May 21, 2026

PanopticAI technologies Limited
% Evie Chen
Consultant
Vee Care (Asia) Limited
Flat A & B, 17f Chung Pont Commercial Bldg.
300 Hennessy Rd., Wanchai
Hong Kong

Re: K260066
Trade/Device Name: PanopticAI Vital Signs (1.6.1-22)
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: April 24, 2026
Received: April 24, 2026

Dear Evie Chen:

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K260066

Please provide the device trade name(s).

PanopticAI Vital Signs (1.6.1-22)

Please provide your Indications for Use below.

The PanopticAI Vital Signs device is intended for non-invasive spot measurement of pulse rate and respiratory rate when the subject is still. It is software for assessing facial video stream captured from a specified smartphone or tablet camera.
The PanopticAI Vital Signs device is intended for use by healthcare professionals.
The PanopticAI Vital Signs device is indicated for use on adults 18 to 60 years old who do not require critical care or continuous vital signs monitoring.
The PanopticAI Vital Signs device is not intended for continuous monitoring, apnea detection, or to independently direct therapy. It is not intended to be the sole method to assess a subject's physical health condition. The pulse rate and respiratory rate measurements it provides should complement, not replace, professional medical care and/or prescribed therapy.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(K) SUMMARY RR

1. Date Prepared

21-May-26

2. Submitter's Information

2.1. Name of Sponsor:

PanopticAI Technologies Limited

2.2. Address:

Room A, Ground Floor, 3 Tin Hau Temple Road, North Point, Hong Kong

2.3. Contact Name:

Kyle Wong

2.4. Telephone No.:

+852 9231 3712

2.5. Fax No.:

+852 2187 2341

2.6. Email Address:

kylewong@panoptic.ai

3. Trade Name, Common Name, Classification

3.1. Trade/Product Name:

PanopticAI Vital Signs

3.2. Common or Usual Name:

Vital Signs

3.3. Regulation name:

Software for optical camera-based measurement of pulse rate, heart rate, breathing, and/or respiratory rate

3.4. Regulation Number:

21 CFR 870.2785

3.5. Device Class:

Class II

3.6. Product Code:

QME

4. Identification of Predicate Device

K240890 PanopticAI Vital Signs and K211906 Oxehealth Vital Signs

5. Indications for Use

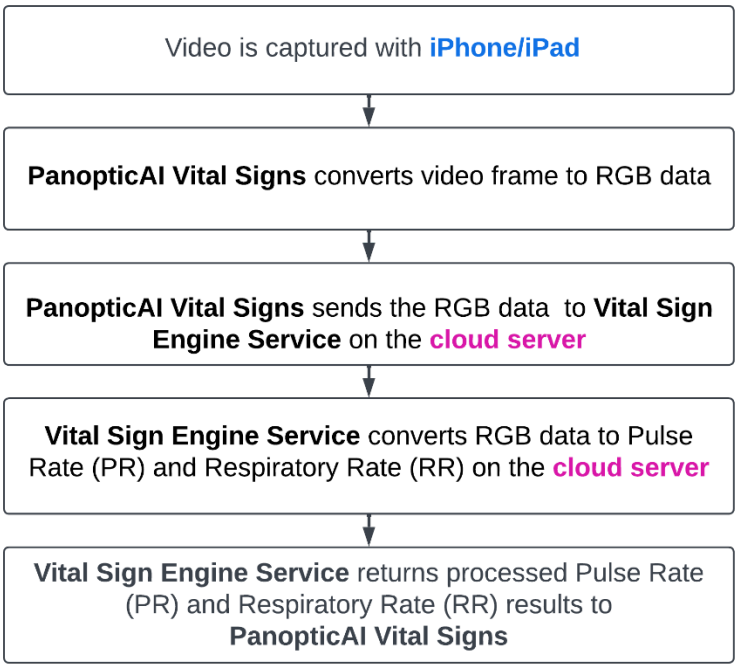
The PanopticAI Vital Signs device is intended for non-invasive spot measurement of pulse rate and respiratory rate when the subject is still. It is software for assessing facial video stream captured from a specified smartphone or tablet camera.

The PanopticAI Vital Signs device is intended for use by healthcare professionals.

The PanopticAI Vital Signs device is indicated for use on adults 18 to 60 years old who do not require critical care or continuous vital signs monitoring.

