June 7, 2024

AliveCor, Inc.
% Prabhu Raghavan
Principal Consultant
Mdqr, LLC.
1790 Montemar Way
San Jose, California 95125

Re: K231010
Trade/Device Name: Corvair
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia detector and alarm (including ST-segment measurement and alarm)
Regulatory Class: Class II
Product Code: MHX
Dated: April 6, 2023
Received: April 7, 2023

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 (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.

FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP). Under section 515C(b)(1) of the Act, a new premarket notification is not

required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively.

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 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 systems (QS) regulation (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.

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,

Kimberly Crowley

For: Jennifer Kozen
Assistant Director
DHT2A: 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K231010

Device Name
Corvair

Indications for Use *(Describe)*
AliveCor's Corvair ECG analysis system assists the healthcare professional (HCP) in measuring and interpreting resting diagnostic ECGs for rhythm and morphological information by providing an initial automated interpretation. The interpretation by the analysis program may then be confirmed, edited, or deleted by the HCP. The analysis program is intended for use in the general population ranging from healthy subjects to patients with cardiac and/or non-cardiac abnormalities. Corvair is intended for use by healthcare professionals, or trained personnel in healthcare facilities (e.g. the doctor's office or hospital) and in acute settings.

Corvair analyses should be used only as an adjunct to clinical history, symptoms, and the results of other non-invasive and/or invasive tests. Corvair analyses are considered unconfirmed and must be reviewed by a qualified physician. The provisional automated ECG analysis should not be used for clinical action if it has not been reviewed by a qualified healthcare professional capable of independently interpreting the ECG signal.

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 K231010

Prepared in accordance with the requirements of 21 CFR 807.92

Submitter Information [807.92(a)(1)]

Submitter/Applicant	AliveCor Inc. 189 N Bernardo, Suite 100 Mountain View, CA 94043 Establishment Registration: 3009715978 Submitter Contact: Samip Shah Phone: (650) 396-8557 Email: sshah323@alivecor.com
Primary Contact Person	Prabhu Raghavan Regulatory Consultant for AliveCor, Inc. Principal Consultant, MDQR, LLC Phone: 408-316-5707 Email: prabhu@mdqr.solutions
Date Prepared	June 06, 2024

Device Information [807.92(a)(2)]

Trade Name	Corvair
Common Name	Monitor, Physiological, Patient(With Arrhythmia Detection Or Alarms)
Regulation	21 CFR§ 870.1025
Device Class	II
Product Code	MHX

Predicate Information [807.92(a)(3)]

Predicate(s)	K141963, 12SL ECG Analysis Program by GE Medical Systems®

Device Description [807.92(a)(4)]

Corvair is Software as a Medical Device (SaMD) intended for use by healthcare professionals to analyze a diagnostic-bandwidth ECG. Corvair analyzes a 10-second ECG and provides rhythm analysis, morphological analysis, and ECG interval estimation. Corvair provides 35 separate determinations with 14 rhythm and 21 morphology determinations. Rhythm determinations include Normal Sinus Rhythm, Sinus Rhythm, Atrial fibrillation, Atrial flutter, Paced Rhythm, Junctional Rhythm, and Bigeminy, with the modifiers of 1st Degree AV Block, Higher Degree AV Block (including 2nd and 3rd degree AV blocks), Sinus Arrhythmia, Marked Sinus Arrhythmia, Marked Bradycardia, Sinus Tachycardia, and PVCs. Morphology determinations include Intraventricular block (RBBB, LBBB, and Other Intraventricular Block), Hypertrophy (LVH, and RVH), Atrial Enlargement (LAE and RAE), Acute Myocardial Infarction (Anterior MI, Inferior MI, Lateral MI), Old/Previous Myocardial Infarction (Anterior Old MI, Inferior Old MI,

Lateral Old MI), Ischemia (Anterior, Inferior, Lateral), Prolonged QT, Paced ECG, Other Morphological Defects (Early Repolarization, Wolff-Parkinson-White Syndrome (WPW)), and Normal or Otherwise Normal. Rhythm and morphology determinations are overlapping, i.e., an ECG could receive multiple rhythm and morphology determinations (e.g., Sinus Rhythm, Acute MI). The device also provides global ECG measurements (PR, QRS, QT, QTcB, QTcF, and Heart Rate). No beat-level analysis is provided by the device. Corvair may fail to detect or misidentify conduction system pacing and demand pacing. Corvair does not detect sinus pause. While Corvair provides PR interval estimation and does detect WPW, it does not have a separate determination of abnormally short PR intervals.

