4/28/2025

FaceHeart Corp.
Dr. Meng Liang Chung
Co-founder & Vice President
PO Box 309, Ugland House
Grand Cayman, KY1-1104
Cayman Islands

Re: K243966
Trade/Device Name: FaceHeart Vitals Software Development Kit (FH vitals SDK-RR)
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing frequency monitor
Regulatory Class: Class II
Product Code: BZQ

Dear Dr. Meng Liang Chung:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated 04/09/2025. Specifically, FDA is updating this substantial equivalence (SE) letter to correct the official correspondent as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Rachana Visaria, OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT, and Dental Devices, 240-402-5628, Rachana.Visaria@fda.hhs.gov.

Sincerely,

Rachana Visaria -S

Rachana Visaria, Ph.D.
Assistant Director
DHT1C: Division of Anesthesia,
Respiratory, and Sleep Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

April 9, 2025

FaceHart Corp.
Dr. Meng Liang Chung
Co-founder & Vice President
PO Box 309, Ugland House
Grand Cayman, KY1-1104
Cayman Islands

Re: K243966
Trade/Device Name: FaceHeart Vitals Software Development Kit (FH vitals SDK-RR)
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: Class II
Product Code: BZQ
Dated: March 7, 2025
Received: March 10, 2025

Dear Dr. Meng Liang Chung:

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,

Rachana Visaria -S

Rachana Visaria, Ph.D.
Assistant Director
DHT1C: Division of Anesthesia,
Respiratory, and Sleep Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental 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.

510(k) Number *(if known)*
K243966

Device Name
FaceHeart Vitals Software Development Kit (FH vitals SDK-RR)

Indications for Use *(Describe)*
FH Vitals SDK-RR is a software-only respiratory rate measurement tool intended to be integrated into third-party software applications on compatible mobile devices, laptops, or computers. It is intended for spot checking of Respiration Rate (RR) in an automatic contactless manner by analyzing chest wall movement from video input when the subject is still and properly positioned in front of the camera in a well-lit environment.

FH Vitals SDK-RR is intended for use under the supervision of a healthcare professional, either in clinical or home environments, and is not intended for continuous monitoring, apnea detection, or as the sole method for evaluating physical health. It is intended to serve as a supplemental tool to assist in the overall assessment of the patient. The software is indicated for use on individuals aged 18 years and older who do not require critical care or continuous vital sign monitoring.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510k Summary

[This summary is submitted according to the requirements of 21 CFR 807.92]

Submitter's Name, Address and Date prepared:

510(K) Number	K243966
Date Prepared	April 8, 2025
Manufacturer	FaceHeart Corporation Address: Rm.1003, 10F., Jan Qi Biomedical Engineering Building, No.75, Bo'ai St., East Dist., Hsinchu City 300, Taiwan (R.O.C.)
Applicant	FaceHeart Corporation PO Box 309, Ugland House, Grand Cayman, KY1-1104, Cayman Islands.
Primary Contact Person:	FaceHeart Corporation Name: MENG-LIANG CHUNG Phone:+886-3-6591088 Email: < ml.chung@faceheart.com>
Secondary Contact	FaceHeart Corporation Name: Yvette Lin Phone:+886-3-6591088 Email: < yvette.lin@faceheart.com>

Device Names and Classifications

Proposed Device

Trade Name	FaceHeart Vitals Software Development Kit (FH vitals SDK-RR)
Classification Name	Monitor, Breathing Frequency
Classification Regulation	21 CFR Part 868.2375
Classification Panel	Anesthesiology
Regulatory Class	Class II
Primary Product Code	BZQ (Monitor, Breathing Frequency)

Predicate Device

Trade Name	Philips VitalSigns Camera Medical Library
Manufacturer	Philips Medical Systems Nederland B.V.
510(k) Clearance Number	K242001
Classification Name	Breathing Frequency Monitor
Classification Regulation	21 CFR Part 868.2375
Classification Panel	Anesthesiology
Device Class	Class II
Primary Product Code	BZQ (Monitor, Breathing Frequency)

Device Description:

The FaceHeart Vitals Software Development Kit (FH Vitals SDK-RR) is a software product designed for integration into various software applications, such as those on mobile devices, laptops, or computers. This SDK is strictly a software-only product and is compatible with the following operating systems: Windows 10, Android 14, and iOS 17. It has been tested and is currently only compatible with the following cameras:

