January 9, 2026

AliveCor Inc.
Samip Shah
Vice President of RA/QA
189 N. Bernardo Avenue
Suite 100
Mountain View, California 95043

Re: K252589
Trade/Device Name: Corvair Monza
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: December 5, 2025
Received: December 8, 2025

Dear Samip Shah:

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), Corvair Monza Predetermined Change Control Plan, Rev. 3.

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.

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,

HETAL B. ODOBASIC -S

for

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.	K252589

Please provide the device trade name(s).

Corvair Monza

Please provide your Indications for Use below.

AliveCor's Corvair Monza 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 Monza 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 Monza analyses should be used only as an adjunct to clinical history, symptoms, and the results of other non-invasive and/or invasive tests. Corvair Monza 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

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)

AliveCor®

510(k) Summary for K252589

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
Date Prepared	August 14, 2025

Device Information [807.92(a)(2)]

Trade Name	Corvair Monza
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)	K231010, Corvair by AliveCor Inc.

Device Description [807.92(a)(4)]

Corvair Monza is Software as a Medical Device (SaMD) intended for use by healthcare professionals to analyze a diagnostic-bandwidth ECG. Corvair Monza analyzes a 10-second ECG and provides rhythm analysis, morphological analysis, and ECG interval estimation. Rhythm and morphology determinations are overlapping, i.e., an ECG could receive multiple rhythm and morphology determinations (e.g., Sinus Rhythm, Acute MI). No beat-level analysis is provided by the device.

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 Monza API library into its device software to provide users with resting ECG analytics. The input ECG is provided by the target device to Corvair Monza, to which the various Corvair Monza algorithms are applied, and outputs generated accordingly. Corvair Monza has a C++ interface and a distributed binary (library), which is used by the target device to statically link to Corvair Monza. Viewing of Corvair Monza's ECG analysis is handled by the target device.

Corvair Monza is intended to be used with standard diagnostic-bandwidth, resting ECG recordings. Corvair Monza only requires 4 ECG leads for analysis, specifically, either Leads {I, II, V2, and V4}, or Leads {I, II, V1, and V4}. The compatible signal input must be acquired from devices that are compliant to IEC 60601-2-25 using with gel/wet electrodes and can provide the

requisite leads for analysis. Regardless of the lead configuration, Corvair Monza provides the same set of rhythm, morphological, and interval determinations. Corvair Monza has two modes of operation, Symptomatic Mode, that is used when the pre-test probability for a specific rhythm is high, and Asymptomatic Mode, that 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.

Corvair Monza 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 Monza 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 Monza 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 Monza analyses should be used only as an adjunct to clinical history, symptoms, and the results of other non-invasive and/or invasive tests. Corvair Monza 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 Monza and the K231010 predicate have identical intended uses, i.e., intended for measuring and interpreting resting a diagnostic, 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 Monza is identical to the predicate K231010 (Corvair) The subject and predicate devices are both intended to provide analysis of diagnostic ECG recordings. Specifically, both devices assists the healthcare professional (HCP) in measuring and interpreting resting diagnostic ECGs for rhythm and morphological information.

Comparison of technological characteristics

The subject device (Corvair Monza) and the predicate (K231010, Corvair) have the same technological characteristics. Both devices use signal processing and machine learning algorithms to detect arrhythmia, perform analysis of ECG morphology, and provide interval estimates.

Both devices use the same machine learning models used to provide the various determinations regarding rhythm, morphology, and intervals. The new determinations in subject device were implemented by applying clinically accepted criteria to interval and axis measurements already provided by the predicate in Corvair (K231010)

Performance Data [807.92(b)]
All necessary testing was conducted on Corvair Monza 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 Monza satisfies its design and software requirements as well as demonstrate that the ECG analysis performance is substantially equivalent to the predicate device (K231010, Corvair).

AliveCor evaluated Corvair Monza 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 Monza's performance. Corvair Monza performance 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)
Corvair Monza includes a PCCP to improve algorithm performance by retraining with additional data without modifying the architecture. There will be no changes to sensor input signal type, no change to output type, and no change in intended use. Parameters such as model weights may change during a retraining attempt, but these changes will only be accepted if they meet the acceptance criteria for the algorithm described in the PCCP and explained below.

- 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 of the improved algorithm will be verified using the protocol identified in the PCCP. Sensitivity and Specificity for each mode and lead set will be reviewed as they compare to the Acceptance Criteria defined in the PCCP; with every iteration of the model, we will continue to benchmark against the Sensitivity/Specificity in the baseline performance to ensure performance is not degraded. AliveCor has established a protocol to demonstrate that the overall performance is equivalent or superior to the baseline version.
- When such improvements are made and found to be acceptable, the Corvair Monza device labeling will be updated to incorporate the updated performance specifications. The changes would be also communicated to Corvair Monza API software integrators so that they can also communicate the changes to the end users.
- All algorithm modifications will be locked prior to release of the software in the field.

Conclusions [807.92(b)(3)]

The results of these testing therefore demonstrate that the device performs as intended and confirm that the device is as safe and as effective for its intended use as the predicate device.