September 1, 2023

FaceHeart Corp.
Morris Chung
AVP
PO Box 309, Ugland House
Grand Cayman, KY1-1104
Cayman Islands

Re: K223622
Trade/Device Name: FaceHeart Vitals Software Development Kit (FH vitals SDK)
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: July 29, 2023
Received: July 31, 2023

Dear Morris 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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K223622

Device Name

FaceHeart Vitals Software Development Kit (FH vitals SDK)

Indications for Use *(Describe)*

The FH Vitals SDK is designed to measure the pulse rate based on the given facial video stream. It is intended for non-invasive spot measurements of pulse rate when the subject is still. This SDK is not intended for use in patients with known or suspected heart arrhythmias.

While the SDK can be used for general healthcare, it is not designed to treat patients. The pulse rate measurement results provided by the FH Vitals SDK should complement, but not replace, the user's usual professional medical care and/or medication. If abnormalities are detected during the measurement with the FH Vitals SDK, users are advised to consult a medical professional.

The FH Vitals SDK is indicated for use in humans 18 years of age or older who do not require critical care or continuous vital signs monitoring. This software should not be the primary or sole method for assessing an individual's health.

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.

FaceHeart

510(k) Summary

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

1. Submitter's Name, Address and Date prepared:

Applicant	FaceHeart Corporation PO Box 309, Ugland House, Grand Cayman, KY1-1104, Cayman Islands.
Correspondent	Name: Morris Chung Address: Rm.1003, 10F., Jan Qi Biomedical Engineering Building, No.75, Bo'ai St., East Dist., Hsinchu City 300, Taiwan (R.O.C.) Phone: +886-3-6591088 Email: < ml.chung@faceheart.com>
Date Prepared	August 31, 2023

2. Device Names and Classifications

Proposed Device

Name of Proposed Device	FH vitals SDK
Common Name:	Pulse Rate Measuring Software
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
Review Panel	Cardiovascular

Predicate Device

Predicate Manufacturer	Oxehealth Limited

Predicate Trade Name	Oxehealth Vital Signs
Predicate 510 (k)	K211906

3. Device Description:

FH vitals SDK is a video-based, non-contact pulse rate measurement software with a face recognition function designed to measure and real-time display the pulse rate of adults. This system uses cameras to detect the user's face and obtains the continuous face image data, with signal processing and algorithm to compute the pulse rate. The software is intended to be installed on commercial mobile devices/laptops/computers equipped with cameras. It can be deployed on Android, iOS platform and Windows platforms.

It is the responsibility of the device manufacturer to integrate FH vitals SDK correctly and to obtain the necessary regulatory approval/clearance for the final device integrating FH vitals SDK. It is also the responsibility of the device manufacturer to ensure that their device or software application has the correct regulatory approvals and meets the required standards for their intended use. Any regulatory clearance and tests FH vitals SDK has do not apply to a device or software integrating FH vitals SDK. These processes and tests should be repeated at the system level.

4. Indications for Use:

The FH Vitals SDK is designed to measure the pulse rate based on the given facial video stream. It is intended for non-invasive spot measurements of pulse rate when the subject is still. This SDK is not intended for use in patients with known or suspected heart arrhythmias.

While the SDK can be used for general healthcare, it is not designed to treat patients. The pulse rate measurement results provided by the FH Vitals SDK should complement, but not replace, the user's usual professional medical care and/or medication. If abnormalities

are detected during the measurement with the FH Vitals SDK, users are advised to consult a medical professional.

The FH Vitals SDK is indicated for use in humans 18 years of age or older who do not require critical care or continuous vital signs monitoring. This software should not be the primary or sole method for assessing an individual's health.

5. Technological Characteristics:

Similar to the predicate device, the FH vitals SDK is a software-only product that measures pulse rate through an optical camera-based mechanism.

This software intended to run on standard PCs, laptops, and mobile devices, analyzing video streams captured by compatible available video cameras to compute pulse rate.

This software is intended to analyze video collected by compatible cameras in stationary conditions. Users are instructed to keep the camera stationary (e.g., by using a stand or another suitable support). When integrating this software for use with camera signals from devices with accelerometers (e.g., smartphones), the manufacturer is instructed to use accelerometer data to only use this software with video collected when the camera is stationary.

