May 11, 2022

AliveCor, INC.
% Prabhu Raghavan
Principal Consultant
MDQR, LLC
189 N. Bernardo Ave. Suite 100
Mountain View, California 94043

Re: K212662
Trade/Device Name: AliveCor QT Service
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable diagnostic computer
Regulatory Class: Class II
Product Code: DQK, DPS

Dear Prabhu Raghavan:

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 April 26, 2022. Specifically, FDA is updating this SE Letter (e.g., typo in correspondent address) as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Jennifer Shih Kozen, OHT2: Office of Cardiovascular Devices, 301-796-5813, Jennifer.Shih@fda.hhs.gov.

Sincerely,

Jennifer W. Shih -S

Jennifer Shih 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

April 26, 2022

AliveCor, Inc.
% Prabhu Raghavan
Principal Consultant
MDQR, LLC
444 Castro Street, Suite 600
Mountain View, California 94041

Re: K212662
Trade/Device Name: AliveCor QT Service
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK, DPS
Dated: March 25, 2022
Received: March 28, 2022

Dear Prabhu Raghavan:

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 Shih 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.

510(k) Number *(if known)*
K212662

Device Name
AliveCor QT Service

Indications for Use *(Describe)*
AliveCor QT Service analyses 30 seconds of a previously acquired electrocardiogram (ECG) from AliveCor designed 6-Lead ambulatory ECG devices analyzed as normal sinus rhythm for QT interval measurements.

AliveCor QT Service is intended for use in a professional medical facility, such as a hospital, clinic, or doctor's office by a qualified health care professional, including trained ECG technician.

AliveCor QT Service is indicated for use on adult patients (older than 18 years). The device has not been tested for and is not intended for pediatric use. The service is not intended for use in life supporting, or sustaining systems, or continuous ECG monitors, or cardiac alarm devices, or OTC use only devices.

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.

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AliveCor®

510(k) Summary for K212662

Prepared in accordance with the requirements of 21 CFR 807.92

Submitter Information [807.92(a)(1)]

Submitter/Applicant	AliveCor, Inc. 189 N. Bernardo Ave. Mountain View, CA 94043 Phone: 650-396-8553 Fax: 650-282-7932
Primary Contact Person	Prabhu Raghavan Regulatory Consultant for AliveCor MDQR, LLC 189 N. Bernardo Ave. Mountain View, CA 94043 Phone: 408-316-5707 Fax: 650-282-7932 Email: prabhu@mdqr.solutions
Submitter and Secondary Contact Person	Susan Noriega VP of Regulatory Affairs, Clinical Affairs and Quality 189 N. Bernardo Ave. Suite 100 Mountain View, CA 94043 Phone: 650-793-1966 Fax: 650-282-7932 Email: snoriega630@alivecor.com
Date Prepared	April 25, 2022

Device Information [807.92(a)(2)]

Trade Name	AliveCor QT Service
Common Name	Programmable diagnostic computer
Classification	21 CFR§870.1425
Device Class	II
Product Code	DQK, Computer, Diagnostic, Programmable
Subsequent Product Code	DPS, Electrocardiograph

Predicate Information [807.92(a)(3)]

Predicate	K170155, GE EK12 Algorithm
Reference Device	K201985, AliveCor KardiaAI

Device Description [807.92(a)(4)]

AliveCor QT Service is a cloud-based Software as a Medical Device (SaMD) that is used to measure the QT and heart-rate corrected QT ("QTc") interval measurements from

electrocardiograms (ECG) recorded from adult patients (older than 18 years) using AliveCor-designed 6-Lead ambulatory ECG devices. AliveCor QT Service provides QT and QTc interval measurements only on ECGs analyzed as Normal Sinus Rhythm by KardiaAI (K201985).

AliveCor QT Service is a prescription (Rx) use only device intended for use by qualified healthcare professionals, including trained ECG technicians. Healthcare professionals can access AliveCor QT Service over the internet from patient management and ECG storage Medical Device Data Systems (MDDS), or from other prescription-use only medical data software devices. These devices provide a previously recorded ECG from an AliveCor-designed 6-Lead ambulatory ECG device, such as the KardiaMobile 6L (K210753), in a compatible format using the AliveCor QT Service's REST-based application program interface (API). REST or REpresentational State Transfer is a software methodology that defines rules for creating web services to access resources over Hypertext Transfer Protocol (HTTP). AliveCor QT Service responds to the analysis request with the following measurements:

- QT interval, measured from the first 30 seconds of the ECG
- Heart-rate corrected QT (QTc) interval based on the Bazett's formula and the Fridericia's formula

