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DE NOVO CLASSIFICATION REQUEST FOR
OXEHEALTH VITAL SIGNS

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REGULATORY INFORMATION

FDA identifies this generic type of device as:

> **Software for optical camera-based measurement of pulse rate, heart rate, breathing rate, and/or respiratory rate.** The device uses software algorithms to analyze video signal and estimate pulse rate, heart rate, respiratory rate and/or breathing rates. This device is not intended to independently direct therapy.

> **NEW REGULATION NUMBER:** 21 CFR 870.2785

> **CLASSIFICATION:** Class II

> **PRODUCT CODE:** QME

BACKGROUND

> **DEVICE NAME:** Oxehealth Vital Signs

> **SUBMISSION NUMBER:** DEN200019

> **DATE DE NOVO RECEIVED:** March 27, 2020

> **SPONSOR INFORMATION:**

> > Oxehealth Limited
> > Magdalen Center North, the Oxford Science Park
> > Oxford OX4 4GA

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.

LIMITATIONS

The subject must be still for a vital sign to be detected. For a pulse rate to be measured, a sufficient area of exposed skin must be visible to the camera. For a breathing rate to be measured, the movement of the chest must be visible to the camera.

The device is not a continuous monitor and is only intended for spot-check measurements of pulse rate and estimated breathing rate (chest wall movements).

The Oxehealth system is intended for use by appropriately trained staff with a duty of care, and should not be used by untrained lay users.

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

PLEASE REFER TO THE LABELING FOR A COMPLETE LIST OF WARNINGS, PRECAUTIONS AND CONTRAINDICATIONS.

DEVICE DESCRIPTION

The device is a software algorithm that reads data collected using off-the-shelf cameras collecting images in the near-infrared spectrum. These images 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. Pulse rate is determined by monitoring pixel intensity changes for exposed skin. Breathing rate is determined with motion tracking of the patient's chest. 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 estimated breathing rates (chest wall movements) of the individual in the room. This allows vital monitoring without disturbing the patient either to allow for patient rest or to protect staff that would otherwise need to enter the room with a potentially dangerous patient.

Off-the-shelf components must meet specifications set by the sponsor in order to ensure they will provide adequate quality video capture for analysis by the medical device.

SUMMARY OF NONCLINICAL/BENCH STUDIES

SOFTWARE

The Oxehealth Vital Signs device has a Moderate Level of Concern (LOC). Appropriate documentation was provided to support the validation of the software for a Moderate

LOC in accordance with FDA's 2005 guidance titled, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The sponsor provided details on how the software algorithm measures pulse and breathing rate. Also in order to ensure that the non-device components will provide adequate information for the software algorithm, the sponsor provided minimum specifications for non-device components. Rationale was provided for choice of the minimum hardware specifications to ensure appropriate functioning of the software algorithm. The workflow and software handling of hardware error or failures were demonstrated.

Because the device is network connected, appropriate documentation was provided in accordance with FDA's 2014 guidance titled "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices" to support adequate cybersecurity measures have been taken and will be monitored and updated throughout the device life cycle.

PERFORMANCE TESTING - BENCH

The majority of performance testing for the Oxehealth device are encapsulated in software section above and through validation of the overall system in clinical studies.

Additionally, system installation instructions require unit-by-unit verification of all hardware and environmental conditions to be installed at a customer site by Oxehealth as well as verifying adequate performance at maximum usage load of the solution before handover to the customer.

Adequate scientific rationale was provided to justify specifications of off-the-shelf components to ensure image quality would be appropriate for the software algorithm to have reliable performance.

HUMAN FACTORS/USABILITY

A human factors study was conducted with 10 users, 8 of which were given the user manual for self-training and 2 of which received no training. These users were asked to operate the Oxehealth Vital Signs device for 30 minutes to repeatedly obtain pulse and breathing measurements on a subject mimicking behaviors expected of patients. The testing verified the critical tasks of (1) ensuring measurement is taken from a patient and (2) distinguishing historical measurements from current measurements. The testing provided adequate assurance that the critical tasks could be performed.

SUMMARY OF CLINICAL INFORMATION

The sponsor provided a clinical study protocol and results to support the safety and effectiveness of the device. The clinical performance study design was an observational, uncontrolled study in patients 18 years of age and older. Patient recruitment was setup to ensure collection on a complete range of skin color types, body mass indices, and ages according to US census data (min. n=6 per Fitzpatrick scale class, where each class includes 2 skin types; 60 adult patients).

Patient age ranged from 18 to 81 years of age. The study evaluated the Oxehealth device performance measuring pulse and breathing rate under a range of expected conditions. Pulse and breathing rate was compared to the Somnoscreen system (standard contact device) in a statistical non-inferiority test. The study also showed that the Oxehealth system provides measurements of pulse rate and estimated breathing rate (chest wall movements) on the majority of occasions on which measurements would be expected.

The primary objective of the study was to assess the accuracy of pulse rate and estimated breathing rate (chest wall movements) measurements made using the Oxehealth Vital Signs device, calculated as the root mean square difference (RMSD) across all measurements when compared to a standard contact device. The pulse rate RMSD was found to be significantly less than the study objective of three beats per minute. The breathing rate RMSD was found to be significantly less than the study objective of two breaths per minute.

One-sided 97.5% confidence intervals (CIs) were calculated for these two endpoints, using the bootstrap method. The pulse rate RMSD was found to be 1.81 bpm (CI 0 - 2.19 bpm). The estimated breathing rate (chest wall movements) RMSD was found to be 1.17 breaths/minute (CI 0 - 1.33) breaths/minute.