6. Comparison with the Predicate Device (Substantial Equivalence):

Table 1. Substantial Equivalent (SE) Comparison Summary

	Subject Device	Predicate Device	Comparison
510(k) Number	K223622	K211906	
Device Name	FH vitals SDK	Oxehealth Vital Signs	
Common Name	Pulse Rate Measuring Software	Vital Signs	
Manufacturer	FaceHeart Corp.	Oxehealth Ltd	

Indications for Use	The FH Vitals SDK is designed to measure the pulse rate based on the given facial video stream. It is intended for non-invasive spot measurements of pulse rate when the subject is still. This SDK is not intended for use in patients with known or suspected heart arrhythmias. While the SDK can be used for general healthcare, it is not designed to treat patients. The pulse rate measurement results provided by the FH Vitals SDK should complement, but not replace, the user's usual professional medical care and/or medication. If abnormalities are detected during the measurement with the FH Vitals SDK, users are advised to consult a medical professional. The FH Vitals SDK is indicated for use in humans 18 years of age or older who do not require critical care or continuous vital signs monitoring. This software should not be the primary or sole method for assessing an individual's health.	Non-invasive spot check measurements of pulse rate and breathing rate (chest wall movements). The Oxehealth Vital Signs device is intended for noninvasive spot measurements 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 for 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.	Similar. FaceHeart's indications are a subset of the OxeHealth Vital Signs indications
Component	Software Only	Software Only	Same
Patient Type	Adults not requiring critical care	Adults not requiring critical care	Same
Use Environment	Light source: above 300 Lux (Depends on camera) Measuring distance: 0.5-1.5m (Depends on camera)	In the presence of sources of flashing or variable light, including other Near Infrared illumination.	Different

<table>
<tr><td>Pulse Rate Measurement Range</td><td>50-180 bpm</td><td>50-130 bpm</td><td>Similar: FH vitals SDK can measure a wider range of pulse rate</td></tr>
<tr><td>Performance (Error Level)</td><td>±3 bpm</td><td>±3 bpm</td><td>Same</td></tr>
<tr><td>Measurement Window</td><td>1 min</td><td>9 seconds</td><td>Different</td></tr>
<tr><td>Compatibility with Hardware-computing</td><td>The pulse rate measurement feature of FH Vitals SDK is a software product that exclusively supports the following three operating systems:
Windows 10
Android 12
iOS 12
The acceptable hardware devices and their required specifications are as follows:</td><td>Standard, off the shelf computers and mobile tablets, specified and installed by Oxehealth, and validated during installation.

Installation will be carried out by an Oxehealth approved installer, according to installation instructions and verification procedures provided by Oxehealth.</td><td>Different</td></tr>
<tr><td>Compatibility with Hardware -Camera and Accessories</td><td>
<table>
<tr><td>Item</td><td>C920 + Laptop</td><td>iPhone 13 Pro</td><td>iPhone 13 Pro Max</td><td>Samsung S22 Ultra</td><td>Samsung S22+</td></tr>
<tr><td>Camera FOV</td><td>78°</td><td colspan="2">77°</td><td>80°</td><td>80°</td></tr>
<tr><td>Camera Sensor Size</td><td>1/3”</td><td colspan="2">1/3.6”</td><td>1/2.82”</td><td>1/3.24”</td></tr>
<tr><td>Camera Aperture Size</td><td>F2.0</td><td colspan="2">F2.2</td><td>F2.2</td><td>F2.2</td></tr>
<tr><td>Streaming</td><td colspan="5">VGA @ 30fps</td></tr>
<tr><td>CPU</td><td>Intel i7-1165G7</td><td colspan="2" rowspan="2">A15</td><td colspan="2">1 x Cortex X2
3 x Cortex A710
4 x Cortex A510</td></tr>
<tr><td>GPU</td><td>Intel Iris Xe Graphics</td><td colspan="2">Adreno 730</td></tr>
<tr><td>OS</td><td>Windows 10</td><td colspan="2">iOS 12</td><td colspan="2">Android 12</td></tr>
<tr><td>Output Range</td><td colspan="5">Heart Rate: 50~180 bpm</td></tr>
<tr><td>Output Time</td><td colspan="5">1 min</td></tr>
<tr><td>Memory Requirement</td><td colspan="5">500 MB and above</td></tr>
<tr><td>Operating Restriction</td><td colspan="5">● Required to stay steady during measurement.
● Support minor movement (speak or nod slightly)</td></tr>
<tr><td>Applicable Environment</td><td colspan="5">● Illumination: above 300 lux
● Measuring distance: 0.5-1.5m</td></tr>
<tr><td>Error Level</td><td colspan="5">within±3 bpm</td></tr>
</table>
</td><td>Standard, off the shelf machine vision camera and infrared illuminators, exact specification determined by Oxehealth and validated during installation</td><td>Different</td></tr>
<tr><td>Software</td><td>C++/Java/Objective-C++</td><td>C++ and Node.js; use of 3rd party libraries</td><td>Different</td></tr>
</table>