AliveCor QT Service utilizes various internal algorithms including deep neural networks (DNN) to analyze an ECG to compute the QT interval. AliveCor QT Service also includes algorithms to compute the RR-interval, which is used to provide both the Bazett's and Fridericia corrected QTc intervals. These algorithms were trained and validated on datasets with ECGs from patients representative of the device's intended use. The training included more than 750K ECGs from over 250K patients. The training dataset included more than 200K ECGs with approximately 49% data from females, approximately 70% from subjects who were reported as whites, 3% non-whites, and 27% from those who did not report their race The validation was conducted on two datasets. The first dataset included more than 34K ECGs with approximately 51% data from females, approximately 80% from subjects who were reported as whites, 3.6% non-whites, and 17% from those who did not report their race. The second dataset included 226 ECGs with approximately 60% data from females, approximately 87% from subjects who were reported as whites, 3.2% non-whites, and 10% from those who did not report their race.

Indications for use [807.92(a)(5)]
AliveCor QT Service analyses 30 seconds of a previously acquired electrocardiogram (ECG) from AliveCor designed 6-Lead ambulatory ECG devices analyzed as normal sinus rhythm for QT interval measurements.

AliveCor QT Service is intended for use in a professional medical facility, such as a hospital, clinic, or doctor's office by a qualified health care professional, including trained ECG technician.

AliveCor QT Service is indicated for use on adult patients (older than 18 years). The device has not been tested for and is not intended for pediatric use. The service is not intended for use in life supporting, or sustaining systems, or continuous ECG monitors, or cardiac alarm devices, or OTC use only devices.

Substantial Equivalence
The Substantial Equivalence utilizes one predicate device and one reference device, namely:

1. *Predicate*: K170155, EK12 Algorithm, that analyzes ECGs to provide rhythm and measurements including QT interval measurements.
2. *Reference Device*: K201985, KardiaAI, which is an API library that analyzes ECGs from AliveCor-designed ECG devices and provides rhythm analysis. The reference device, like the subject device is used to analyze ECGs recorded from AliveCor-designed ambulatory ECGs including the K210753, KardiaMobile 6L, an AliveCor-designed 6-Lead ambulatory ECG device that the subject device is compatible with. The subject device also incorporates this reference device internally to perform rhythm analysis to determine if the provided ECG is Normal Sinus Rhythm.

AliveCor QT Service has the same intended use as the predicate device, K170155, GE EK12 Algorithm. Both devices analyze prerecorded multi-lead ECG signals and measure the QT and heart-rate corrected QT intervals. Both devices are intended to be used by qualified health care professional, including trained ECG technicians. The subject device additionally shares key safety and technological characteristics with the predicate device: both devices are SaMDs that may not be used for active patient monitoring and do not provide any time sensitive information, continuous display of information, alarms, or alerts intended to alert a caregiver to take an immediate clinical action. Both devices do not directly interface with the patient, and both are provided digital ECG samples and output digital information containing the requested analysis. Both devices are provided in the form of a service. The predicate is additionally provided as a compiler linked library and as a command-line interface application.

The subject device utilizes a mix of algorithms that utilize adaptive filters, and features extracted using signal processing to compute a representative ECG beat, which is then used by a deep neural network to compute the QT interval measurement[1]. The predicate computes a representative beat and uses ECG signal processing, pattern recognition, regression methods, as well as modeling of cardiac action potentials to establish the key time points in the overall ECG and thus compute the QT interval[2]. Both devices account for poor T-waves in the ECG. Any differences between the technological characteristics of the interval measurement algorithms have been evaluated through performance testing and do not raise different questions of safety or effectiveness. Differences between the subject device and the predicate have been tested to ensure that the device meets its intended use. Therefore, AliveCor QT Service is substantially equivalent to the predicate device.

[1] Giudicessi, Schram, et al. Artificial Intelligence–Enabled Assessment of the Heart Rate Corrected QT Interval Using a Mobile Electrocardiogram Device. Circulation. 2021 Mar 30;143(13):1274-1286. doi: 10.1161/CIRCULATIONAHA.120.050231. Epub 2021 Feb 1.
[2] Xue J. Q. (2009). Robust QT interval estimation--from algorithm to validation. Annals of noninvasive electrocardiology : the official journal of the International Society for Holter and Noninvasive Electrocardiology, Inc, 14 Suppl 1(Suppl 1), S35–S41. https://doi.org/10.1111/j.1542-474X.2008.00264.x

Comparison of Technological Characteristics with the Predicate Device [807.92(a)(6)]

