June 7, 2024

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

Re: K232035
Trade/Device Name: Impala
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS
Dated: July 7, 2023
Received: July 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.

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)*
K232035

Device Name
Impala

Indications for Use *(Describe)*
Impala is intended to record, store, and transfer a 12-lead resting electrocardiogram (ECG). Impala acquires four standard diagnostic-bandwidth leads (Leads I, II, V2, V4, or Leads I, II, V1, V4). The device derives four standard diagnostic-bandwidth, Lead-III and unipolar limb leads aVR, aVF and aVL. The device also synthesizes Leads V1 or V2, V3, V5, V6, which are similar to but not identical to the same leads of a standard diagnostic 12-lead. The 4 synthesized chest leads are not intended for diagnostic use and may fail to show important findings limited to those leads. This device is not a substitute for a diagnostic 12-lead ECG and is contraindicated for use in ruling out any condition (including but not limited to certain ischemia/infarcts, Brugada syndrome) for which the diagnosis may be solely dependent on the synthesized leads.

The device also provides ECG measurements and ECG analysis (rhythm and morphological interpretation) using the acquired leads. The automated ECG analysis results are provisional and should not be used for clinical action if it has not been reviewed by a qualified physician capable of independently interpreting the ECG signal in the context of the patient's condition. The automated analysis may then be confirmed, edited, or deleted by a qualified physician. ECG analysis should be used only as an adjunct to clinical history, symptoms, and the results of other non-invasive and/or invasive tests.

Impala is intended for use with patients aged 18 years and older. Impala 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.

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.

ALIVECOR®

510(k) Summary for K232025

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	Impala
Common Name	Electrocardiograph
Regulation	21 CFR§870.2340
Device Class	II
Product Code	DPS

Predicate Information [807.92(a)(3)]

Predicate(s)	K173952, Universal SmartECG by VectraCor, Inc

Device Description [807.92(a)(4)]

Impala is a portable 12-Lead resting electrocardiograph (ECG) device that acquires 4 standard diagnostic-bandwidth ECG leads from a patient (I, II, V1 or V2, V4), derives 4 standard diagnostic-bandwidth leads (aVL, aVR, aVF, III), and using software generates the remaining leads (V2 or V1, V3, V5, V6) to create a 12-Lead ECG recording. The device can be used by healthcare professionals (HCPs) to record a reduced lead, diagnostic-bandwidth, resting ECG, where traditional 10 electrode, 12 lead ECG recorders are not practical to administer due to size, time, or need for specialized clinicians to administer. Examples may include physician offices, and remote and field locations.

The Impala hardware consists of the Impala ECG Module that connects to the Patient Lead Wire. The Patient Lead Wire is a single cable that includes five snap-on electrodes. Impala also consists of a mobile software application, the Impala App that executes on a mobile computing

platform (MCP), such as an Apple iPhone smartphone. To record an ECG, the user positions standard off-the-shelf (OTS) ECG gel electrodes on the patient and snaps on the connectors in the Patient Lead Wire on to the electrodes. Impala allows for two options for which set of leads are acquired:

1. *Lead Set 1*: Leads {I, II, V2, and V4}, with electrodes on RA, LA, LL, V2, V4; and
2. *Lead Set 2*: Leads {I, II, V1, and V4} with electrodes on RA, LA, LL, V1, and V4.

Impala utilizes a machine learning model for lead synthesis. This model was trained on a dataset of approximately 110,000 12-Lead ECGs acquired from clinical patients at the Mayo Clinic over several decades between 1985 and 2010. Each ECG has a physician overread confirmed diagnosis with multiple diagnostic codes. This dataset included various types of morphology including intraventricular blocks, hypertrophy, atrial enlargement, myocardial infarction, ischemia, and prolonged QT. The dataset had a 56%/44% ratio of ECGs from male and female patients, respectively. The dataset included patients with a wide distribution of age groups from 18-99 years.

Impala incorporates AliveCor's Corvair (K231010), a software as a medical device, to provide rhythm analysis, morphological analysis, and ECG measurements. Corvair has two modes of operation, Symptomatic Mode, which is used when the pre-test probability for a specific rhythm is high, and Asymptomatic Mode, which optimizes the PPV, by optimizing the specificity, to detect the various rhythms and morphologies. The user can choose which Impala Lead Set and which Corvair mode of determinations to utilize based on the target clinical application.

Indications for use [807.92(a)(5)]

Impala is intended to record, store, and transfer a 12-lead resting electrocardiogram (ECG). Impala acquires four standard diagnostic-bandwidth leads (Leads I, II, V2, V4, or Leads I, II, V1, V4). The device derives four standard diagnostic-bandwidth, Lead-III and unipolar limb leads aVR, aVF and aVL. The device also synthesizes Leads V1 or V2, V3, V5, V6, which are similar to but not identical to the same leads of a standard diagnostic 12-lead. The 4 synthesized chest leads are not intended for diagnostic use and may fail to show important findings limited to those leads. This device is not a substitute for a diagnostic 12-lead ECG and is contraindicated for in ruling out any condition (including but not limited to certain ischemia/infarcts, Brugada syndrome) for which the diagnosis may be solely dependent on the synthesized leads.