7. Clinical Performance Data

FH vitals SDK was verified and validated in accordance with the special controls for optical camera-based measurement of pulse rate, heart rate, breathing rate, and/or respiratory rate (21 CFR 870.2785-Reclassification Order of DEN200019). The testing demonstrated that the device performed according to its specifications and that the technological and performance criteria were comparable to the predicate device.

Performance data is demonstrated by 1000-CSR-02-V2.0 clinical studies Report. The performance of the FH vitals SDK was tested in a clinical study of 527 participants, age 18 and older. Study demographic characteristics are summarized in Table 2.

Table 2. Clinical Validation Study subject demographic

Sample size	N=527
Gender	• Females: 314 subjects • Males: 213 subjects
Age Group	• 18-39: 213 subjects • 40-59: 184 subjects • Above 60:
BMI	• 0-18.5: 29 subjects • 18.5-24.9: 270 subjects • 25-29.9: 149 subjects • 30+: 79 subjects
Makeup	• With: 44 subjects • Without: 483 subjects
Glasses	• With: 183 subjects • Without: 344 subjects
Facial hair	• With: 48 subjects • Without: 419 subjects
Skin type according to Fitzpatrick Scale	• Types I and II: The number of subjects was 34 • Types III and IV: The number of subjects was 410 • Types V and VI: The number of subjects was 83
Facial Shapes	• Heart: 28 subjects • Oblong: 169 subjects • Oval: 58 subjects • Round: 232 subjects • Square: 40 subjects

Disease History	• Arrhythmia: 55 subjects • Coronary Artery Disease (CAD): 90 subjects • Heart Failure (HF): 23 subjects • Hypertension: 125 subjects • Other CVDs> 21 subjects

The data showed that compared with Philips MX100 ECG, the pulse rate deviation of FH Vitals SDK installed on laptops with C920, iPhone 13 Pro, iPhone 13 Pro Max, Samsung S22 Ultra, and Samsung S22+ were within ±3bpm, accounting for about 90.3, 95.4%, 95.4%, 93.7%, and 94.3% in 527 subjects, respectively. On average, about 93.8% of the 527 subjects.

8. Non-Clinical Software Testing:

Our software underwent comprehensive non-clinical testing, as detailed in the "Full System Testing" report. Importantly, these tests were conducted on a system that integrates with our device and represents the final configuration. This testing approach encompassed both functionality tests and system performance tests.

- **Device Compatibility:**

The software's compatibility was verified on specific devices, ensuring that the final application functions correctly. The tested devices are as follows:

- Laptop (Asus Zenbook UX435EAL) with C920
- iPhone 13 Pro
- iPhone 13 Pro Max
- Samsung S22+
- Samsung S22

- **Motion Impact on Performance Decay**

According to our internal test, under the scenario of doing exercise or performing large movement, the mean absolute error of pulse rate measurement can range from 11.77 bpm to 42.06 bpm. Such error range indicates that motion has significant impact on the precision of pulse rate measurement.

- **Software Functionality:**

The software is designed to track only one face, even in scenarios where multiple faces are present within the image frames. All warning messages were also validated to ensure they are triggered appropriately.

