February 6, 2026

SafeBeat Rx Inc.
Rachita Navara
Chief Executive Officer
813 D St., Suite 3
San Rafael, California 94901-2813

Re: K251218
Trade/Device Name: SafeBeat Rx App
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK, DPS
Dated: December 30, 2025
Received: December 30, 2025

Dear Rachita Navara:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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,

JENNIFER W. SHIH -S

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.	K251218

Please provide the device trade name(s).

SafeBeat Rx App

Please provide your Indications for Use below.

The SafeBeat Rx App analyzes ECG data recorded in compatible formats. This ECG signal may originate from a full 12-lead ECG or a reduced lead set ECG. The device provides ECG signal processing and provisional analysis, including interval measurements (QT interval, QTc, QRS duration, heart rate, and RR interval), along with visible display of QRS onset (Q-start), R-peak, and QRS offset (S-end). The SafeBeat Rx App can electronically interface with, and perform analysis of, data transferred from other computer-based ECG systems, such as an ECG management system. The SafeBeat Rx App does not provide real-time ECG display, continuous monitoring, or alarm functions. The device is not for use in life-supporting or sustaining systems or ECG monitor and alarm devices. The SafeBeat Rx App ECG analysis is intended for adult patient populations (18 years and older).

SafeBeat Rx App provisional ECG analysis is not intended to be the sole means of diagnosis. The SafeBeat Rx App is not validated for use in lead I alone. The SafeBeat Rx App is intended to be used on an advisory basis only by qualified healthcare personnel to evaluate provisional ECG data. ECG data should be reviewed in conjunction with the patient's clinical history, symptoms, and/or other diagnostic tests, and the professional clinical judgement of the qualified healthcare provider.

The SafeBeat Rx App can be used in a professional healthcare environment such as a hospital, clinic or similarly equipped facility. The SafeBeat Rx App has an optional long term monitoring workflow intended for monitoring and evaluating a patient's home acquired ECG. The software workflow that is intended for use in the professional healthcare environment should not be used in the home environment to adjust QT prolonging medications as is contraindicated for applicable drugs.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

SafeBeat Rx Inc.
Suite 1530, 450 Sutter St.
San Francisco, CA 94108, US
Phone: 415-952-3354
Fax: 984-220-9323

Contact Person: Dr. Rachita Navara
February 6, 2026

Identification of the Device
Proprietary-Trade Name: SafeBeat Rx App
Device Class: Class II
Classification Name: Programmable diagnostic computer (21 CFR 870.1425 Product Code DQK), Electrocardiograph (21 CFR 870.2340 Product Code DPS)
Common/Usual Name: ECG Analysis Program

Equivalent Legally Marketed Devices
CardioLogs Technologies, CardioLogs ECG Analysis Platform, K170568

Reference Devices
AliveCor, Inc., AliveCor QT Service, K212662

Description of the Device
The SafeBeat Rx App is a Software as a Medical Device (SaMD) that provides: (1) ML-based provisional ECG interval measurements of third-party ECG signals (e.g., HR, RR-interval variability, QT/QTc interval and QRS interval); and (2) optional non-device functions, including suggested antiarrhythmic drug (AAD) dosing consistent with manufacturer drug label for amiodarone, dofetilide, flecainide, sotalol and IV sotalol. The device analyzes ECG signals acquired by other ECG acquisition and storage devices. The device is only intended for traditional “wet” electrode inputs. The SafeBeat app does not directly acquire ECG data from patients. ECG data is obtained programmatically through an application programming interface (API) with the ECG acquisition and storage device, or manually via data upload through a secure web interface. The device is solely intended to analyze raw digital ECG data and does not allow the analysis of ECG signals imported by images.
Provisional ECG analysis is performed by the device. The device includes both beat-level feature identification and interval estimation. The beat-level parameters are:

- R-peak
- QRS onset
- ST onset
- T-wave offset

The interval estimation parameters:

- Heart rate
- RR interval variability
- QRS duration
- QT interval
- QT interval variability
- Heart rate corrected QT (e.g., QTcF)
- Heart rate corrected QT variability

Provisional ECG interval measurements are displayed on a user interface for review and interpretation by a qualified healthcare professional. The provisional ECG analysis can be viewed, edited, approved, or rejected by the qualified healthcare professional via the user interface.

The SafeBeat App does not provide continuous cardiac monitoring. The SafeBeat App does not provide rhythm interpretation or diagnosis cardiac arrhythmias (e.g. atrial fibrillation). The device does not include automated rhythm analysis. The device is intended for adult patient populations.

