July 20, 2021

Oxehealth Limited
Hugh Lloyd-Jukes
Chief Executive Officer
Magdalen Centre North, The Oxford Science Park
Oxford, OX4 4GA
United Kingdom

Re: K211906
Trade/Device Name: Oxehealth 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: June 17, 2021
Received: June 21, 2021

Dear Hugh Lloyd-Jukes:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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 Shih
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)*
K211906

Device Name
Oxehealth 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.

510(k) SUMMARY

Oxehealth's modified Vital Signs software medical device

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Submitter's Name: Hugh Lloyd-Jukes

Address: Magdalen Centre North
The Oxford Science Park
Oxford
OX4 4GA
UK

Phone: +44 1865 900599

Facsimile: None

Contact Person: Hugh Lloyd-Jukes

Date Prepared: June 17 2021

Name of Device and Name/Address of Sponsor:

Vital Signs

Oxehealth Limited
(Address as above)

Common or Usual Name:

Vital Signs

Classification Name: QME, Software for optical camera-based measurement of pulse rate, heart rate, breathing rate, and/or respiratory rate.

Predicate Devices: Oxehealth Vital Signs version 1.30.0 (classified in DEN200019)

Purpose of the Special 510(k) Notice:

The Oxehealth Vital Signs medical device is a modification to Oxehealth Vital Signs version 1.30.0.

Indications for Use: The modified Oxehealth Vital Signs is intended to be used for Non-invasive spot check measurements of pulse rate and breathing rate (chest wall movements).

The **modified Oxehealth Vital Signs** is indicated for use are as follows:

"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: The modified Oxehealth Vital Signs device uses custom-designed software to read data collected using off-the-shelf cameras. Data collected in this manner can be used to act as a non-contact monitor of pulse and breathing rates for individuals aged 18 and older in single-subject room environments. Video is collected through video cameras installed in each room. When run through proprietary software- controlled algorithms, the software will allow a user to make spot checks for pulse and breathing rates of the individual in the room. Validation testing has demonstrated that the algorithms show pulse and breathing rates that are statistically non-inferior when compared to conventional methods and technology that determine pulse and breathing rates.

Consideration of Special Controls Guidance:

The De Novo grant identified several special controls to be applied to products submitted under 21 CFR 870.2785. The following information assesses the special controls in light of the proposed modifications to the Oxehealth Vital Signs device.

(1) A software description and the results of verification and validation testing based on a comprehensive hazard analysis and risk assessment must include:
(i) A full characterization of the software technical parameters, including algorithms;
(ii) If required image acquisition hardware is not included with the device, full specifications of the hardware requirements and testing to demonstrate the specified hardware ensures adequate data for validated and accurate measurements.

(iii) A description of the expected impact of all applicable sensor acquisition hardware characteristics and associated hardware specifications;
(iv) A description of all mitigations for user error or failure of any subsystem components (including signal detection, signal analysis, data display, and storage) on output accuracy; and
(v) Software documentation must include a cybersecurity vulnerability and management process to assure software functionality.

A complete set of software documentation, demonstrating that the software Special Controls are met, is described in section VIII (Software) of this submission and objective evidence appended in the identified attachments.

(2) Clinical data must be provided. This assessment must fulfill the following:
(i) The clinical data must be representative of the intended use population for the device. Any selection criteria or sample limitations must be fully described and justified.
(ii) The assessment must demonstrate output consistency using the expected range of data sources and data quality encountered in the intended use population and environment.
(iii) The assessment must compare device output with a clinically accurate patient-contacting relevant comparator device in an accurate and reproducible manner.

Clinical evidence was supplied and reviewed in DEN200019. The proposed modifications discussed in this Special 510(k) submission do not affect any of the fundamental principles of operation or performance of the device in measuring pulse rate and estimating breathing rate (chest wall movements). As that clinical evidence is still applicable now, no new clinical evidence is required, and this Special Control is met.

(3) A human factors and usability engineering assessment must be provided that evaluates the risk of improper measurement.

Human factors and usability engineering assessments were provided and reviewed in DEN200019. The proposed modifications discussed in this Special 510(k) submission do not affect the manner in which the modified Oxehealth Vital Signs device is interfaced with, therefore no new human factors testing is required, and this Special Control is met.