- Logitech C930 webcam
- Samsung S24+, S24+ smartphone front-facing cameras
- iPhone 15 Pro, and iPhone 15 Pro Max front-facing cameras

The SDK is non-contact and designed to measure the respiratory rate in breaths per minute based on facial video streams. When the SDK receives a video stream, it first identifies and tracks the face within the video, ensuring consistent positioning of the face. Based on the tracked facial region, the system identifies the chest as the region of interest (RoI) and locates reliable key points. The system then focuses on the movement of the chest within the RoI to further determine the number of respiratory cycles. By analyzing the frequency of chest elevation and depression, the SDK calculates the respiratory rate in breaths per minute.

FH Vitals SDK-RR is designed for non-invasive respiratory rate measurement with a validated measurement range of 5-36 bpm. The SDK is not intended for apnea monitoring or detecting the cessation of breathing. FH Vitals SDK-RR is a prescription-use software device that must be used under the clinical supervision or instruction of a licensed healthcare professional (HCP).

Indications for Use:

FH Vitals SDK-RR is a software-only respiratory rate measurement tool intended to be integrated into third-party software applications on compatible mobile devices, laptops, or computers. It is intended for spot checking of Respiration Rate (RR) in an automatic contactless manner by analyzing chest wall movement from video input when the subject is still and properly positioned in front of the camera in a well-lit environment.

FH Vitals SDK-RR is intended for use under the supervision of a healthcare professional, either in clinical or home environments, and is not intended for continuous monitoring, apnea detection, or as the sole method for evaluating physical health. It is intended to serve as a supplemental tool to assist in the overall assessment of the patient. The software is indicated for use on individuals aged 18 years and older who do not require critical care or continuous vital sign monitoring.

Comparison with the Predicate Device (Substantial Equivalence):

Table 1. Substantial Equivalent (SE) Comparison Summary

	Subject Device	Predicate Device	Comparison
510(k) Number	K243966	K242001	N/A
Device Name	FH vitals SDK-RR	Philips VitalSigns Camera Medical Library	N/A
Common Name	Respiratory Rate Measuring Software	Breathing Frequency Monitor	N/A
Manufacturer	FaceHeart Corp.	Philips Medical Systems Nederland B.V.	N/A
Indications for Use	FH Vitals SDK-RR is a software-only respiratory rate measurement tool intended to be integrated into third-party software applications on compatible mobile devices, laptops, or computers. It is intended for spot checking of Respiration Rate (RR) in an automatic contactless manner by analyzing chest wall movement from video input when the subject is still and properly positioned in front of the camera in a well-lit environment. FH Vitals SDK-RR is intended for use under the supervision of a healthcare professional, either in clinical or home environments, and is not intended for continuous monitoring, apnea detection, or as the sole method for evaluating physical health. It is intended to serve as a supplemental	VitalSigns Camera Medical Library is a software library that can be integrated into a customer application for use during virtual consults or health screening. It is intended for spot checking of Respiration Rate (RR) in an automatic contactless manner as a data point in the overall assessment of the patient. It is used under the supervision of a health care professional, either in the home or in a clinical environment when the subject is still and positioned properly in front of the camera (Samsung Galaxy A20e), which is placed on a stable surface in an adequately lit environment. It is intended to be used on patients aged 22 years and older that classify as ASA I (American	**Substantially Equivalent** Both intended for contactless spot-check RR measurement under supervision, for non-critical adult patients. Neither for apnea or continuous monitoring.