The PanopticAI Vital Signs device is not intended for continuous monitoring, apnea detection, or to independently direct therapy. It is not intended to be the sole method to assess a subject's physical health condition. The pulse rate and respiratory rate measurements it provides should complement, not replace, professional medical care and/or prescribed therapy.

6. Device Description



PanopticAI Vital Signs is a medical software device that uses remote photoplethysmography (rPPG) to measure a person's pulse rate and uses motion analysis of chest wall movement to measure respiratory rate.

The app utilizes the surrounding light as the light source and works by capturing video of the subject with the front camera of an iPhone or iPad.

- Pulse rate is derived using remote photoplethysmography (rPPG). The algorithm detects and tracks the subject's face to capture subtle color changes caused by light absorption and reflection by blood vessels beneath the skin. These changes in RGB pixel values are analyzed to estimate the pulse rate.

- Respiratory rate is derived from small periodic movements associated with breathing, detected through motion analysis of the subject's upper torso regions of interest.

Captured signal data are transmitted securely to PanopticAI's cloud server for further processing. The calculated results are then returned to the PanopticAI Vital Signs app for display. Neither the app nor the cloud server stores any personally identifiable information (PII).

The device is intended to provide non-contact, spot-check measurements of pulse rate and respiratory rate. It is not designed for continuous monitoring, apnea detection, or to independently direct therapy. It is important to note that while the PanopticAI Vital Signs app can be a useful tool for monitoring vital sign trends over time, it should not be relied upon for the diagnosis or treatment of medical conditions.

7. Consideration of Special Control Guidance

1) A complete set of software documentation, demonstrating that the software Special Controls are met, is described in D-730-14 Software Verification and Validation Report_V4 and objective evidence appended in the identified attachments.
2) Clinical evidence was supplied in RD-730-04-20260413 [Clinical Validation Study Report] and objective evidence appended in the identified attachments (Appendix 1, 2, 3).
3) Human factors and usability engineering assessments were provided in 049_RD-730-05-2024-11-26 Usability Test Report and D-730-34 Usability Engineering Impact Assessment Report V1.
4) Labelling complying with special controls and the proposed instructions for use are provided in D-910-03 PanopticAI Vital Signs-PanopticAI-Instructions For Use_US. Relevant information supporting the continued conformance with Special Controls are provided in more detail in D-910-03 and D-910-12.

8. Comparison to the Predicate Device

The PanopticAI Vital Signs device is substantially equivalent to the predicate devices, K240890 PanopticAI Vital Signs and K211906 Oxehealth Vital Signs, in terms of intended use and technological characteristics. The differences between the subject device and predicate devices do not affect the basic design principle, usage, effectiveness, and safety of the subject device.

A detailed comparison to the predicate is provided in the following table:

	Subject Device	Primary Predicate Device (K240890)	Secondary Predicate Device (K211906)	
Trade Name	PanopticAI Vital Signs	PanopticAI Vital Signs	Oxehealth Vital Signs	
Manufacturer	PanopticAI Technologies Limited	PanopticAI Technologies Limited	Oxehealth Limited	Comments
Device Class	Class II	Class II	Class II	Same
Product Code	QME	QME	QME	Same
Regulation number	870.2785	870.2785	870.2785	Same