Indications for Use

The SafeBeat Rx App analyzes ECG data recorded in compatible formats. This ECG signal may originate from a full 12-lead ECG or a reduced lead set ECG. The device provides ECG signal processing and provisional analysis, including interval measurements (QT interval, QTc, QRS duration, heart rate, and RR interval), along with visible display of QRS onset (Q-start), R-peak, and QRS offset (S-end). The SafeBeat Rx App can electronically interface with, and perform analysis of, data transferred from other computer-based ECG systems, such as an ECG management system. The SafeBeat Rx App does not provide real-time ECG display, continuous monitoring, or alarm functions. The device is not for use in life-supporting or sustaining systems or ECG monitor and alarm devices. The SafeBeat Rx App ECG analysis is intended for adult patient populations (18 years and older).
SafeBeat Rx App provisional ECG analysis is not intended to be the sole means of diagnosis. The SafeBeat Rx App is not validated for use in lead I alone. The SafeBeat Rx App is intended to be used on an advisory basis only by qualified healthcare personnel to evaluate provisional ECG data. ECG data should be reviewed in conjunction with the patient's clinical history, symptoms, and/or other diagnostic tests, and the professional clinical judgement of the qualified healthcare provider.
The SafeBeat Rx App can be used in a professional healthcare environment such as a hospital, clinic or similarly equipped facility. The SafeBeat Rx App has an optional long term monitoring workflow intended for monitoring and evaluating a patient's home acquired ECG. The software workflow that is intended for use in the professional healthcare environment should not be used in the home environment to adjust QT prolonging medications as is contraindicated for applicable drugs.

Comparison of Technological Characteristics with the Predicate Device

The SafeBeat Rx App has the same overall technological characteristics as CardioLogs ECG Analysis Platform, including providing measurements and analysis of ECG for physician review. There are minor differences in the SafeBeat Rx App as compared to the predicate device. The SafeBeat Rx App identifies beat-by-beat waveform features and interval measurements and it provides general functions for inputting ECG data from a separate source, processing the ECG data, analyzing the ECG and labeling the beat-by-beat annotations on the ECG. The SafeBeat Rx App displays the resulting analysis along with the original ECG and provides tools for the physician to adjust or confirm results and also provides a report to the physician which is similar to the predicate device. The SafeBeat Rx App does not alter the ECG acquisition device.

Because the Subject device uses a machine learning–based approach for QT interval measurement that is not present in the Predicate device, a Reference device was included in the comparison. The Reference device similarly utilizes a machine learning–based algorithm to compute the QT interval. The inclusion of this Reference device provides an appropriate technological benchmark for evaluating the use of machine learning in QT interval measurement.

This comparison demonstrates that the use of machine learning for QT interval calculation is well established in FDA-cleared devices and does not introduce new questions of safety or effectiveness. Any

technological differences between the Predicate, Reference, and Subject devices have been evaluated through hazard analysis and mitigated through appropriate risk controls and verification testing. Based on this assessment, these differences do not impact the substantial equivalence of the Subject device.

Tables 1 and 2 and the accompanying discussion below provide a detailed comparison of the intended use and technological characteristics of the SafeBeat Rx App and the predicate device.

As demonstrated below, the intended use of the SafeBeat Rx App and the predicate device are the same. There are minor differences in technological characteristics, but the testing and validation activities described in this 510(k) submission show that the minor technological differences do not raise new or different questions of safety and effectiveness and that the SafeBeat Rx App is at least as safe and effective as the predicate device.

Table 1 Comparison of Use of the SafeBeat Rx app, AliveCor QT service, and CardioLogs ECG analysis platform

	Predicate Device **[CardioLogs Technologies, CardioLogs ECG Analysis Platform]** **(K170568)**	**Reference Device** **[AliveCor Inc.]** **[AliveCor QT Service]** **(K212662)**	**New Device** **[SafeBeat Rx]** **[SafeBeat Rx App]**
Manufact./ Name	CardioLogs Technologies	AliveCor	SafeBeat Rx
510(k) Number	K170568	K212662	K251218
Product code	DQK/DPS	DQK/DPS	DQK/DPS
Classification Regulation	21 CFR §870.1425	21 CFR §870.1425	21 CFR §870.1425

