November 18, 2024

Mindset Medical, Inc.
Jeremy Markovich
Vice President of Regulatory and Clinical Affairs
12439 N 32nd St.
Phoenix, Arizona 85032

Re: K241633
Trade/Device Name: Informed Vital Core Application (IVC App)
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: October 19, 2024
Received: October 21, 2024

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241633

Device Name

Informed Vital Core Application (IVC App)

Indications for Use *(Describe)*

The Informed Vital Core Application (IVC App) is intended for non-invasive spot measurement of pulse 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. 32nd St Phoenix, AZ 85032 602.481.4139
Primary Contact Person:	Chris Joslin Vice President of Product Management and Compliance
Date Prepared:	October 18, 2024
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 submission is seeking clearance for the IVC App.
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) developed by Mindset Medical. The IVC App software algorithms will provide spot checks for PR 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. Evidence was provided to demonstrate compliance with the special control for product code, QME, per 21 CFR 870.2785 for the software for optical camera-based measurement of pulse rate, heart rate, breathing rate, and/or respiratory rate.

Indications for Use:

The Informed Vital Core Application (IVC App) is intended for non-invasive spot measurement of pulse 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. 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.	Non-invasive spot check measurements of pulse rate and breathing rate (chest wall movements).
Indications for use	The Informed Vital Core Application (IVC App) is intended for non-invasive spot measurement of pulse 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.	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 indicated 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.

Device	Subject Device, Informed Vital Core Application (IVC App)	Predicate Device (K211906) Oxehealth Vital Signs
		The device is not intended to be the sole method of checking the physical health of a subject.
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. The IVC App's Vital Core Algorithm applies proprietary signal processing techniques to the patient video to estimate pulse rate.	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.
Measurement site	Face	Face
Measurement type	Spot	Spot
Performance, Heart rate (pulse rate)	50 to 103 bpm, ± 3 bpm	50 to 130 bpm, ± 3 bpm
Measurement window	60 seconds	30 seconds

Performance Testing:

Test	Results
Software testing	• Verification and validation testing of the IVC App software's 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 pulse rates using the IVC App. The accuracy of the measured IVC App pulse rates compared to a legally marketed pulse rate measurement device during bench testing demonstrated within ±3 bpm root mean square error (RMSE). • Verification and validation testing was performed to ensure hardware compatibility based on the defined minimally required specifications (e.g., physical parameters and performance characteristics) for the cameras to ensure the quality of captured images/videos and the PPG signals. • A risk-based approach was utilized for human factors and usability assessment. This included testing to evaluate the application response (e.g., prompts, labeling, and user alerts) 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.

Bench Testing Subject Demographics

Description		Number of Sessions
Subjects (Unique)	711	1,413
Age Range	18 to 21	135
	22 to 29	290
	30 to 39	222
	40-49	169
	50-59	268
	60-69	208
	70-79	89
	80-89	20
	90-99	7
Sex	Males	515
	Females	898
Race	American Indian/Alaskan	12

	Asian	26
	Black/African American	279
	Pacific Islander	14
	White	1003
	Other	79
BMI ranges	<18.5	15
	18.5 to 24.9	462
	25 to 29.9	450
	30 to 39.9	409
	>40	77
Skin type according to Fitzpatrick Scale	Type 1 and 2	719
	Type 3 and 4	424
	Type 5 and 6	270
Glasses (Y/N)	Yes	448
	No	965
Facial Hair (Y/N)	Yes	309
	No	1104
Environment	Office	38
	Clinic	1042
	Home	81
	Indoors (general)	44
	Outdoors	3
	Not reported	205

Summary of Clinical Testing:
Study design – A multicenter, prospective, open-label clinical study was conducted on the IVC App demonstrating its accuracy for pulse rate measurements compared to a legally marketed, electrocardiogram (ECG) device.

Primary endpoint – The primary objective of the study was to establish that pulse rates measured with the IVC App are accurate to within ±3 beats per minute (BPM) average root mean square (ARMS) of heart rates (HR) measured with the reference ECG device.

The hypothesis was tested by comparing the IVC PR to the subject's HR simultaneously measured with a legally marketed reference device. The study recruited subjects from six study sites located in the United States. The PR obtained by the IVC App was compared to the heart rate obtained by the ECG reference device. The Average Root Mean Square (ARMS) and its 95% confidence interval were calculated. The hypothesis that the IVC App can measure PR within ± 3 BPM ARMS is accepted. The study was not powered to demonstrate statistical significance in sub-groups; however, sub-group

accuracy was calculated to ensure adequate performance. Based on the results of the study, the IVC App is effective at determining pulse rate in an intended use population.

Clinical Study Subject Demographics

Description		Number
Subjects	Total	67
Age	22-29	6
	30-39	16
	40-49	9
	50-59	10
	60-69	20
	70-77	6
Gender	Males	30
	Females	37
Race/Ethnicity	American Indian or Alaska Native	1
	American Indian or Alaska Native/Black or African American	1
	Asian	5
	Black/African American	18
	Pacific Islander	1
	White	40
	Other	1
Skin type according to Fitzpatrick Scale	Type I and II	31
	Type III and IV	18
	Type V and VI	18

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).