February 2, 2026

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

Re: K251200
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: December 19, 2025
Received: December 29, 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K251200

Device Name
Vital Signs

Indications for Use *(Describe)*
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 Oxehealth Vital Signs device is indicated for use on humans 18 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.

Type of Use *(Select one or both, as applicable)*

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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 Eastern Avenue, Milton Oxfordshire OX14 4SB, UK
Phone:	+44 (0) 1865 900 599
Contact Person:	John Kemeny
Email:	john.kemeny@oxehealth.com

Date Prepared:	30 Jan 2026

Device Information

Trade name:	Vital Signs
Common Name:	Vital Signs
Address of Sponsor:	Oxehealth Limited Bee House Eastern Avenue, Milton Oxfordshire OX14 4SB, UK
Classification Name:	QME, Software for optical camera-based measurement of pulse rate, heart rate, breathing rate, and/or respiratory rate, 21 CFR 870.2785
Predicate Device:	Vital Signs - K211906

Indication for Use: 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 Oxehealth Vital Signs device is indicated for use on humans 18 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: Vital Signs is a software-only medical device (SaMD) that provides non-contact pulse rate and breathing rate (chest wall movements) 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 breathing rate data from the analysis of this video data, once the user has followed a workflow to initiate the system's data analysis.

Technological Characteristics and Comparison:

The subject device is substantially equivalent to the Vital signs device (K211906) as this predicate device is a direct predecessor to the subject device.

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 recognised 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:

The substantial equivalence analysis can be seen in 27. VS.DOC.748 - Oxevision Vital Signs Device 510(k) - Substantial Equivalence document. In summary the device is substantially equivalent to the predicate device (K211906), with the difference being that the device is to run on Ubuntu operating system rather than CentOS to ensure ongoing state of the art with regards to security and vulnerability protection.

Conclusions

Based on the comparison to the predicate devices and performance characteristics, the Oxevision Vital Signs is substantially equivalent to the currently legally marketed device Oxevision Vital Signs predicate for the US (K211906).