June 11, 2026

Nuralogix Corporation
Jessica Mavadia-Shukla
Director of Regulatory Strategy & Health Science
250 University Ave.
Suite 209
Toronto, ON M5H3E5
Canada

Re: K253650
Trade/Device Name: Anura Mobile Core SDK (M1)
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, BZQ
Dated: June 10, 2026
Received: June 10, 2026

Dear Jessica Mavadia-Shukla:

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.	K253650

Please provide the device trade name(s).

Anura Mobile Core SDK (M1)

Please provide your Indications for Use below.

Anura Mobile Core SDK (AMC-SDK) is designed to use Transdermal Optical Imaging (TOI) for non-invasive spot (discrete) measurement of pulse rate and breathing rate (chest wall movements) when the subject is relaxed, still, and seated upright.

AMC-SDK can be used for general healthcare in adults 18 years of age or older, but is not designed to treat or diagnose patients. The measurement results should complement, but not replace, the user's professional medical care and/or medication. If abnormalities are detected during the measurement with the SDK, users are advised to consult a medical professional.

AMC-SDK is not intended to be the sole method of checking the physical health of a subject.

AMC-SDK is not designed to function as an apnea monitor or to detect cessation of breathing.

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)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

510(k) Summary

[As per 21 CFR 807.92]

Submitter's Information

Applicant	NuraLogix Corporation
Address	250 University Avenue, Suite 209 Toronto, Ontario M5H 3E5 Canada
Correspondent	Jessica Mavadia-Shukla, PhD Director of Regulatory Strategy & Health Sciences Phone: +1 (732)-688-7843 Email: compliance@nuralogix.ai
Date Prepared	June 9th, 2026

Device Names and Classification

Proposed Device

Device Propriety Name	Anura Mobile Core SDK
Common or Usual Name	Anura Mobile Core SDK or AMC-SDK
Classification Name	Pulse Rate and Breathing Rate Measuring Software
Primary Product Code	
Product Code	QME
Regulation Number	21 CFR 870.2785
Regulation Description	Software For Optical Camera-based Measurement of Pulse Rate, Heart Rate, Breathing Rate, And/Or Respiratory Rate
Regulation Class	Class II
Review Panel	Cardiovascular
Secondary Product Code	
Product Code	BZQ
Regulation Number	21 CFR 868.2375
Regulation Description	Breathing Frequency Monitor
Regulation Class	Class II
Review Panel	Anesthesiology

Predicate Devices

Trade Name	**FH vitals SDK**	**FH vitals SDK-RR**
Manufacturer	FaceHeart Corporation	FaceHeart Corporation
510(k) Number	K223622	K243966
Date Cleared	September 1, 2023	April 9, 2025

Device Description

Anura Mobile Core SDK (AMC-SDK) is a software development kit designed to facilitate video-based, non-invasive, contactless measure of pulse rate and breathing rate. The software uses cameras to detect the user's face and upper body, extracts blood flow and movement information from image stream, and then with signal

processing and computational algorithms to estimate the pulse rate and breathing rate, and returns the results of such measurements. The software is intended to be integrated into applications that are installed on commercial mobile devices (including smartphones) equipped with cameras and internet connectivity. It can be deployed on Android and iOS platforms.

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

Indications for Use

Anura Mobile Core SDK (AMC-SDK) is designed to use Transdermal Optical Imaging (TOI) for non-invasive spot measurement of pulse rate and breathing rate (chest wall movement) when the subject is seated and still.

AMC-SDK can be used for general healthcare in adults 18 years of age or older, but is not designed to treat or diagnose patients. The measurement results provided by the SDK should complement, but not replace, the user's professional medical care and/or medication. If abnormalities are detected during the measurement with the SDK, users are advised to consult a medical professional.

AMC-SDK is not intended to be the sole method of checking the physical health of a subject.

AMC-SDK is not designed to function as an apnea monitor or to detect cessation of breathing.

