December 23, 2024

PanopticAI Technologies Limited
% Jing Chen
Regulatory Manager
Vee Care (Asia) Limited
17th Chung Pont Commercial Building
300 Hennessy Road
Hong Kong, 0000
Hong Kong

Re: K240890
Trade/Device Name: PanopticAI 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: November 26, 2024
Received: November 26, 2024

Dear Jing 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 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,

Kimberly N. Crowley -S

Digitally signed by Kimberly N. Crowley -S

For: Jennifer Kozen
Assistant Director
DHT2A: Division of Cardiac Electrophysiology, Diagnostics, and Monitoring Devices
OHT2: 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)*

K240890

Device Name

PanopticAI Vital Signs

Indications for Use *(Describe)*

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 device is only intended to be used in healthy subjects.
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.

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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007_510K SUMMARY

1. Date Prepared

25-Nov-24

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

K211906 Oxehealth Vital Signs

5. Indications for Use

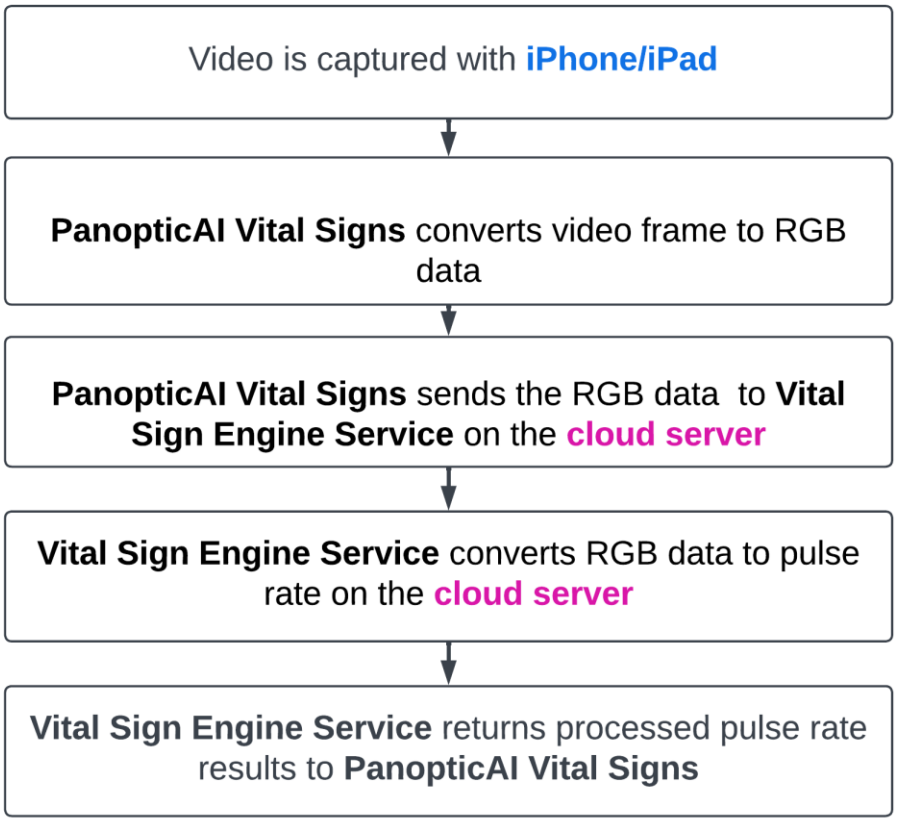
The PanopticAI Vital Signs device is intended for non-invasive spot measurement of pulse rate when the subject is still. It is software for assessing facial video stream captured from a specified smartphone or tablet camera.

The PanopticAI Vital Signs device is intended for use by healthcare professionals. The device is only intended to be used in healthy subjects.

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.