	Subject Device	Primary Predicate Device (K240890)	Secondary Predicate Device (K211906)	
Trade Name	PanopticAI Vital Signs	PanopticAI Vital Signs	Oxehealth Vital Signs	
Manufacturer	PanopticAI Technologies Limited	PanopticAI Technologies Limited	Oxehealth Limited	Comments
Regulation Name	Software for optical camera-based measurement of pulse rate, heart rate, breathing rate, and/or respiratory rate	Software for optical camera-based measurement of pulse rate, heart rate, breathing rate, and/or respiratory rate	Software for optical camera-based measurement of pulse rate, heart rate, breathing rate, and/or respiratory rate	Same
Intended Use	Non-invasive spot measurement of pulse rate and respiratory rate	Non-invasive spot measurement of pulse rate	Non-invasive spot check measurements of pulse rate and breathing rate (chest wall movements)	Similar
Indications for Use	The PanopticAI Vital Signs device is intended for non-invasive spot measurement of pulse rate and respiratory rate when the subject is still. It is software for assessing facial video stream captured from a specified smartphone or tablet camera. The PanopticAI Vital Signs device is intended for use by healthcare professionals. The PanopticAI Vital Signs device is indicated for use on adults 18 to 60 years old who do not require critical care or continuous vital signs monitoring. The PanopticAI Vital Signs device is not intended for continuous monitoring, apnea detection, or to independently direct therapy. It is not intended to be the sole method to assess a subject's physical health condition. The pulse rate and respiratory rate measurements it provides should complement, not replace, professional medical care and/or prescribed therapy.	The PanopticAI Vital Signs device is intended for noninvasive spot measurement of pulse rate when the subject is still. It is software for assessing facial video stream captured from a specified smartphone or tablet camera. The PanopticAI Vital Signs device is intended for use by healthcare professionals. The PanopticAI Vital Signs device is indicated for use on humans 18 to 60 years of age who do not require critical care or continuous monitoring. The PanopticAI Vital Signs device is not intended to be the sole method to assess a subject's physical health condition. The pulse rate measurements it provides should complement, not replace, professional medical care and/or medication.	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.	Different [(a)]
Product Availability	Prescription use	Prescription use	Prescription use	Same

	Subject Device	Primary Predicate Device (K240890)	Secondary Predicate Device (K211906)	
Trade Name	PanopticAI Vital Signs	PanopticAI Vital Signs	Oxehealth Vital Signs	
Manufacturer	PanopticAI Technologies Limited	PanopticAI Technologies Limited	Oxehealth Limited	Comments
Target Population	Adults 18 to 60 years of age who do not require critical care or ongoing vital signs monitoring.	Adults 18 to 60 years of age who do not require critical care or ongoing vital signs monitoring.	Adults 18 years of age or older who do not require critical care or continuous vital signs monitoring.	Same
Users	Healthcare practitioners	Healthcare practitioners	Trained professional healthcare	Same
Clinical setting	Well-lit room; home use & General clinic use	Well-lit room; home use & General clinic use	Single occupancy rooms within hospitals, general care and secured environments.	Different [a]
Human Factors	Compliance with IEC 62366	Compliance with IEC 62366	Compliance with IEC 62366	Same
Design	Software medical device designed to capture signals from video and measure pulse rate and respiratory rate from a user. Software user interface designed to allow users to take a spot measurement of pulse rate and respiratory rate.	Software medical device designed to capture signals from video and measure pulse rate from a user. Software user interface designed to allow users to take a spot measurement of pulse rate.	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 previously obtained measurements.	Similar
User Interface	User interface accessed by iPad/iPhone	User interface accessed by iPad/iPhone	Web-based user interface accessed by touch screen monitor exclusively serving the Oxehealth software.	Different [b]
Compatibility with Hardware	iPad Air (5th generation) and siPhone 13 Pro with operating system iOS/iPadOS 16.0 or above	iPad Air (5th generation) and iPhone 13 Pro with operating system iOS/iPadOS 16.0 or above	Standard, off the shelf computers and mobile devices, specified and installed by Oxehealth, and validated during installation.	Different [b]
Compatibility with Hardware – camera & accessories	iPad Air (5th generation) and iPhone 13 Pro with operating system iOS/iPadOS 16.0 or above	iPad Air (5th generation) and iPhone 13 Pro with operating system iOS/iPadOS 16.0 or above	Standard, off the shelf machine vision camera and infrared illuminators, exact specification determined by Oxehealth and validated during installation.	Different [b]
Performance for Pulse Rate	Pulse rate measurement 50 to 130 ± 3 beats per minute	50 to 130 ± 3 beats per minute*, 30 second	Pulse rate measurement 50 to 130 ± 3 beats per	Same

	Subject Device	Primary Predicate Device (K240890)	Secondary Predicate Device (K211906)	
Trade Name	PanopticAI Vital Signs	PanopticAI Vital Signs	Oxehealth Vital Signs	
Manufacturer	PanopticAI Technologies Limited	PanopticAI Technologies Limited	Oxehealth Limited	Comments
	* Accuracy uses Bias (Mean of Absolute Difference) and Arms.	measurement window. * Accuracy uses Bias (Mean of Absolute Difference).	minute*, 9 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.	
Performance for Respiratory rate	Respiratory rate measurement 6 to 34 ± 3 breaths per minute * Accuracy based on Bland-Altman analysis, Limits of Agreement, 95% CI, and Arms/RMSE Criterion	N/A	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.	Same

9. Discussion of differences in technological characteristics

The subject device uses the previously cleared version of the software as the primary predicate (K240890), while a legally marketed device (K211906) is referenced as a secondary predicate solely to support the technological characteristics of the newly added measurement function (Respiratory Rate).