Scenario	Software Response
There are multiple faces in camera view.	The software tracks only one face during the measurement.
Use a finger to cover the camera.	Warning message: Missing Face.
Use a hand to cover the face.	Warning message: Missing Face.
Turn off lights in the room to make the face unrecognizable.	Warning message: Missing Face.
Enlarge the camera focus to have a blurred face which is unrecognizable.	Warning message: Missing Face.
Wear a hat to block a large portion of the face.	Warning message: Missing Face.
Wear a facial mask.	Warning message: Missing Face.
Make the face outside Rectangle.	Warning message: Bad Face Position.
Make the face-camera distance larger than 1.5M.	Warning message: Bad Face Position.
Nod slightly.	Warning message: Motion.
Shake the head slightly.	Warning message: Motion.
Move back and forth.	Warning message: Motion.
Stand up suddenly.	Warning message: Motion.
Shake the camera.	Warning message: Motion.
Low camera frame rate.	Warning message: Low Frame Rate.

- **System Performance Metrics:**

For each device, the following performance metrics were observed:

Device	Memory (MB)	CPU (%)	Average Image Frame Processing Time: Time Cost (ms/frame)
C920 with Asus Zenbook UX435EAL	155	10	4.09
iPhone 13 Pro	58.5	43	3.58
iPhone 13 Pro Max	46.3	40	3.91
Samsung S22+	187	10	9.79
Samsung S22 Ultra	225	10	8.71

It's worth noting that the image processing speed of the software exceeds the frame rate of the camera, indicating that device performance meets real-time requirements.

9. Consideration of Special Controls Guidance

In combination with the general controls of the FD&C Act, the software for optical camera-based measurement of pulse rate, heart rate, breathing rate, and/or respiratory rate (products submitted under 21 CFR 870.2785-Reclassification Order of DEN200019) is subject to the following special controls:

Special controls	Evidence of compliance
(1) A software description and the results of verification and validation testing based on a comprehensive hazard analysis and risk assessment must include: (i)A full characterization of the software technical parameters, including algorithms; (ii)If required image acquisition hardware is not included with the device, full specifications of the hardware requirements and testing to demonstrate the specified hardware ensures adequate data for validated and accurate measurements. (iii)A description of the expected impact of all applicable sensor acquisition hardware characteristics and associated hardware specifications; (iv)A description of all mitigations for user error or failure of any subsystem components (including signal detection, signal analysis, data display, and storage) on output accuracy; and (v)Software documentation must include a cybersecurity vulnerability and management process to assure software functionality.	Software documentation included a description of algorithm training and validation data, a discussion of the specifications of compatible hardware and the impact of these specifications on the device, and testing of all mitigations for user error. Software documentation also included cybersecurity testing and a vulnerability analysis.
(2) Clinical data must be provided. This assessment must fulfill the following: (i)The clinical data must be representative of the intended use population for the device. Any selection criteria or sample limitations must be fully described and justified. (ii)The assessment must demonstrate output consistency using the expected range of data sources and data quality encountered in the intended use population and environment. (iii)The assessment must compare device output with a clinically accurate patient-contacting relevant comparator device in an accurate and reproducible manner.	Clinical validation study is provided in Section 7 above.

(3) A human factors and usability engineering assessment must be provided that evaluates the risk of improper measurement.	A Use-Related-Risk-Analysis was conducted and A Human Factors Validation Study was conducted with 15 health care providers and 15 patients that showed minimal user errors, close calls, or use difficulties.
(4) Labeling must include: (i)A description of what the device measures and outputs to the user; (ii)Warnings identifying sensor acquisition factors or subject conditions or characteristics (garment types/textures, motion, etc.) that may impact measurement results; (iii)Guidance for interpretation of the measurements, including a statement that the output is adjunctive to other physical vital sign parameters and patient information; (iv)The expected performance of the device for all intended use populations and environments; and (v)Robust instructions to ensure correct system setup. In addition, this is a prescription device and must comply with 21 CFR 801.109.	Labeling requirements are incorporated in the user manuals.

10. Conclusion

In conclusion, the FH Vitals SDK shares a similar intended use to that of the already cleared predicate device, with its function encapsulating a subset of the features provided by the Oxehealth systems. Moreover, the proposed device aligns closely in technological characteristics and operational principles with the predicate device. The distinctions that do exist between the two devices do not introduce additional concerns regarding safety or performance. Consequently, we posit that the FH Vitals SDK is substantially equivalent to the predicate device.