Indications for Use	The CardioLogs ECG Analysis Platform is intended for use by qualified healthcare professionals for the assessment of arrhythmias using ECG data in subjects over 18 years of age. The product supports downloading and analyzing data recorded in compatible formats from any device used for the arrhythmia diagnostics such as Holter, event recorder, 12 lead ambulatory ECG devices, or other similar devices when assessment of the rhythm is necessary. The Cardiologs ECG Analysis Platform can also be electronically interfaced, and perform analysis with data transferred from other computer based ECG systems, such as an ECG management system. The Cardiologs ECG Analysis Platform provides ECG signal processing and analysis, QRS and Ventricular Ectopic Beat detection, QRS feature extraction, interval measurement, heart rate measurement, and rhythm analysis. The Cardiologs ECG Analysis Platform is not for use in life supporting or sustaining systems or ECG monitor and Alarm devices.	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.	The SafeBeat Rx App analyzes ECG data recorded in compatible formats. This ECG signal may originate from a full 12-lead ECG or a reduced lead set ECG. The device provides ECG signal processing and provisional analysis, including interval measurements (QT interval, QTc, QRS duration, heart rate, and RR interval), along with visible display of QRS onset (Q-start), R-peak, and QRS offset (S-end). The SafeBeat Rx App can electronically interface with, and perform analysis of, data transferred from other computer-based ECG systems, such as an ECG management system. The SafeBeat Rx App does not provide real-time ECG display, continuous monitoring, or alarm functions. The device is not for use in life-supporting or sustaining systems or ECG monitor and alarm devices. The SafeBeat Rx App ECG analysis is intended for

	The product can be integrated into computerized ECG monitoring devices. In this case, the medical device manufacturer will identify the indication for use depending on the application of their device. Cardiologs ECG Analysis Platform interpretation results are not intended to be the sole means of diagnosis. It is offered to physicians and clinicians on an advisory basis only in conjunction with the physician's knowledge of ECG patterns, patient background, clinical history, symptoms, and other diagnostic information.		adult patient populations (18 years and older). SafeBeat Rx App provisional ECG analysis is not intended to be the sole means of diagnosis. The SafeBeat Rx App is not validated for use in lead I alone. The SafeBeat Rx App is intended to be used on an advisory basis only by qualified healthcare personnel to evaluate provisional ECG data. ECG data should be reviewed in conjunction with the patient's clinical history, symptoms, and/or other diagnostic tests, and the professional clinical judgement of the qualified healthcare provider.

	Predicate Device **[CardioLogs Technologies, CardioLogs ECG Analysis Platform]** **(K170568)**	**Reference Device** **[AliveCor Inc.]** **[AliveCor QT Service]** **(K212662)**	**New Device** **[SafeBeat Rx]** **[SafeBeat Rx App]**
			The SafeBeat Rx App can be used in a professional healthcare environment such as a hospital, clinic or similarly equipped facility. The SafeBeat Rx App has an optional long term monitoring workflow intended for monitoring and evaluating a patient's home acquired ECG. The software workflow that is intended for use in the professional healthcare environment should not be used in the home environment to adjust QT prolonging medications as is contraindicated for applicable drugs.
Intended Use	The CardioLogs ECG Analysis Platform is intended for use by qualified healthcare professionals for the assessment of arrhythmias using ECG data in subjects over 18 years of age.	The 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. The AliveCor QT Service is indicated for use on adult patients (older than 18 years).	Same

	Predicate Device **[CardioLogs Technologies, CardioLogs ECG Analysis Platform]** **(K170568)**	**Reference Device** **[AliveCor Inc.]** **[AliveCor QT Service]** **(K212662)**	**New Device** **[SafeBeat Rx]** **[SafeBeat Rx App]**
Environment of Use	Professional Healthcare Facility	Professional Healthcare facility	Professional Healthcare facility Home Environment
Intended User	Qualified healthcare professionals	Same	Same
Intended Patient Population	Adult population of 18 years of age	Adult population of 18 years of age	ECG Analysis: Adult population of 18 years of age Dose recommendation: Patients with arrhythmias
Target Anatomic Area	Heart	Heart	Same

TABLE 2 COMPARISON OF TECHNOLOGICAL CHARACTERISTICS OF THE SAFEBEAT RX APP, ALIVECOR QT SERVICE, AND CARDIOLOGS ECG ANALYSIS PLATFORM

	Predicate Device **[CardioLogs Technologies, CardioLogs ECG Analysis Platform]** **(K170568)**	**Reference Device** **[AliveCor Inc.]** **[AliveCor QT Service]** **(K212662)**	**New Device** **SafeBeat Rx** **SafeBeat Rx App**
Principle of Operation	- ECG signal processing and analysis - QRS detection - Interval measurement - Heart rate measurement -	- QT Interval measurement - Heart rate measurement -	- ECG signal processing and analysis - QRS feature extraction - Interval measurement (QTc) - Heart rate measurement
Filtering	- Noise Filtering	- N/A	- Noise Filtering
Measurements	- Tachycardia - Bradycardia - Atrial fibrillation - Atrial Fibrillation - Ventricular Tachycardia - Premature Supraventricular Complexes - Ventricular Couplets - Ventricular Bigeminy - Ventricular Trigeminy - Sinus rhythms	- N/A	- N/A