This SaMD provides these capabilities in the form of an Application Program Interface (API) library. Any software or device ("target device") can incorporate the Corvair API library into its device software to provide users with resting ECG analytics. The input ECG is provided by the target device to Corvair, to which the various Corvair algorithms are applied, and outputs generated accordingly. Corvair has a C++ interface and a distributed binary (library), which is used by the target device to statically link to Corvair. Viewing of Corvair's ECG analysis is handled by the target device.

Corvair is intended to be used with standard diagnostic-bandwidth, resting ECG recordings collected using 'wet' Ag/AgCl electrodes with conductive gel/paste. Corvair only requires 4 ECG leads for analysis, specifically, either Leads {I, II, V2, and V4}, or Leads {I, II, V1, and V4}. Compatible devices include resting ECGs from GE Medical Systems® (e.g., K081437, MAC 1600, K110266, MAC 5500, K173830, MAC VU360, etc.), and AliveCor's Impala (K232035). Regardless of the lead configuration, Corvair provides the same set of rhythm, morphological, and interval determinations. Corvair has two modes of operation, Symptomatic Mode, which is used when the pre-test probability for a specific rhythm or morphology is high, and Asymptomatic Mode, which optimizes the PPV, by optimizing the specificity, to detect the various rhythms and morphologies. The target device can choose which lead set and which mode of determinations to utilize based on the target clinical application and the patient's clinical presentation.

Corvair utilizes several deep neural networks (DNNs) for its analysis. These DNNs were trained on a dataset of approximately 1 million 12-Lead ECGs acquired from about 400K clinical patients at the Emory University Hospital over several decades between 1985 and 2010. Each ECG has a physician overread confirmed diagnosis with multiple diagnostic codes. The dataset had a 52%/48% ratio of ECGs from male and female patients, respectively. The average age of the patient was 61.3 ± 16. The dataset included 56% white, 33% African American, 2.2% Asian, 9% other races/ethnicities.

Indications for use [807.92(a)(5)]
AliveCor's Corvair ECG analysis system assists the healthcare professional (HCP) in measuring and interpreting resting diagnostic ECGs for rhythm and morphological information by providing an initial automated interpretation. The interpretation by the analysis program may then be confirmed, edited, or deleted by the HCP. The analysis program is intended for use in the general population ranging from healthy subjects to patients with cardiac and/or non-cardiac

abnormalities. Corvair is intended for use by healthcare professionals, or trained personnel in healthcare facilities (e.g. the doctor's office or hospital) and in acute settings.

Corvair analyses should be used only as an adjunct to clinical history, symptoms, and the results of other non-invasive and/or invasive tests. Corvair analyses are considered unconfirmed and must be reviewed by a qualified physician. The provisional automated ECG analysis should not be used for clinical action if it has not been reviewed by a qualified healthcare professional capable of independently interpreting the ECG signal.

Substantial Equivalence

Comparison of intended use and indications for use

Both Corvair and the K141963 predicate have identical intended uses, i.e., intended for measuring and interpreting diagnostic-bandwidth, resting ECG. For both devices, the ECG analysis outputs represent potential findings for review and interpretation by a qualified healthcare professional and do not represent complete diagnoses.

The Indications for Use (IFU) statement for Corvair is largely equivalent to the predicate K141963 device IFU. The subject and predicate devices are both intended to provide analysis of resting ECG recordings. Specifically, both devices assists the healthcare professional (HCP) in measuring and interpreting resting diagnostic-bandwidth ECGs for rhythm and morphological information. In both devices, the provisional automated ECG analysis should not be used for clinical action if it has not been reviewed by a qualified healthcare professional capable of independently interpreting the ECG signal.