The study was not powered to demonstrate statistical significance in sub-groups of the 60 participants. However, RMSD point estimates and their one-sided 97.5% confidence intervals for sub-groups were calculated to ensure adequate performance throughout the expected patient demographics.

For measurements for which the device could be used within its label (that is, with the participant not moving at the time of measurement, and, in the case of pulse rate measurement, with skin visible), 58% (95% CI 51% - 65%) of measurement attempts resulted in a displayed pulse rate, and 73% (95% CI 68% - 79%) of measurement attempts resulted in a displayed breathing rate. The study was intended to be a worst case scenario, as the study protocol required a reading to be taken at the same specified time during all activities, including those activities where the likelihood of a valid measurement being taken was reduced. Experience with the device (user reported outcomes) outside the United States suggest that proposed device is more commonly used when patients are resting, sleeping, or are moribund.

Pediatric Extrapolation

The Oxehealth Vital Signs device is indicated for patients age 18 and older. For medical devices, the FD&C Act defines patients before their 22nd birthday as pediatric patients. In this De Novo request, data from patients between 18-22 were used to support the use of the device in patients over the age of 18. It was appropriate to indicate the device for individuals 18 and older because of this data and patients aged 18 to 21 do not carry additional differences or risks relative to the patient population studied.

LABELING

The labeling includes a description of what the device measures and outputs to the user. The user must be still in order for a measurement to be taken with adequate skin visible for pulse rate measurement and the motion of the chest visible for estimated breathing rate (chest wall movements) measurement. Importantly, the vital signs measured are pulse and breathing rate, which is distinct from heart rate and respiration rate. As certain cardiac arrhythmias may confound accurate readings, patients with known cardiac arrhythmias should not use this device. Further, clinical data used to support the safety and effectiveness of the device did not include subjects with elevated pulse rates, so accuracy may be reduced when the subject has a pulse rate greater than 110 beats per minute. Other patient conditions that may affect performance of the device are listed in the labeling. Certain room conditions may affect performance (bright lights, shower, etc.). If the Oxehealth Vital Signs device fails to respond as described, discontinue use until the situation has been corrected.

The device is not a continuous monitor and is only intended for spot-check measurements of breathing and pulse rate. The reported accuracy of the system is described for both measurements in accordance with what was measured in the clinical study. The device should not be used with any subject receiving critical care. The Oxehealth system is intended for use by appropriately trained staff with a duty of care, and should not be used by untrained lay users. The device is not intended to be the sole method of checking the physical health of a subject.

Installation will be carried out by an Oxehealth trained installer, according to installation instructions and verification procedures provided by Oxehealth.

RISKS TO HEALTH

The table below identifies the risks to health that may be associated with use of software for optical camera-based measurement of pulse rate, heart rate, breathing rate, and/or respiratory rate and the measures necessary to mitigate these risks.

Identified Risks to Health	Mitigation Measures
Delayed or incorrect treatment due to erroneous output as a result of software malfunction or algorithm error	Software verification, validation, and hazard analysis Cybersecurity assessment Clinical data Labeling
Delayed or incorrect treatment due to user misinterpretation	Human factors assessment Labeling
Delayed or incorrect treatment due to non-device components failing to provide inputs for software to adequately analyze	Software verification, validation, and hazard analysis Clinical data Human factors assessment Labeling

SPECIAL CONTROLS

In combination with the general controls of the FD&C Act, the software for optical camera-based measurement of pulse rate, heart rate, breathing rate, and/or respiratory rate is subject to the following special controls:

(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.

(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.

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

(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.

BENEFIT-RISK DETERMINATION

The risks of the device are based on data collected in a clinical study described above.

The consequences of an incorrect reading would be a delay in the provision of care or unnecessary testing. The patient could suffer harm from the delay in providing care. However, the device has been validated to have clinically acceptable accuracy and the probability of a patient harm related to false results is minimum.

The probable benefits of the device are also based on data collected in a clinical study as described above.

The device can benefit the patient by minimizing intrusion due to regular bedside vital signs measurements. In certain settings and circumstances, the non-contact measurement method offers a more practical and safer alternative to the conventional way of vital signs measurements. The device is especially valuable in environments (e.g., isolation rooms, secure facilities, and psychiatric wards) where routine physical interaction with a patient may be risky for to both the patient and health care provider. Remote monitoring provided by the device can also minimize personnel exposure to the patient.

In situations where regular access to subjects is impractical or unsafe, there are few alternatives. While contact sensors may be considered, their use is often limited by poor compliance and device-associated physical discomfort. For basic vital sign monitoring in these settings, there is a high likelihood that the Oxehealth device can offer significant advantages over existing alternatives.

Patient Perspectives

Patient perspectives considered for the Oxehealth Vital Signs during the review include surveys from patients who had been checked with the Oxehealth system in an existing hospital installation outside. The results demonstrated preference for the contactless checks as it didn't disturb their sleep and may result in less complaints from patients.

Benefit/Risk Conclusion

In conclusion, given the available information above, for the following indication statement:

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.

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The probable benefits outweigh the probable risks for the Oxehealth Vital Signs. The device provides benefits and the risks can be mitigated by the use of general controls and the identified special controls.

CONCLUSION

The De Novo request for the Oxehealth Vital Signs device is granted, and the device is classified as follows:

Product Code: QME
Device Type: Software for optical camera-based measurement of pulse rate, heart rate, breathing rate, and/or respiratory rate
Regulation Number: 21 CFR 870.2785
Class: II