October 27, 2026

PulseAI, Ltd.
Alan Kennedy
CEO
58 Howard Street
Belfast, United Kingdom BT1 6PL

Re: K254226
Trade/Device Name: PulseAPI SmartWatch
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK
Dated: October 26, 2026
Received: October 26, 2026

Dear Alan Kennedy:

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Office of Industry and Consumer Education (OICE) to ask a question about a specific regulatory topic. See the OICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-office-industry-and-consumer-education-oice) for more information or contact OICE by email (AskOICE@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
OHT2: 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.	K254226

Please provide the device trade name(s).

PulseAPI SmartWatch

Please provide your Indications for Use below.

PulseAPI SmartWatch is a software analysis library intended to assess ambulatory electrocardiogram (ECG) rhythms from adult subjects (when prescribed or used under the care of a physician). The device supports analyzing data recorded in compatible formats from ECG devices from lead I or lead II recorded using wet-electrodes, or compatible dry-electrode devices.
The device is not intended for use in patients who have pacemakers or ICDs or other implanted electronic devices.
The device is not intended for use in life supporting, or sustaining systems, or ECG monitors, or as part of an alarm system.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Notification K254226

GENERAL INFORMATION [807.92(a)(1)]

Applicant:

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Date Prepared: October 9th, 2026

DEVICE INFORMATION [807.92(a)(2)]

Trade Name:

PulseAPI SmartWatch

Generic/Common Name:

Programmable Diagnostic Computer

Classification:

21 CFR§870.1425, Computer, Diagnostic, Programmable, Class II

Product Code:

DQK

Subsequent Product Code(s):
N/A

PREDICATE DEVICE(S) [807.92(a)(3)]

K201985 – AliveCor KardiaAI V2

DEVICE DESCRIPTION [807.92(a)(4)]

PulseAPI SmartWatch is a software analysis library intended to assess ambulatory electrocardiogram (ECG) rhythms from adult subjects (when prescribed or used under the care of a physician). The PulseAPI SmartWatch software receives ECG waveform data and associated metadata from lead I or lead II recorded using wet-electrodes, or compatible dry-electrode devices. The software is intended to be integrated into other device software.

When used with wet-electrode ECGs from lead I and II and dry-electrode Apple Watch series 6 it provides the following automated analysis:

- Filtering ECG noise
- Reporting heart rate measurement from ECGs
- Detecting noisy ECGs
- Reporting ECG rhythm analysis for the presence of sinus rhythm, atrial fibrillation, bradycardia, and tachycardia
- ECGs detected as sinus rhythm, detecting normal sinus rhythm and sinus rhythm with premature ventricular contractions (PVC)
- Detecting QRS complexes in an ECG, For ECGs detected as sinus rhythm, classifying individual beats as a PVC or non-PVC beat and generating an average beat from an ECG

When used with ECGs from other compatible dry-electrode hardware (i.e., Samsung Galaxy Watch, Fitbit Sense, Withings ScanWatch, AliveCor KardiaMobile and KardiaMobile 6L, Lead I only) it provides the following automated analysis:

- Filtering ECG noise,
- Reporting heart rate measurement from ECGs,
- Detecting noisy ECGs,
- Reporting ECG rhythm analysis for the presence of sinus rhythm and atrial fibrillation
- Generating an average beat from an ECG

INDICATIONS FOR USE [807.92(a)(5)]

PulseAPI SmartWatch is a software analysis library intended to assess ambulatory electrocardiogram (ECG) rhythms from adult subjects (when prescribed or used under the care of a physician). The device supports analyzing data recorded in compatible formats from ECG devices from lead I or lead II recorded using wet-electrodes, or compatible dry-electrode devices.

The device is not intended for use in patients who have pacemakers or ICDs or other implanted electronic devices. The device is not intended for use in life supporting, or sustaining systems, or ECG monitors, or as part of an alarm system.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE[807.92(a)(6)]

Feature	PulseAPI SmartWatch	KardiaAI V2
510(k)	K254226	K201985
Regulation Number(s)	***21 CFR 870.1425***	***21 CFR 870.1425***
Regulation Name	• Programmable Diagnostic Computer	• Programmable Diagnostic Computer
Regulatory Class	Class II	Class II
Classification Product Code	DQK	DQK
Subsequent Product Code(s)	N/A	DPS
Over The Counter	No	No
Indications for use	PulseAPI SmartWatch is a software analysis library intended to assess ambulatory electrocardiogram (ECG) rhythms from adult subjects (when prescribed or used under the care of a physician). The device supports analyzing data recorded in compatible formats from ECG devices from lead I or lead II recorded using wet-electrodes, or compatible dry-electrode devices. The device is not intended for use in patients who have pacemakers or ICDs or other implanted electronic devices. The device is not intended for use in life supporting, or sustaining systems, or ECG monitors, or as part of an alarm system.	KardiaAI is a software analysis library intended to assess ambulatory electrocardiogram (ECG) rhythms from adult subjects (when prescribed or used under the care of a physician). The device supports analyzing data recorded in compatible formats from any ambulatory ECG devices such as event recorders, or other similar devices. The library is intended to be integrated into other device software. The library is not intended for use in life supporting, or sustaining systems, or ECG monitors, or cardiac alarm, or OTC use only devices. The KardiaAI library provides the following capabilities: Filtering ECG noise, Reporting heart rate measurement from ECGs, Detecting noisy ECGs, Reporting ECG rhythm analysis for the presence of sinus rhythm, atrial fibrillation, bradycardia, and tachycardia; for ECGs detected as sinus rhythm, detecting normal sinus rhythm, sinus rhythm with wide QRS, sinus rhythm with premature ventricular contractions (PVC), and sinus rhythm with supraventricular ectopy, Detecting QRS complexes in an ECG, For ECGs detected as sinus rhythm, classifying individual beats as a PVC or non-PVC beat, and