	tool to assist in the overall assessment of the patient. The software is indicated for use on individuals aged 18 years and older who do not require critical care or continuous vital sign monitoring.	Society of Anesthesiologists), which is defined as a normal healthy patient, non-smoking and no or minimal alcohol use. It is not intended for continuous patient monitoring system or as the sole method of checking the physical health of the patient, nor as an apnea monitor, but as a part of a framework which mandates periodic checks by a health care professional to ensure appropriate clinical diagnosis and treatment can be reached.	
Component	Software Only	Software Only	Same
Patient Type	Adults ≥18, not requiring critical care	ASA I patients ≥22	Substantially Equivalent (Subject device covers adults ≥18 not requiring critical care, which is a broader but lower-risk subset compared to ASA I patients ≥22. Use remains under HCP supervision.)
Use Environment	Mobile/PC-based use; 300 lux+, 0.5–1.5m distance, indoor use with general restrictions	Home & hospital settings; fixed camera on stable surface, adequate lighting	Similar
Respiratory Rate Measurement Range	5-36 bpm	7–30 bpm	Similar (The FH Vitals SDK-RR's respiratory rate range (5-36 bpm) is validated through clinical testing and aligns with the intended use population.)
Performance (Error Level)	±2 bpm	±3 bpm	Substantially Equivalent
Measurement Window	60 seconds	60 seconds	Same
Compatibility with Hardware-computing	This SDK is strictly a software-only product and is compatible with common operating systems, including Windows 10, Android 14, and iOS 17. It has been tested and is compatible with the following cameras: • Logitech C930 webcam • Samsung S24+, S24+ smartphone front-facing cameras • iPhone 15 Pro, and iPhone 15 Pro Max front-facing cameras	Not specified; camera and app integration assumed	Different, but functionally compatible
Camera Type	Built-in or external mobile/computer cameras	External camera in platform/device	Similar

Operating Principle	Chest motion analysis	Chest motion via torso movement	Similar
Use During Rest/Motion	Designed for still subjects	Still subjects only	Same
Alarm/Apnea Monitoring	No alarms, not for apnea detection	No alarms, not for apnea detection	Same

Summary of Non-Clinical Performance Data

Non-clinical performance testing has been conducted for the FH Vitals SDK-RR, demonstrating conformance to applicable FDA-recognized consensus standards and relevant guidance documents, including:

- **IEC 62304** – Medical Device Software – Software Life Cycle Processes
- **IEC 62366-1** – Usability Engineering for Medical Devices
- **ISO 14971** – Application of Risk Management to Medical Devices
- **FDA Guidance** – Content of Premarket Submissions for Device Software Functions
- **FDA Guidance** – Applying Human Factors and Usability Engineering to Medical Devices
- **FDA Guidance** – Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions
- **FDA Guidance** – Off-The-Shelf Software Use in Medical Devices

Non-clinical software verification testing was conducted to ensure all functional and non-functional requirements defined in the Product Requirements Specification have been implemented. This includes the safety risk control measures derived from the risk assessment matrix and cybersecurity requirements.

Software validation confirmed that FH Vitals SDK-RR performs as intended, meets user needs, and is suitable for its intended environment. Usability validation was performed with both healthcare professionals and general users under simulated use scenarios.

Summary of Clinical Performance Data

The performance of the FH vitals SDK-RR was evaluated in a clinical study involving 420 participants aged 18 and older. The study was conducted in Taiwan (377 subjects) and the United States (43 subjects). The demographic characteristics of the study are summarized in Table 2.

Table 2. Clinical Validation Study subject demographic

Sample size	N=420
Sex Distribution	• Male: 48.8% (205 subjects) • Female: 51.2% (215 subjects)
Age Group	• 18-21 years: 6% (25 subjects) • 22-64 years: 74% (311 subjects) • 65+ years: 20% (84 subjects)
BMI Distribution	• Normal weight (18.5-24.9): 33% (139 subjects)

	• Overweight (25-29.9): 27% (113 subjects) • Obesity (30+): 40% (168 subjects)
Health Conditions	• Cardiac diseases: 25% (105 subjects) • Pulmonary diseases: 31.4% (132 subjects) • Neurological diseases: 3.48% (15 subjects) • Diabetes: 10.3% (43 subjects) • Hypertension: 50% (210 subjects) • Congestive heart failure: 1.82% (8 subjects)

Performance Comparison with Philips MX100
The FH Vitals SDK-RR was installed on laptops equipped with a C930 webcam, iPhone 15 Pro Max, iPhone 15 Pro, Samsung S24+, and Samsung S24 Ultra. The software processed facial and chest data captured via the devices' cameras to measure respiratory rates (RR).

The accuracy of the respiratory rate (RR) measurements derived from the FH Vitals SDK-RR was evaluated against a gold standard etCO2 device (manually counted/annotated respiratory rate from analysis of waveform output from the Philips MX100 with Microstream CO2 Extension). When compared to the Philips MX100 RR as the ground truth, the respiratory rate measurements derived from the FH Vitals SDK-RR demonstrated deviations consistently within ±2 breaths per minute (bpm) across all devices.