Feature	AliveCor QT Service (Subject Device)	K170155 EK12 Algorithm (Predicate Device)	K201985 KardiaAI (Reference Device)
Product Code	DQK, Computer, Diagnostic, Programmable DPS, Electrocardiograph	MHX, Monitor, Physiological, Patient (With Arrhythmia Detection or Alarms)	DQK, Computer, Diagnostic, Programmable DPS, Electrocardiograph
Regulation	21 CFR§870.1425, Programmable diagnostic computer	21 CFR 870.1025, Arrhythmia detector and alarm	21 CFR§870.1425, Programmable diagnostic computer
Classifi-cation	II	II	II
Indications for Use	AliveCor QT Service analyses 30 seconds of a previously acquired electrocardiogram (ECG) from AliveCor designed 6-Lead ambulatory ECG devices analyzed as normal sinus rhythm for QT interval measurements. AliveCor QT Service is intended for use in a professional medical facility, such as a hospital, clinic, or doctor's office by a qualified health care professional, including trained ECG technician. AliveCor QT Service is indicated for use on adult patients (older than 18 years). The device has not been tested for and is not intended for pediatric use. The service is not intended for use in life supporting, or sustaining systems, or	EK12 Algorithm analyzes ten or more seconds of a previously acquired electrocardiogram (ECG) from physiological ECG signal recording devices for rhythm and measurements. EK12 Algorithm is used to create reports intended for use by a Qualified Medical Professional, including a trained ECG Technician operating within Independent Diagnostic Testing Facility (IDTF) requirements and performance standards for the review and assessment of an ECG. EK12 Algorithm is indicated for use on adults and pediatric patients older than 2 years. The device is intended for use in an IDTF or a	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 devices, or OTC use only devices. The KardiaAI library provides the following capabilities: ● Filtering ECG noise,

Comparison of Technological Characteristics with the Predicate Device [807.92(a)(6)]

Feature	AliveCor QT Service (Subject Device)	K170155 EK12 Algorithm (Predicate Device)	K201985 KardiaAI (Reference Device)
	continuous ECG monitors, or cardiac alarm devices, or OTC use only devices.	professional medical facility, such as a hospital, clinic, or doctor's office.	● 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 ● 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
Target population	Adults (over 18)	Adults and pediatric patients older than 2 years	Adults (over 18)

Comparison of Technological Characteristics with the Predicate Device [807.92(a)(6)]

Feature	AliveCor QT Service (Subject Device)	K170155 EK12 Algorithm (Predicate Device)	K201985 KardiaAI (Reference Device)
Indicated Use Method	Prescription Use	Prescription Use	Prescription Use
Form Factor	Software only	Software only	Software only
Compatible ECG Leads	Lead-I and Lead-II from AliveCor-designed six-lead ambulatory ECG	12-lead or any subset of 12-leads	Lead-I from AliveCor-designed ambulatory ECG
Technology	Software algorithm	Software algorithm	Software algorithm
ECG Analysis	QT and heart-rate corrected QT intervals	Rhythm and measurement analysis including QT and heart-rate corrected QTc intervals	Rhythm analysis
Technological characteristics	Adaptive filtering, signal processing, deep neural networks	Adaptive filtering, signal processing, regression models	Adaptive filtering, signal processing, deep neural networks

Performance Data [807.92(b)]
All necessary testing was conducted on AliveCor QT Service to support a determination of substantial equivalence to the predicate device.

Nonclinical Testing Summary [807.92(b)(1)]
AliveCor conducted bench performance testing of the subject device to validate that the device meets its performance specifications and to demonstrate that, in light of the technological differences between AliveCor QT Service and its predicate, the subject device is at least as safe and as effective as the predicate device for the same intended use.

Nonclinical testing was conducted to assess algorithm performance and to verify that the AliveCor QT Service estimated QT and heart-rate corrected QT intervals have a mean interval difference $\leq \pm$ 20ms and a standard deviation of interval difference $\leq$ 25ms when compared to an expert annotated reference interval from a supine, diagnostic bandwidth, 12-lead ECG. Algorithm performance was evaluated using standards-based and AliveCor proprietary ECG databases. The databases were selected or developed to demonstrate that the QT interval measurement is accurate and can be used to measure the interval on ECGs recorded from AliveCor designed six-lead ECG devices by adults. Additionally, the subject device and the predicate were comparatively evaluated against appropriate databases to demonstrate substantially equivalent performance.

In summary, the results of the nonclinical testing demonstrate that AliveCor QT Service performs to its specifications, meets its intended use with substantially equivalent performance to that of the predicate device and does not raise different questions of safety or effectiveness.

Clinical Testing Summary [807.92(b)(2)]
No clinical testing was required to establish substantial equivalence.

Conclusions [807.92(b)(3)]
AliveCor QT Service has the same intended use as the predicate device, and the labeling differences do not raise different questions of safety or effectiveness. Therefore, AliveCor QT Service is substantially equivalent to the predicate device.