510(k) Notification K182396

GENERAL INFORMATION [807.92(a)(1)]

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DEVICE INFORMATION [807.92(a)(2)]

Trade Name:

KardiaMobile System

Generic/Common Name:

Telephone electrocardiograph transmitter and receiver

Classification:

21 CFR§870.2920, Transmitters and Receivers, Electrocardiograph, Telephone, Class II

Product Code:

DXH, DPS

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

K142672 – AliveCor Heart Monitor (predicate device, currently marketed as "KardiaMobile")

K181823 – AliveCor KardiaAI (reference device)

DEVICE DESCRIPTION [807.92(a)(4)]

The KardiaMobile System is a trans-telephonic (transmission by telephone) ECG (electrocardiogram) event recorder that records, stores and transfers single-channel electrocardiogram rhythms. The device utilizes the computing power of Apple iOS- and Google Android-based smartphones to obtain and analyze single-channel ECG. These smartphones are termed Mobile Computing Platforms (MCPs). The device consists of the hardware (that has the electrodes), and the Kardia phone app (installed on an MCP). The same software is implemented in the iOS and Android MCP. In either configuration, the same hardware is used to sense the ECG. The KardiaMobile Hardware transmits the ECG signal from the electrode to the Kardia phone app on the MCP to be analyzed and presented to the user. All ECGs are synced with the user's account.

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

The KardiaMobile System is intended to record, store and transfer single-channel electrocardiogram (ECG) rhythms. The KardiaMobile System also displays ECG rhythms and output of ECG analysis from AliveCor's KardiaAI platform including detecting the presence of normal sinus rhythm, atrial fibrillation, bradycardia, tachycardia, and others (when prescribed or used under the care of a healthcare professional). The KardiaMobile System is intended for use by healthcare professionals, patients with known or suspected heart conditions and health conscious individuals. The device has not been tested and is not intended for pediatric use.

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

Feature	KardiaMobile System K182396 (subject device)	AliveCor Heart Monitor K142672 (predicate device)	KardiaAI K181823 (reference device)
Product Code	DXH, DPS	Same	DQK, DPS
Mechanism of Action	User completes circuit with skin contact and hardware transmits audio signal to MCP to convert and display ECG waveform	Same	API library analyzes ECGs and provides analysis to target application.
Where used (intended use)	Mobile/active users at rest (ambulatory)	Same	Same
Anatomical sites	Left hand fingers to right hand fingers Left leg to right hand fingers On or below chest	Same	N/A (SaMD)
Available Algorithms	Atrial Fibrillation Noise Algorithm Normal Sinus Rhythm Tachycardia Bradycardia (implements the same algorithms of the KardiaAI reference device, K181823)	Atrial Fibrillation	Atrial Fibrillation Noise Algorithm Normal Sinus Rhythm Tachycardia Bradycardia
Data Acquisition: *Frequency Response*	0.5Hz – 40Hz	Same	Same
ECG electrodes	Dry electrodes		
ECG channels	Single Channel		
Resolution	16 bit		
Sample Rate	300 Samples/Second		
Number of ECG Leads	Single lead, 2 electrodes	Same	Single lead
Power Supply: *Battery* *Battery Life (typical)*	1 Lithium Manganese Dioxide Coin Cells 100 hours operational	Same	N/A (SaMD)
User Interface: *Primary Lead* *Data acquisition* *Hardware* *Software interface*	Lead I, Left to Right Ultrasonic acoustics Two-electrode sensor Apple iOS-based or Google Android-based software	Same Same Same Same	Application Program Interface (API)
Physical Specs: *Dimensions* *Weight*	82 x 32 x 4mm 15 grams	82 x 32 x 3.5mm 15 grams	N/A (SaMD)
Prescribed:	Prescription and OTC	Same	Prescription and OTC
Communications	Ultrasonic Acoustics acquired by phone	Same	N/A (SaMD)

SUBSTANTIAL EQUIVALENCE

The KardiaMobile System subject device has the same intended use and similar technological characteristics as the AliveCor Heart Monitor 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 KardiaMobile System to support a determination of substantial equivalence to the predicate device.

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

All necessary performance testing was conducted on the KardiaMobile System to support a determination of substantial equivalence to the predicate device. This testing included the following:

- validation of KardiaAI integration
- verification of the device's specification
- testing to software level of concern requirements
- evaluation to the following standards:
    - ISO 10993-1:2009 (CORR 2010), Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process
    - IEC 60601-1:2012, Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance,
    - IEC 60601-1-2:2007, Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests,
    - IEC 60601-1-11:2015, Medical electrical equipment -- Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment, and
    - IEC 60601-2-47:2012, Medical Electrical Equipment -- Part 2-47: Particular Requirements For The Basic Safety And Essential Performance Of Ambulatory Electrocardiographic Systems.

The collective results of the performance testing demonstrate that the KardiaMobile System meets the established specifications and complies with the aforementioned standards.

SUMMARY

The KardiaMobile System subject device has the same intended use and similar technological characteristics as the AliveCor Heart Monitor 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. The KardiaMobile System is substantially equivalent to the predicate device.