Feature	PulseAPI SmartWatch	KardiaAI V2
		generating an average beat from an ECG The device is not intended for use in patients who have pacemakers, ICDs, or other implanted electronic devices
Software Functionalities	An interface that provides tools to process and analyze ECGs through various algorithms. The automated proprietary ECG algorithms provide supportive information for ECG diagnosis. The library can be accessed by directly connecting to the PulseAPI Smartwatch's Application Programming Interface The PulseAPI SmartWatch library provides the following capabilities: Filtering ECG noise, Reporting heart rate measurement from ECGs, detecting noisy ECGs, and provide the following analysis: Wet electrodes and compatible dry-electrode devices (Apple Watch Series 6*) - Reporting ECG rhythm analysis for the presence of sinus rhythm, atrial fibrillation, bradycardia*, and tachycardia*; for ECGs detected as sinus rhythm, detecting normal sinus rhythm and sinus rhythm with premature ventricular contractions (PVC)*, Detecting QRS complexes in an ECG, For ECGs detected as sinus rhythm, classifying individual beats as a PVC* or non-PVC beat, and generating an average beat from an ECG. Compatible dry-electrode devices: (i.e., Samsung Galaxy Watch, Fitbit Sense, Withings ScanWatch, AliveCor KardiaMobile and KardiaMobile 6L, Lead I only) it provides the following automated analysis: • Filtering ECG noise, • Reporting heart rate	An interface that provides tools to process and analyze ECGs through various algorithms The automated proprietary ECG algorithms provide supportive information for ECG diagnosis. The library can be accessed by directly connecting to the KardiaAI's Application Programming Interface

Feature	PulseAPI SmartWatch	KardiaAI V2
	measurement from ECGs, • Detecting noisy ECGs, • Reporting ECG rhythm analysis for the presence of sinus rhythm and atrial fibrillation • Generating an average beat from an ECG	
Compatible dry-electrode ECG Devices	Apple Watch Series 6* • Samsung Galaxy Watch • Fitbit Sense • Withings ScanWatch • AliveCor KardiaMobile and KardiaMobile 6L, Lead I only	• Triangle System (K183319) KardiaMobile System (K182396) • KardiaBand System (K171816) • Omron Model BP7900 Blood Pressure Monitor + EKG (K182579)

SUBSTANTIAL EQUIVALENCE

The PulseAPI SmartWatch subject device has the same intended use and similar technological characteristics as the KardiaAI V2 predicate device. The differences in technological characteristics have been analyzed and addressed through performance testing. The evaluation and testing results showed that differences between the subject and predicate device do not raise different questions of safety or effectiveness.

PERFORMANCE DATA [807.92(b)]

All necessary performance testing was conducted on the PulseAPI Smartwatch to support a determination of substantial equivalence to the predicate device.

[807.92(b)(1)] Nonclinical Testing Summary:

Nonclinical testing, consistent with that performed for the predicate device, was conducted to evaluate algorithm performance and verify that PulseAPI SmartWatch functions as intended. Analyses were conducted using standard reference datasets, including those specified in ANSI/AAMI EC57. Additional clinical datasets were used to support performance assessment including wet-electrodes ECGs and model-specific dry-electrode ECGs. All analysis outputs supported the claims of substantial equivalence. The results confirm that PulseAPI SmartWatch performs according to its design specifications and intended use, supporting a determination of substantial equivalence to the predicate device.

SUMMARY

The results of the validation testing demonstrate that the PulseAPI SmartWatch Software is

substantially equivalent to the predicate device.

Across multiple independent datasets comprising segments from diverse populations and device types, the algorithm consistently demonstrated substantially equivalent performance. The PulseAPI SmartWatch subject device has similar intended use and technological characteristics as the KardiaAI V2 predicate device. The evaluation and testing results showed that any differences between the subject and predicate device do not raise different questions of safety or effectiveness. The PulseAPI SmartWatch is substantially equivalent to the predicate device.