Comparison with Predicate Devices (Substantial Equivalence)

The subject device AMC-SDK is substantially equivalent to the predicate devices with respect to indications for use, measurement method, and performance claims. The subject device and the predicate devices all employ contactless remote measuring of patient vital information. The primary difference between the subject and predicate devices is the hardware each system is compatible with. Detailed comparison information is provided below.

Table 3. Comparison of Anura Mobile Core SDK with Predicate Devices				
	Subject Device **Anura Mobile Core SDK**	**Primary Predicate** **FH vitals SDK**	**Secondary Predicate** **FH vitals SDK**	**Comparison**
510(k) #	**K253650**	**K223622**	**K243966**	N/A
Indications for Use	Anura Mobile Core SDK (AMC-SDK) uses Transdermal Optical Imaging (TOI) for non-invasive spot (discrete) measurement of pulse rate and breathing rate (chest wall movements) when the subject is relaxed, still, and seated upright. AMC-SDK can be used for general healthcare in adults 18 years of age or older, but is not designed to treat or diagnose patients. The measurement results should complement, but not replace, the user's professional medical care and/or medication. If abnormalities are detected during the measurement, users are advised to consult a medical professional. AMC-SDK is not intended to be the primary or sole method of checking the physical health of a subject. AMC-SDK is not designed to function as an apnea monitor or to detect cessation of breathing.	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.	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.	Similar – AMC-SDK, and FH vitals SDK are non-contacting, non-invasive spot checking devices for pulse rate (FH vitals) and breathing rate (chest wall movements). AMC-SDK includes both pulse rate and respiration rate features which are separately cleared via 2 510(K)s for FH Vitals in K223622 and K243966.
Device Type	Software as a Medical Device (SaMD)	SaMD	SaMD	Identical
Type of Use	Prescription Use	Prescription Use	Prescription Use	Identical
Use Population	Adults not requiring critical care	Adults not requiring critical care	Adults ≥18, not requiring critical care	Identical
Use Environment	Hospitals, clinics, long-term care facilities, and telemedicine-based home use	Unknown, presumably telemedicine-based home use	Clinical or home environments	Similar – comparable settings across devices
Monitoring	Spot-checking	Spot-checking	Spot-checking	Identical
Measurement Site	Pulse rate: surface of facial skin Breathing rate: upper body	Pulse rate: surface of facial skin Breathing rate: N/A	Chest wall movement	Identical (Pulse Rate) – AMC-SDK and FH vitals SDK (K223622) take measurements on the face Identical (Breathing Rate) – AMC-SDK and FH Vitals-RR (K243966) both take measurements of the upper body (including the chest).
Measuring Distance	Measuring between 30 to 91 cm (or 12 to 36 inches) camera distance from face	Measuring distance of 50 to 150 cm (or 0.5 to 1.5m) depends on camera	Mobile/PC-based use; 0.5–1.5m distance, indoor use with general restrictions	Similar – All devices measure vitals remotely; AMC-SDK operates at a closer distance than FH vitals
Environmental Conditions	Lighting: ambient indoor lighting, generally above 100 Lux	Illumination above 300 Lux depends on camera	300 lux+,	Similar lighting to FH vitals
Operating Restriction	• Required to stay steady during measurement • Support minor movement such as breathing, as long as the signal passes quality checks • Required to be seated	• Required to stay steady during measurement • Support minor movement (speak or nod slightly)	• Designed for still subjects	Identical