(4) Labeling must include:
(i) A description of what the device measures and outputs to the user;
(ii) Warnings identifying sensor acquisition factors or subject conditions or characteristics (garment types/textures, motion, etc.) that may impact measurement results;
(iii) Guidance for interpretation of the measurements, including a statement that the output is adjunctive to other physical vital sign parameters and patient information;
(iv) The expected performance of the device for all intended use populations

and environments; and
(v) Robust instructions to ensure correct system setup. In addition, this is a prescription device and must comply with 21 CFR 801.109.

Labeling complying with special controls are described in section V and the proposed instructions for use are provided in Attachment 01. Relevant information supporting the continued conformance with Special Controls are provided in more detail in Section V (labeling) and Section VIII (Software).

Technological Characteristics:

The technical specifications for the modified Oxehealth Vital Signs device are as reviewed in DEN200019; Oxehealth Vital Signs is a software only medical device, intended to run on standard, off the shelf computing hardware with an off the shelf video camera and infrared illuminator. The technological characteristics of the software are largely unchanged, with details provided in VIII (Software).

Performance Data: As the modified Oxehealth Vital Signs device is solely software, performance testing is demonstrated through software validation. Therefore this Special 510(k) notice is accompanied by software verification and validation testing described further below and provided in Attachment 04.

The special controls document additionally requires clinical and human factors evidence to demonstrate the safety and effectiveness of the device. Oxehealth has assessed the changes that are proposed for implementation in the US; as none of them affect the algorithm or the functionality of the software, the evidence supplied in support of DEN200019 is still applicable and does not need to be repeated.

Substantial Equivalence:

The modified Oxehealth Vital Signs device has the same intended use and similar indications, principles of operation, and technological characteristics as Oxehealth Vital Signs version 1.30.0. The minor differences in the modified Oxehealth Vital Signs do not raise any new questions of safety or effectiveness. Thus, the modified Oxehealth Vital Signs device is substantially equivalent to its predicate device.

	Oxehealth Vital Signs Predicate	**Oxehealth Modified Device**
Intended Use	Non-invasive spot check measurements of pulse rate and breathing rate (chest wall movements).	No change.

Indications 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.	No change.
Population	Adults not requiring critical care	No change.
Where used	Single occupancy rooms within hospitals, general care and secured environments.	No change.
Human Factors	Operation of a software user interface.	No change.
Design	Software medical device designed to extract signals from video to and measure pulse rate and breathing rate from a patient. Software user interface designed to allow users to take a spot check measurement of pulse rate and breathing rate, and to see	No change.

	previously obtained measurements.	
Performance	Pulse rate measurement 50 to 130 ± 3 beats per minute*, 9 second measurement window. Estimated breathing rate (chest wall movements) measurement 8 to 31 ± 2 breaths per minute*, 30 second measurement window. * Accuracy uses the RMSE criterion Pulse rate accuracy may be reduced when the subject has a pulse rate greater than 110 beats per minute.	No change.
User Interface	Web-based user interface accessed by touch screen monitor exclusively serving the Oxehealth software	Web-based user interface accessed by touch screen monitor or mobile device provided and installed by Oxehealth, exclusively serving the Oxehealth software.
Compatibility with Hardware – computing	Standard, off the shelf computers, specified and installed by Oxehealth, and validated during installation.	Standard, off the shelf computers and mobile tablets, specified and installed by Oxehealth, and validated during installation. No change to standard computer specifications, with newer makes and models included according to specified minimum performance requirements
Compatibility with Hardware – camera & accessories	Standard, off the shelf machine vision camera and infrared illuminators, exact specification determined by Oxehealth and validated during installation.	No change to specification, make or models used.
Software	C++ and Node.js; use of third party libraries.	C++ and Node.js; some minor modifications to third party libraries as discussed in Software Information section VIII.

Conclusions: In summary, the company's modified Oxehealth system has the same intended use as the previously cleared predicate device. In addition, the modified Oxehealth system has very similar indications, technological characteristics, and principles of operation as its predicates. Although there

are minor differences between the modified Oxehealth system and its predicate devices as described above, those differences do not raise new questions of safety or efficacy. Thus, the modified Oxehealth system is substantially equivalent.