI.

- The heart rate MAE is found to be significantly (P-value <= 0.05) less than three beats per minute;
- The respiratory rate MAE is found to be significantly (P-value <= 0.05) less than two breaths per minute.

All of the different subgroups were within the stated performance metrics of the device (±2 breaths per minute or ±3 beats per minute) for both the MAD and 95% CI. Therefore, the performance of the subject device is substantially equivalent to the predicate and meets the stated performance of the subject device over the extended age range and measurement ranges.

All performance endpoints have been met, which substantiate the claim of substantial equivalence to the predicate device.

Conclusions

The new data presented here demonstrate that the Vital Signs device is accurate against its designed accuracy targets (±3 bpm for pulse rate and ±2 breaths/min for respiratory rate) against gold standard reference data, under realistic conditions, for:

- Adolescents (ages 12-17) performing realistic activities;
- Adults performing realistic activities;
- Adolescents and adults exhibiting elevated respiratory rates up to 39 breaths/min.

Based on the comparison to the predicate devices and performance characteristics, the subject Vital Signs device is substantially equivalent to the currently U.S. legally marketed device Oxehealth Vital Signs predicate (K211906).