6. Device Descriptions



- The **Vital Sign Engine Service** is a proprietary cloud-based software developed by PanopticAI that uses algorithms to analyze and convert RGB data collected from PanopticAI Vital Signs to pulse rate

PanopticAI Vital Signs is a medical software device that uses remote photoplethysmography (rPPG) to measure a person's pulse rate. The app utilizes the surrounding light as the light source and works by capturing and measuring the subtle color changes on the skin caused by light absorption and reflection by the blood vessels beneath the skin. The app uses the front camera of an iPhone or iPad to capture videos of the subject. Then, the algorithm in the app detects and

tracks the subject's face to capture the subtle light changes reflected in the changes in RGB pixel values. This information is sent to PanopticAI's cloud server for further processing to calculate the pulse rate. The pulse rate value is then returned to the PanopticAI Vital Signs app, and the result is displayed on the app. Please note that neither the PanopticAI Vital Signs app nor PanopticAI's cloud server saves any personal identifiable information (PII).

It is important to note that while the PanopticAI Vital Signs app can be a useful tool for tracking pulse rate trends over time, however, it should not be relied on 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 Section 018 of this submission and objective evidence appended in the identified attachments.
2) Clinical evidence was supplied in Section 022 of this submission and objective evidence appended in the identified attachments.
3) Human factors and usability engineering assessments were provided in Section 020 of this submission.
4) Labelling complying with special controls is described in Section 015 and the proposed instructions for use are provided in Appendix 15A. Relevant information supporting the continued conformance with Special Controls are provided in more detail in Section 015 and Section 018.

8. Comparison to the Predicate Device

The PanopticAI Vital Signs device is substantially equivalent to the predicate device, K211906 Oxehealth Vital Signs, in terms of intended use and technological characteristics. The differences between the subject device and predicate device 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	Predicate Device (K211906)	
Trade Name	PanopticAI Vital Signs	Oxehealth Vital Signs	
Manufacturer	PanopticAI Technologies Limited	Oxehealth Limited	Comments
Device Class	Class II	Class II	Same
Product Code	QME	QME	Same
Regulation number	870.2785	870.2785	Same
Regulation Name	Software for optical camera-based measurement of pulse rate	Software for optical camera-based measurement of pulse rate, heart rate, breathing rate, and/or respiratory rate	Same
Intended Use	Non-invasive spot pulse rate assessment while the subject is motionless.	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 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 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	Different [(a)]

	Subject Device	Predicate Device (K211906)	
Trade Name	PanopticAI Vital Signs	Oxehealth Vital Signs	
Manufacturer	PanopticAI Technologies Limited	Oxehealth Limited	Comments
	The PanopticAI Vital Signs device is intended for use by healthcare professionals. The device is only intended to be used in healthy subjects. 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.	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.	
Product Availability	Prescription use	Prescription use	Same
Target Population	Adults 18 to 60 years of age who do not require critical care or ongoing vital signs monitoring. Healthy subjects.	Adults 18 years of age or older who do not require critical care or continuous vital signs monitoring.	Same
Users	Healthcare practitioners	Trained professional healthcare	Same
Clinical setting	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	Same
Design	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
Performance	50 to 130 ± 3 beats per minute, 30 second measurement window.	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.	Same
User Interface	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 iPhone 13 Pro with operating system iOS/iPadOS 16.0 or above	Standard, off the shelf computers and mobile devices, specified and installed	Different (b)

	Subject Device	Predicate Device (K211906)	
Trade Name	PanopticAI Vital Signs	Oxehealth Vital Signs	
Manufacturer	PanopticAI Technologies Limited	Oxehealth Limited	Comments
		by Oxehealth, and validated during installation.	
Compatibility with Hardware – camera & accessories	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)]
Clinical Performance	iPhone: 95% CI for the Upper [LoA]= (2.3094 to 3.0645) 95% CI for the Lower [LoA]= (-2.1954 to -1.4402) Bias (Mean of Absolute Difference) =0.9935 iPad: 95% CI for the Upper [LoA]= (2.5285 to 3.4571) 95% CI for the Lower [LoA]= (-3.0104 to -2.0818) Bias (Mean of Absolute Difference) =1.1598 RMSE demonstrated to be substantially equivalent	RMSD - bpm 1.81 bpm (97.5% CI, 0 - 2.19)	Same

9. Discussion of differences in technological characteristics

The subject device has similar intended use, design, and performance when compared to the 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

10.4.1. Glasses

A bench test was undertaken to verify the accuracy of the **PanopticAI Vital Signs app** with subjects wearing glasses versus those without.