Key Performance Results:
The FH Vitals SDK-RR underwent performance testing to evaluate its measurement accuracy and consistency across different devices. The evaluation included five distinct hardware platforms:

- Laptop with C930 webcam
- iPhone 15 Pro Max
- iPhone 15 Pro
- Samsung S24+
- Samsung S24 Ultra

Each device was tested under standardized conditions, and the measurement performance was assessed based on Root Mean Square Error (RMSE) and coefficient of determination (R^2).

Key Findings:

1. Accuracy: The Root Mean Square Error (RMSE) for all tested devices was 1.2 bpm, with a 95% confidence interval (CI).
2. Statistical Significance: Hypothesis testing showed that p-values for RMSE > 2 bpm were below 0.001, confirming that the results were statistically significant.
3. Consistency Across Devices: The coefficient of determination (R^2) values exceeded 0.98 across all devices, indicating that the respiratory rate measurements from FH Vitals SDK-RR closely aligned with those of the clinical reference device.

The table below summarizes the performance results across different devices.

Table 3: Overall Performance Summary

Device	#Records	RMSE 95% CI	p-value (RMSE > 2)	R^2
C930	2100	1.2	$p < 0.001$	0.9867
iPhone 15 Pro Max	2100	1.2		0.9859
iPhone 15 Pro	2100	1.2		0.9866
Samsung S24+	2100	1.2		0.9855
Samsung S24 Ultra	2100	1.2		0.9861

These results demonstrate that FH Vitals SDK-RR provides consistent and reliable respiratory rate measurements across multiple hardware configurations. The low RMSE and high R^2 values indicate that the software performs accurately under varied conditions.

Performance Across Respiratory Rate Levels

The results in Table 4 demonstrate that across all tested respiratory rate ranges, the RMSE remains well within 2 bpm, confirming that the device meets its claimed accuracy threshold (≤2 bpm). Additionally, the p-values for all groups are less than 0.001, indicating that the results are statistically significant.

Table 4: Performance Across Respiratory Rate Levels

(*Each element is expressed as: RMSE 95% CI. p-value < 0.001 for all cases*)

RR Group	C930	iPhone 15 Pro Max	iPhone 15 Pro	Samsung S24+	Samsung S24 Ultra
5-8 (#420)	1.7	1.8	1.7	1.7	1.7
9-11 (#420)	1.0	1.1	1.0	1.1	1.1
12-19 (#420)	1.0	1.0	1.0	1.3	1.2
20-29 (#420)	0.9 /	1.0	0.9	0.9	0.9
30+ (#420)	1.1 /	1.2	1.1	1.1	1.1

Other Findings

- **Performance Across Demographics**: No significant differences in accuracy were found based on sex, age, or BMI, confirming consistent performance across demographic groups.

- **Performance Across Disease Subgroups**: No major performance issues were noted in cardiovascular, neurological, or pulmonary patients, with minor underestimation in some conditions (e.g., Alzheimer's) still within acceptable limits.
- **Clothing Impact on Accuracy**: Analysis showed negligible correlation between clothing texture and accuracy confirming robustness across different clothing types.
- **Performance Under Limiting Conditions (Note:** Device is not intended for motion conditions):
    - **Motion**: Up-and-down or back-and-forth motion increased errors; left-and-right motion had the least impact.
    - **Behavior**: Coughing caused significant errors; shallow breathing had minimal effect.
    - **User Pose**: No difference in accuracy between sitting or lying positions.
    - **Illumination**: Stable performance across various lighting conditions.
    - **Measurement Distance**: Accuracy was reliable within 1.5 meters but decreased beyond that range.

Conclusion

These results confirm that FH Vitals SDK-RR maintains a measurement accuracy of ≤2 bpm across all respiratory rate levels, including low (5-8 bpm), normal (12-19 bpm), and high (30+ bpm) respiratory rates when measured using compatible software and hardware platforms.

Substantial Equivalence Conclusion

In summary, the FH Vitals SDK-RR has a similar intended use as the cleared predicate device, Philips VitalSigns Camera Medical Library (K242001). Additionally, the proposed device shares similar technological characteristics and operational principles with the predicate device. The differences between the two devices do not raise new questions of safety or effectiveness. Therefore, FH Vitals SDK-RR is considered substantially equivalent to the predicate device.