Table 3. Comparison of Anura Mobile Core SDK with Predicate Devices

	Subject Device **Anura Mobile Core SDK**	**Primary Predicate** **FH vitals SDK**	**Secondary Predicate** **FH vitals SDK**	**Comparison**
Physiological parameters measured	Pulse rate and breathing rate (chest wall movements)	Pulse rate	Breathing rate (chest wall movements)	Identical
Pulse Rate Measurement Range	45-105 beats per minute (bpm)	50-180 bpm	N/A	Similar – AMC-SDK measures a slightly narrower range than FH Vitals based upon the clinical data that supports AMC-SDK.
Pulse Rate Performance (Error Level)	± 3 bpm	± 3 bpm	N/A	Identical
Breathing Rate Measurement Range	8-39 breaths per minute (brpm)	N/A – Does not measure breathing rate	5-36 bpm	Similar.
Breathing Rate Performance (Error Level)	± 2.3 brpm	N/A – Does not measure breathing rate	± 2 brpm	Similar – both device measures accurately ≤ 2.5 brpm
Measurement Window	30 seconds	60 seconds (1 minute)	60 seconds (1 minute)	Similar – AMC-SDK takes a shorter time to measure than FH vitals
Compatibility with Hardware - Computing	AMC-SDK is a software product that exclusively supports the following systems: • Apple mobile devices with ARMv8-A CPU architecture, Apple A10 or more performant CPU and Apple iOS 18 or newer compatible OS • Android mobile devices with ARMv8-A CPU architecture, Qualcomm Snapdragon 855 or more performant CPU and Android 13 or newer compatible OS	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	This SDK is strictly a software-only product and is compatible with common operating systems, including Windows 10, Android 14, and iOS 17.	Similar
Compatibility with Hardware – Camera	Item / Camera Aperture Size / Streaming: iPhone 13 f/2.2; iPhone XR f/2.2; Samsung S23 f/2.2; Streaming 30 fps	Item / Camera FOV / Camera Sensor Size / Camera Aperture Size / Streaming: C920+ Laptop 78°, 1/3”, F2.0; iPhone 13 Pro 77°, 1/3.6”, F2.2; iPhone 13 Pro Max 77°, 1/3.6”, F2.2; Samsung S22 Ultra 80°, ½.82”, F2.2; Samsung S22+ 80°, 1/3.24”, F2.2; Streaming VGA @ 30 fps	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	Similar to FH vitals, where AMC-SDK uses camera on mobile phones
Compatibility with Hardware – Accessories	Item / CPU / GPU / OS / Memory: iPhone 13 Apple A15 Bionic (5 nm), 4GB, iOS 17; iPhone XR Apple A12 Bionic (7 nm), 3GB, iOS 15+; Samsung S23 Qualcomm SM8550-AC Snapdragon 8 Gen 2, Adreno 740, Android 14, 8GB	Item / CPU / GPU: C920+ Laptop Intel i7-1165G7, Intel Iris Xe Graphics; iPhone 13 Pro A15; iPhone 13 Pro Max A15; Samsung S22 Ultra 1 x Cortex X2, 3 x Cortex A710, 4 x Cortex A510, Adreno 730; Samsung S22+ 1 x Cortex X2, 3 x Cortex A710, 4 x Cortex A510, Adreno 730		Similar to FH vitals, where AMC-SDK can be installed on off the shelf mobile phones

Table 3. Comparison of Anura Mobile Core SDK with Predicate Devices				
	Subject Device **Anura Mobile Core SDK**	**Primary Predicate** **FH vitals SDK**	**Secondary Predicate** **FH vitals SDK**	**Comparison**
		OS: Windows 10 / iOS 12 / Android 12 Memory Required: 500 MB and above		
Software Language	Python, Go, SQL, TypeScript, Node.js, ReactJS, Java, Kotlin, Swift, Objective-C, C++, C; use of 3rd party libraries	C++/Java/Objective-C++		Different

Non-Clinical/Bench Testing

Non-clinical performance testing was conducted for Anura Mobile Core SDK (AMC-SDK) to ensure device performance across the intended range of pulse rate and breathing rate. The testing consists of software verification and validation, Human Factors (Usability) testing, and Simulation Testing of Pulse Rate.