It is concluded that there is no significant difference between the reference method and the subject devices across the participants with or without glasses.

10.4.2. Extreme heart rate

A bench test was conducted to verify whether extreme heart rate, specifically defined as 50-60 BPM and 100-130 BPM, would affect **PanopticAI Vital Signs app**'s accuracy and performance on both types of subject devices, iPhone and iPad.

It is concluded that there is no significant difference between the reference method and the subject devices across the participants with a heart rate range of 50-60 BPM or with a heart rate range of 100-130 BPM.

10.4.3. Make-up

A bench test was conducted to verify whether make-up covering the face would affect **PanopticAI Vital Signs app**'s accuracy and performance for both types of subject devices - iPhone and iPad.

It is concluded that there is no significant difference between the reference method and the subject devices across the participants with or without make-up.

10.4.4. Distance

A bench test was conducted to verify **PanopticAI Vital Signs app**'s accuracy and performance between a measuring range of 0.4 m and 0.6m for both types of subject devices – iPhone and iPad.

It is concluded that there is no significant difference between the reference method and the subject devices at a measuring range of 0.4 m and 0.6m.

10.4.5. Facial hair

A bench test was conducted to verify whether facial hair covering the face would affect **PanopticAI Vital Signs app**'s accuracy and performance for both types of subject devices - iPhone and iPad.

It is concluded that there is no significant difference between the reference method and the subject devices across the participants with or without facial hair.

10.4.6. Luminosity

A bench test was conducted to verify **PanopticAI Vital Signs app**'s accuracy and performance between 100 lux and 500 lux for both types of subject devices – iPhone and iPad.

It is concluded that there is no significant difference between the reference method and the subject devices at different lighting conditions.

11. Clinical Testing Summary

This clinical study aimed to assess the agreement between Vital Sign App and the standard pulse rate measurement by a clinician 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=107
Gender	Females: 52 Males: 55
Age Group	18-30: 41 31-50: 35 51-60: 31
BMI	Normal: 46 Obese: 10 Overweight: 51
Facial Shape	Heart: 10 Oblong: 19 Oval: 27 Round: 37 Square: 14
History of Hypertension	With: 6 Without: 101
Race/Ethnicity	Asian: 17 Black: 25 Hispanic: 30 White: 35
Skin Type According to Fitzpatrick Scale	I: 23 II: 26 III: 19 IV: 13 V: 12 VI: 14

It was shown that all of the following endpoint criteria were met.

- Bias
- 95% CI of Upper/Lower Limit of Agreement
- Correlation coefficient
- The intercept of zero and the slope of one are contained within the 95% CIs

These results were shown consistently across the following subgroups: -

- Gender
- Age
- Race/Ethnic
- Skin Color
- BMI
- Facial Shape
- History of Hypertension

For Subgroup analysis, please refer to page 16-25 of RD-730-04-20241121 [Clinical Validation Study Report].

The analysis revealed that, the overall RMSE, the overall mean bias, the mean bias of the subgroups were below the criteria of 3 BPM, indicating minimal systematic differences between the two measurement methods.

- Majority of 95% CI of upper and lower Limits of Agreement [LoA] across all the subgroups were consistently found to be within the endpoint criteria of ± 5 BPM (inclusive), suggesting that that the majority of differences fall within the acceptable range. The only two exceptions existed for iPad subjects with Heart Shape and History of Hypertension. Given that their absolute bias is still within 3 BPM, these 2 deviations are probably due to small sample size where normality may not be adequately attained. This does not have significant impact on the device accuracy.

The PanopticAI Vital Signs device is an accurate and high-performance device in pulse rate measurement.

Device accuracy was not compromised by gender, age, skin color, blood pressure, BMI, race/ethnic as well as facial shape.

This study has demonstrated that the device is accurate and comparable to the standard measurement in the intended conditions.

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 device.