



May 30, 2025

Mindset Medical, Inc.
Jeremy Markovich
Official Correspondent
12439 N 32nd St.
Phoenix, Arizona 85032

Re: K250078

Trade/Device Name: Informed Vital Core Application (IVC App) (v2.0.0.2.0.0)

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: May 5, 2025

Received: May 5, 2025

Dear Jeremy Markovich:

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

Submission Number (if known)

K250078

Device Name

Informed Vital Core Application (IVC App) (v2.0.0.2.0.0)

Indications for Use (Describe)

The Informed Vital Core Application (IVC App) is intended for non-invasive spot measurement of pulse and respiration rate of adult patients in home use, hospitals, clinics, and long-term care settings.

The Informed Vital Core Application is indicated for use on adults 22 years of age or older who do not require critical care or continuous vital signs monitoring.

Informed Vital Core is not intended to independently direct therapy.

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.

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510(k) Summary

Company Address:	Mindset Medical, Inc. 14239 N. 32 nd St Phoenix, AZ 85032 602.481.4139
Primary Contact Person:	Jeremy Markovich Vice President, Regulatory and Clinical Affairs
Date Prepared:	January 10, 2025
Device Name:	Informed Vital Core Application (IVC App)
Common Name:	Cardiovascular Monitoring Device
Classification:	21 CFR 870.2785 Software for Optical Camera-Based Measurement of Pulse Rate, Heart Rate, Breathing Rate, and/or Respiratory Rate Product Code: QME Regulatory Class: II
Predicate Device:	Oxehealth Vital Signs (K211906)
Purpose:	This IVC App is a modification to the existing pulse rate platform to include respiration rate.
Device Description:	The IVC App is a Software as a Medical Device (SaMD) progressive web application that utilizes existing optical camera technology embedded in a smart-phone, tablet, laptop, or desktop computer to estimate an individual's vital signs including pulse rate (PR) and respiration rate (RR) developed by Mindset Medical. The IVC App software algorithms will provide spot checks for PR and RR of the individual. The IVC App software uses proprietary software algorithms to extract a raw video signal through remote plethysmography (rPPG) by detecting subtle color variations in the microvasculature around a patient's face that occur with each cardiac cycle due to changes in blood volume to measure PR. Additionally, this system utilizes software for optical camera-based measurement of respiration rate. The non-contact, periodic, spot measurement of respiration rate is taken when the subject is at rest based on shoulder movement.

Indications for Use:

The Informed Vital Core Application (IVC App) is intended for non-invasive spot measurement of pulse and respiration rate of adult patients in home use, hospitals, clinics, and long-term care settings.

The Informed Vital Core Application is indicated for use on adults 22 years of age or older who do not require critical care or continuous vital signs monitoring.

Informed Vital Core is not intended to independently direct therapy.

Technological Characteristics:

The IVC App has similar technological characteristics to the predicate device, including remote photoplethysmography (rPPG) technology, algorithms for video analysis, off the shelf system components such as a computer, laptop, or mobile device, and utilization of software to measure the pulse rate using commercially available cameras. Additionally, both systems include software for optical camera-based measurement of breathing/respiration rate. The non-contact, periodic, spot measurement are taken when the subject is at rest based on chest/shoulder movement. The IVC App is comparable to the predicate in terms of intended use, fundamental scientific technology, technological characteristics, and principle of operation.

Substantial Equivalence Comparison Summary:

Device	Subject Device, Informed Vital Core Application (IVC App)	Predicate Device (K211906) Oxehealth Vital Signs
Manufacturer	Mindset Medical	Oxehealth Limited
Intended Use	Non-invasive spot check measurements of pulse rate and respiration rate.	Non-invasive spot check measurements of pulse rate and breathing rate (chest wall movements).

Device	Subject Device, Informed Vital Core Application (IVC App)	Predicate Device (K211906) Oxehealth Vital Signs
Indications for use	<p>The Informed Vital Core Application (IVC App) is intended for non-invasive spot measurement of pulse and respiration rate of adult patients in home use, hospitals, clinics, and long-term care settings.</p> <p>The Informed Vital Core Application is indicated for use on adults 22 years of age or older who do not require critical care or continuous vital signs monitoring.</p> <p>Informed Vital Core is not intended to independently direct therapy.</p>	<p>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.</p> <p>The Oxehealth system is indicated for use by appropriately trained staff with a duty of care, and should not be used by untrained users.</p> <p>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.</p> <p>The device is not intended to be the sole method of checking the physical health of a subject.</p>
Regulation names and numbers	21 CFR 870.2785 Software for optical camera-based measurement of pulse rate, heart rate, and respiratory rate.	21 CFR 870.2785 Software for optical camera-based measurement of pulse rate, heart rate, and respiratory rate.
Product codes and classifications	Code: QME Class: II	Code: QME Class: II
Use population	Adults not requiring critical care	Adults not requiring critical care
Use environment	Homes, hospitals, clinics, long-term care settings	Hospitals, general care, and similar professional healthcare environments
System components	Computer, laptop, mobile phone, or tablet IVC software application No additional hardware components required	Computer or laptop Software application Optical sensors installed in patient's room in healthcare facility
Technology Characteristics	Remote Photoplethysmography (rPPG) technique is used to detect volumetric changes in peripheral blood circulation by using a color model based on red, green, and blue imaging derived from real-time video obtained from a patient using a computer, laptop, or mobile device.	Remote Photoplethysmography (rPPG) technique is used to detect volumetric changes in peripheral blood circulation by using a color model based on red, green, and blue imaging derived from real-time video obtained from a patient using a computer, laptop, or mobile device. The device uses proprietary software algorithms to analyze video signal and estimate pulse rate, heart rate, respiratory rate and/or breathing rates.