In addition, AMC-SDK was tested 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). The testing demonstrated that the technological and performance criteria were comparable to the predicate devices.
The software's compatibility was verified on specific devices, ensuring that the final application functions correctly. The tested devices are as follows:

- iPhone 13
- iPhone XR
- Samsung S23

Human Factors (Usability) Testing

A human factors summative study was conducted on 30 participates, including 15 lay users (patients), and 15 healthcare professionals (8 doctors and 7 nurses). The results demonstrate that AMC-SDK controls use-related risks for the intended users, uses, and use environments.

Clinical Testing

Clinical performance of Anura Mobile Core SDK (AMC-SDK) was tested to support the safety and performance of the device, and to ensure device performance and device accuracy across the intended range of pulse rate and breathing rate. A clinical validation study was conducted with 57 subjects ranged from 18 to 74 years of age.

Clinical Validation Study Subject Demographics		
Characteristic		**Count**
Sample Size		57
Sex at Birth	Male	30
	Female	27
Age Group	≤ 50	36
	> 50	21
Body Mass Index (BMI) (kg/m^2)	Normal (< 25.0)	16
	Overweight (25.0-29.9)	24
	Obese (> 30.0)	17
Skin Type (Fitzpatrick Scale)	Light (Type I & II)	13
	Medium (Type III & IV)	25
	Dark (Type IV & V)	19
Race & Ethnicity	White	26
	Black/African American	6
	Asian	5
	Hispanic (Ethnicity)	7
	Other	4
	Not Reported	16
Smoker	Yes	9
	No	48

Clinical Validation Study Subject Demographics		
Characteristic		**Count**
Disease History / Comorbidity	Chronic obstructive pulmonary disease (COPD)	4
	Congestive Heart Failure (CHF)	3
	Hypertension	10
	Asthma	11
	Diabetes	4

The study evaluated the AMC-SDK device performance measuring pulse and breathing rate under expected conditions. Pulse and breathing rates were compared to the standard contact device, GE Healthcare (Datex-Ohmeda) S5 Multi-parameter Monitor, as the reference device.

The primary objective of the study was to assess the accuracy of pulse rate and estimated breathing rate (upper body movements) measurements made using AMC-SDK, calculated as the root mean square difference (RMSD) across all measurements when compared to the reference device (summarized in Table 2). The pulse rate RMSD was found to be 2.5 beats per minute (bpm), below the study objective of 3 bpm. The breathing rate RMSD was found to be 2.3 breaths per minutes (brpm), slightly above the study objective of 2 brpm.

Consideration of Special Controls Guidance

In combination with the general controls of the FD&C Act, AMC-SDK was also tested and demonstrated compliance in accordance with the following special controls per 21 CFR 870.2785 for the software for optical camera-based measurement of pulse rate, heart rate, breathing rate, and/or respiratory rate.

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 the software technical parameters, including algorithm, specifications of compatible hardware and the impact of these specifications on the device, as well as testing of all mitigations for user error. All system components were assessed for potential cybersecurity vulnerabilities. Additional third-party penetration testing was conducted to identify any cybersecurity vulnerabilities. Any detected vulnerabilities were addressed by design and/or testing. Information regarding cybersecurity vulnerability and management process are provided in the Cybersecurity section.

Special Controls	Evidence of Compliance
(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.	A clinical validation study was conducted on 57 subjects (41 CRO study participants, 16 internal study participants) representative of the intended population and demonstrated the expected range and accuracy of AMC-SDK as compared to the clinically accurate patient-contacting comparator devices. Details of the clinical validation study is provided in the Clinical Testing section.
(3) A human factors and usability engineering assessment must be provided that evaluates the risk of improper measurement.	A human factors (usability) summative study was conducted with 30 subjects: 15 healthcare professionals 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.	Labelling requirements are incorporated in the labelling of AMC-SDK.

Conclusion

Anura Mobile Core SDK is shown through comparison and performance testing to be substantially equivalent to the identified predicate devices. Specifically, the subject device has the same intended use and technological characteristics as the predicate devices. Hence, Anura Mobile Core SDK is substantially equivalent to its predicate devices.