Note that while the intended use population of both devices include adults 18 years old and over, the predicate is also intended for use with a pediatric patient population. As such, the subject device's intended use population is a subset of the predicate device's intended use population.

Comparison of technological characteristics

While there are many similarities between the two devices, there are three main differences:

a) *Number of leads analyzed*: While the predicate requires and analyzes all 12 ECG leads, the subject device is intended to analyze a reduced set of 4 standard leads.
b) *Number of determinations*: The subject device provides determinations that are a subset of all the determinations provided by the predicate device.
c) *Machine Learning Models*: While both devices utilize machine learning models, the architecture of these models are different. The predicate device utilizes traditional signal processing and regression based learning models, and the subject device utilizes signal processing as well as deep neural networks.

Both devices use signal processing and machine learning algorithms to detect arrhythmia, perform analysis of ECG morphology, and provide interval estimates. Both the predicate and subject devices focus on providing high specificity to improve the positive predictive value (PPV) of the final determinations, especially since many of the determinations have low prevalence in the intended use population. The subject device additionally offers a mode where the sensitivity is improved at the cost of some reduction in specificity. This is intended to assist

HCPs who have a sense of the pretest probability and can choose the results of this mode in case they are able to tolerate more false positives and a reduced PPV.

The differences noted above do not by themselves raise different questions of safety and effectiveness. The differences were addressed through an extensive performance validation using a large ECG dataset to demonstrate safety and effectiveness and substantial equivalence. The proposed methods to validate the subject device and to demonstrate ECG analysis performance utilize well understood scientific methods.

In conclusion, Corvair has the same intended use as the predicate device, and any differences in technological characteristics do not raise different questions of safety or effectiveness.

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

Nonclinical Testing Summary [807.92(b)(1)]
Nonclinical performance testing was conducted to demonstrate that Corvair satisfies its design and software requirements as well as demonstrate that the ECG analysis performance is substantially equivalent to the predicate device (K141963, 12SL ECG Analysis Program).

AliveCor evaluated Corvair against a large set of ECGs and compare its analysis output against a known reference. The comparison uses standard ECG performance metrics including, sensitivity, specificity, and PPV for the interpretive outputs, mean error and standard deviation of error for the interval outputs, and mean absolute error for heart rate accuracy. These outputs were evaluated against a clinically relevant acceptance criteria to demonstrate Corvair's effectiveness. PR, QRS, QT interval estimation performance was demonstrated using the Common Standards for Quantitative Electrocardiography Standard Database (CSEDB) as referenced in the IEC 60601-2-25 and against an AliveCor proprietary dataset developed from ECGs that were collected in a clinical study at the Mayo Clinic's Genetic Heart Rhythm Clinic. Heart rate and QTc were also validated using ECGs from the latter database. Corvair performance of was also compared against the predicate and the subject device demonstrated substantially equivalent performance.

Clinical Testing Summary [807.92(b)(2)]
No clinical testing was required or conducted to support a determination of substantial equivalence.

Predetermined Change Control Plan (PCCP)
As part of K231010, Corvair includes a PCCP to improve algorithm performance by retraining with additional data without modifying the architecture:

- Such improvements will be made by acquiring additional high quality, diverse training data from major clinical institutions similar to the data used to train the models within the 510(k).
- The performance of the retrained models will be evaluated using the same datasets used within the 510(k). Additional large validation datasets will also be created from sites

independent of the training data to ensure model generalization. The performance will be acceptable when the overall performance is noninferior to the performance of the models used in the 510(k). Some minor individual determination performance variation would be acceptable.

- When such improvements are made and found to be acceptable, the Corvair device labeling will be updated to incorporate the updated performance specifications. The changes would be also communicated to Corvair API software integrators so that they can also communicate the changes to the end users.

Conclusions [807.92(b)(3)]

The results of these testing therefore demonstrate that the device performs as intended and confirm that the technological differences between the subject device and the predicate devices do not raise different questions of safety and effectiveness, and that the device is as safe and as effective for its intended use as the predicate device.