The subject device has similar intended use, design, and performance when compared to the secondary predicate device. The basic technological and operating principles are the same for both devices.

a) There are differences between the subject and predicate devices indicated uses. The differences can be described as below:
   - Product Availability - The subject device is intended for home and general clinic use. The predicate device is intended for use in hospitals, general care, and secured environments.

The usability study and product performance test were conducted to demonstrate the safety of the subject device.

b) The difference in platform hardware compatibility and user interface does introduce any new risk because software validation was conducted to demonstrate the safety and performance of the subject device.

The above differences do not raise questions of safety and effectiveness. Thus, the devices are substantially equivalent.

10. Non-clinical Testing Summary

10.1. Software

Software verification and validation testing was conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff "Guidance for the Content of Premarket Submissions for Device Software Functions". The software for this device only requires basic documentation.

10.2. Usability

The Usability evaluation for the PanopticAI Vital Signs is conducted in accordance with ANSI AAMI IEC 62366-1:2015+AMD1:2020. The usability verification and validation are well defined with criteria specified in the Usability Engineering Report. Usability testing results and improvement action demonstrated that residual risk regarding usability is minimized and acceptable. It is concluded that the usability evaluation is well performed and acceptable.

10.3. Cybersecurity

Because the device is network connected, cybersecurity testing was conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff "Guidance for the 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.

10.4. Performance Testing - Bench

Bench performance testing was conducted to evaluate device performance under various operating conditions and representative use scenarios.

Testing included evaluation under varying environmental and use conditions, including operating distance, ambient lighting, clothing and appearance conditions, as well as software verification activities related to system processing and data handling.

The verification testing included:

- Distance testing at validated operating distances
- Ambient lighting testing under representative indoor lighting conditions
- Testing under various clothing and appearance conditions representative of intended use scenarios
- Cloud computation and backend processing verification testing to verify software transmission and computational integrity

Across all testing, the app demonstrated consistent performance under the tested conditions and intended use scenarios.

11. Clinical Testing Summary

This study aimed to assess the agreement between the PanopticAI Vital Signs app and the gold standard for respiratory rate measurement (blinded, manually-counted end-tidal CO2 waveforms from an FDA-cleared device) by using Bland-Altman and regression analysis.

The demographic characteristics of the study participants are summarized in the table below.

Clinical Validation Study Subject Demographic

Sample Size	N=73
Gender	Females: 34 Males: 39
Age Group	18-21: 08 22-30: 17 31-50: 30 51-60: 18
BMI	Underweight (<18.5): 3 Healthy Weight (18.5–<25): 43 Overweight (25–<30): 17 Obese (≥ 30): 10
History of Hypertension	With: 21 Without: 52
Race/Ethnicity	Asian: 19 Black: 14 Hispanic: 10 White: 30
Skin Type According to Fitzpatrick Scale	I: 8 II: 22 III: 12 IV: 14 V: 12 VI: 5
Chronic Illness	With: 27 Without: 46

All endpoints have been met, which substantiate the claim of substantial equivalence to the predicate device.

11.1. Clinical Testing – Metronome Breathing

Controlled metronome-guided breathing testing (D-730-37 Design Verification Test – Metronome Breathing) was conducted to evaluate respiratory rate performance across respiratory rates that are unlikely to occur naturally within the intended use population.

The metronome-guided breathing data were combined with the spontaneous clinical validation study data to support evaluation across the entire claimed respiratory rate range. The combined dataset was included in the overall Bland-Altman and agreement analysis for respiratory rate validation.

12. Conclusions

Based on the information provided in this 510(k) submission, the differences between the predicate and the subject device do not raise any new or different questions of safety or effectiveness. The proposed subject device is substantially equivalent to the predicate device and is as safe and as effective as the legally marketed predicate devices