Device	Subject Device, Informed Vital Core Application (IVC App)	Predicate Device (K211906) Oxehealth Vital Signs
	<p>The IVC App's Vital Core Algorithm applies proprietary signal processing techniques to the patient video to estimate pulse rate.</p> <p>This system utilizes software for optical camera-based measurement of breathing rate. The non-contact, periodic, spot measurement of breathing rate is taken when the subject is at rest based on shoulder movement.</p>	<p>This system utilizes software for optical camera-based measurement of breathing rate. The non-contact, periodic, spot measurement of breathing rate is taken when the subject is at rest based on chest wall movement.</p>
Measurement site	Face and thorax (shoulder movements)	Face and thorax (chest wall movements)
Measurement type	Spot	Spot
Performance, Heart rate (pulse rate)	50 to 103 bpm, ± 3 bpm	50 to 130 bpm, ± 3 bpm
Performance, Respiration Rate (Breathing Rate)	<p>8 – 30 ± 3 breaths per minute*</p> <p>*Accuracy uses the RMSE criterion.</p>	<p>Estimated breathing rate (chest wall movements) measurement 8 to 31 ± 2 breaths per minute*.</p> <p>* Accuracy uses the RMSE criterion.</p>
Measurement window	60 seconds	30 seconds

Performance Testing:

Test	Results
Software testing	<ul style="list-style-type: none"> • Verification and validation testing of the IVC App software was conducted to confirm that the device meets the performance requirements and indications for use across different system configurations of smartphones, tablets, and laptops. This includes a full characterization of software technical parameters and algorithms. • Non-clinical tests were conducted to demonstrate the accuracy of the measured respiration rates using the IVC App. This verification of performance requirements included a quantitative characterization of the use environment and device reliability across the range of compatible hardware. • Compatibility testing was performed on specified operating systems and browsers, ensuring that the App functions correctly across different operating systems and browsers. • A risk-based approach was utilized for human factors and usability assessment. This included testing to evaluate the application response (e.g.,

Test	Results
	prompts, labeling, and warnings) to expected fault conditions caused by patients or incompatibility from the hardware of mobile devices such as phones or tablets.
Cybersecurity testing	A cybersecurity threat analysis was conducted using FDA Guidance and AAMI/TIR57:2016/R2019 as a framework. All system components were assessed for potential cybersecurity vulnerabilities. Additional third-party penetration testing was conducted to identify any cybersecurity vulnerabilities in the IVC System. Any detected vulnerabilities were addressed by design and/or testing.

Summary of Clinical Testing:

Study design – A single-arm cohort, open-label clinical study was conducted on the IVC App, demonstrating its accuracy for respiratory rate measurements compared to the gold standard: blinded, manually-counted end-tidal CO₂ (EtCO₂) with an FDA-cleared capnography device.

Primary endpoint – The primary objective of this study is to compare the accuracy of the Device Under Test for measuring respiratory rate compared to the gold standard. The EtCO₂ waveform was scored by counting the breath peaks per minute. The clinicians counting the raw EtCO₂ waveform were blinded to the results from the test device.

The study recruited subjects representative of the intended population from six study sites located in the United States. The Average Root Mean Square (ARMS) and its 95% confidence interval were calculated. The hypothesis that the IVC App can measure RR within ± 3 breaths per minute ARMS is accepted. Based on the results of the study, the IVC App can effectively measure respiration rate within the claimed range in the intended use population.

Clinical Study Subject Demographics

Description		Number
Age	≤ 50	34
	> 50	31
Sex	Males	33
	Females	32
Race	American Indian or Alaska Native	2
	Asian	5
	Black/African American	11
	Pacific Islander	1
	White	43
	Other	8
Hispanic/ Latino	Yes	15
	No	50
BMI	< 25.0	11
	25.0 to 29.9	28
	> 30.0	26
Total	Healthy Patients	35
	Patients with Comorbidities	29

Conclusion:

The IVC App has been found to be substantially equivalent to the predicate device with respect to technical characteristics, performance, and intended use. The information provided within this premarket notification supports substantial equivalence to the predicate device(s).