The device also provides ECG measurements and ECG analysis (rhythm and morphological interpretation) using the acquired leads. The automated ECG analysis results are provisional and should not be used for clinical action if it has not been reviewed by a qualified physician capable of independently interpreting the ECG signal in the context of the patient's condition. The automated analysis may then be confirmed, edited, or deleted by a qualified physician. ECG analysis should be used only as an adjunct to clinical history, symptoms, and the results of other non-invasive and/or invasive tests.

Impala is intended for use with patients aged 18 years and older. Impala 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.

Substantial Equivalence

Comparison of intended use and indications for use

Both Impala and the predicate are intended to record a reduced lead, diagnostic-bandwidth, resting ECG. Both Impala and the predicate are intended for Adult patients. Note that similar to other AliveCor devices, the proposed "Adult" population for Impala would include Transitional Adolescents, i.e., Adults 18 and over. Both Impala and the predicate are intended to be used by healthcare professionals, or trained personnel.

Like the predicate, the subject device is also intended to record a reduced lead set but utilizes a standard lead position instead of the Frank X, Y, Z leads. The subject device does not include the capability to directly record a 12-lead ECG using the standard 10 electrodes. As such, the subject device provides a subset of the predicate's feature set, and this difference does not raise different questions of safety or effectiveness.

Comparison of technological characteristics

Both Impala and the predicate allow for recording reduced set of ECG leads. The K173952 predicate uses 5-electrodes to acquire a 3-lead recording. Like the Impala subject device, the K173952 predicate derives or produces a full 12-lead ECG output from these reduced leads. This derivation of the full 12-lead utilizes VectraCor's K102378, VectraplexECG that can derive a 12 to 15-lead ECG report with the recorded 5-electrodes. Both Impala and the K173952 predicate use standard gel-electrodes with both devices including lead wires that clip onto these electrodes. While both Impala and the K173952 predicate can record reduced leads, the predicate records 3 leads instead of the 4 leads needed by Impala. The K173952 predicate requires the electrodes to be placed in RA, LA, V2, RL, LL, from which it records 3 leads (L1, L2, and V2 based on available public information). Impala records Leads I, II, V1 or V2, and V4. However both devices are utilizing the same location on the patient, i.e., arms, legs, and torso.

The K173952 predicate device utilizes the K102378, VectraplexECG device to provide the ECG Lead Generation. In Impala, this Lead Generation has been incorporated within the device software. Like the predicate, the synthesized leads are not intended for diagnostic use and may fail to show important findings limited to those leads.

In conclusion, Impala 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 Impala to support a determination of substantial equivalence to the predicate device.

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

The subject device has equivalent safety and technological characteristics and the differences have been addressed through the following performance testing:

- Electrical safety and electromagnetic compatibility testing verified that the subject device complies with the requirements of IEC 60601-1, IEC 60601-1-2, and IEC 60601-2-25, IEC 60601-1-11, and IEC 60601-1-12.

- The patient lead wire was verified and conforms to ANSI EC53.
- Bench performance testing was conducted to demonstrate that Impala satisfies its design, hardware and software requirements.
- Bench performance testing was also conducted to evaluate the 4 synthesized chest leads generated by Impala from the 4 recorded leads in comparison with the corresponding chest leads of a standard 10-electrode resting 12-lead ECG. This validation utilized a proprietary AliveCor database as well as two public databases (Physionet PTB-XL and the Common Standards for Quantitative Electrocardiography Standard Database (CSEDB) as referenced in the IEC 60601-2-25). The proprietary dataset consisted of ECGs recorded 3,000 12-Lead ECGs acquired from clinical patients at the Mayo Clinic over several decades between 1985 and 2010. Each ECG has a physician overread confirmed diagnosis with multiple diagnostic codes. This dataset included various types of morphology including intraventricular blocks, hypertrophy, atrial enlargement, myocardial infarction, ischemia, and prolonged QT. The dataset had a 56%/44% ratio of ECGs from male and female patients, respectively. The dataset included patients with a wide distribution of age groups from 18-99 years. This dataset was independent from the training dataset. Results suggest that the synthesized leads tend to be similar to the corresponding 12-leads, so the display of these leads is not likely to confuse human interpreter. However significant differences exist in many cases. Thus the 4 synthesized chest leads are not intended for diagnostic use and may fail to show important findings limited to those leads. Further, this device is contraindicated for the diagnosis of any condition (including but not limited to certain ischemia/infarcts, Brugada syndrome) for which the diagnosis may be solely dependent on the synthesized leads.
- Human factors usability testing of Impala demonstrated that representative users could use the device as intended, including collecting data using Impala hardware and the associated Impala App, and understand the data presented on the App.

As such, the subject device has substantially equivalent safety and technological characteristics and any differences, based on the performance testing, do not raise different questions of safety and effectiveness.

Clinical Testing Summary [807.92(b)(2)]

No clinical testing was required or conducted to support a determination of substantial equivalence.

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.