	Predicate Device **[CardioLogs Technologies, CardioLogs ECG Analysis Platform]** **(K170568)**	**Reference Device** **[AliveCor Inc.]** **[AliveCor QT Service]** **(K212662)**	**New Device** **SafeBeat Rx** **SafeBeat Rx App**
In-Patient Setting	- 12 lead ECG standard bandwidth electrode	- 6 lead ambulatory	- 12 lead ECG standard bandwidth electrode (GE Medical Systems)
Out-patient Setting	- Compatible reduced lead set ECG.	- Compatible reduced lead set ECG consisting of at least Lead I or Lead II.	- Compatible reduced lead set ECG
User Interface	● Interface which provides tools to measure, analyze and review numerous ECGs.	● N/A	● Interface which provides tools to measure, analyze and review numerous ECGs.
Technical attributes	● An automated proprietary ECG interpretation support algorithm which measures and analyzes ECGs to provide supportive information for ECG diagnosis, written in Python language	● Adaptive filtering, signal processing, deep neural networks	● An automated proprietary ECG interpretation support algorithm which measures and analyzes ECGs to provide supportive information for ECG analysis, written in Python language

	Predicate Device **[CardioLogs Technologies, CardioLogs ECG Analysis Platform]** **(K170568)**	**Reference Device** **[AliveCor Inc.]** **[AliveCor QT Service]** **(K212662)**	**New Device** **SafeBeat Rx** **SafeBeat Rx App**
	● In cases where the third party filtered data is not available: The device .	● N/A	● In cases where the third party filtered data is not available: The baseline is calculated and the signal around it is normalized. Signal processing algorithms are used to measure the QT and RR intervals, which are used to calculate the QRS and QTc intervals of each beat.
	N/A	N/A	N/A
Shelf life	The device is a cloud-based software as a medical device.	The device is a cloud-based software as a medical device.	No change

Non-clinical Testing

Testing has been performance in compliance with the following recognized consensus standards:

- AAMI ANSI IEC 62304 - Medical device software - Software life-cycle processes
- IEC 60601-2-25 Medical electrical equipment - Part 2-25: Particular requirements for the safety of electrocardiographs
- IEC 60601-2-47 - Medical Electrical Equipment - Part 2-47: Particular Requirements For The Basic Safety And Essential Performance Of Ambulatory Electrocardiographic Systems
- IEC 62366-1 - Medical devices - Application of usability engineering to medical devices

Testing described in the 510(k) consisted of verification of all design input requirements and product specifications. Integration testing was done which tested the system from input to output. Software validation testing was completed successfully and demonstrated the device met customer requirements. No anomalies were detected during design verification and validation testing.

Human Factors usability testing met all requirements for all use groups.

Clinical Testing

The training dataset consisted of broad distribution of cardiac rhythms and less common supraventricular rhythms. QRS and QTc morphology were diverse. The dataset ensured generalization across age, sex, rhythm classes and ECG waveform variations.

The software validation included:

- QTc Measurement Validation (SafeBeat Proprietary Dataset): Comparing software-generated QTc measurements to expert cardiologist annotations
- QRS Measurement Validation (SafeBeat Proprietary Dataset): Comparing QRS measurements to expert cardiologist annotations
- HR and R-R Peak Measurement Validation (SafeBeat Proprietary Dataset): Comparing heart rate (HR) and R-R peak measurements to expert cardiologist annotations
- Edge Case Testing: Assessing ECGs with morphological changes in T-waves, U-waves, and T-U wave fusion, and QT prolongation cases.
- QTc and QRS mean difference using the Common Standards for Electrocardiography (CSE) Dataset (n=100) ECGs in accordance with IEC 60601-2-25.
- Arrhythmia Detection Validation: Evaluating beat-segment detection/QRS sensitivity and positive predictive value against test datasets referenced in IEC 60601-2-47.
- Arrhythmia Detection Validation: Evaluating heart rate (HR) and R-R peak against test datasets referenced in IEC 60601-2-47.

SafeBeat Proprietary Validation Dataset

The clinical validation for the SafeBeat Rx App consisted of retrospective testing using publicly available clinical datasets to assess the algorithm's ability to measure QT, QRS, and HR/RR. The SafeBeat Rx App measurements were compared with the annotations performed by board-certified cardiologists. The cohort had a mean age of 40.9 years (range 18-87) with balanced male and female representation (51.5% male). The race and ethnicity distribution included White (60.9%), Asian (3.8%), Black or African American (10%), Hispanic or Latino (4.8%), Other (4.1%), or Unknown (16.5%) individuals. Body mass index (BMI, kg/m^2) ranged from normal (<25, 18.9%), overweight (≥25 and <30, 22.3%), obese (≥30, 22.6%), and Unknown (36.2%). Data was assembled from multiple independent sources.

The validation datasets included ECG recordings from diverse patient populations collected across multiple geographically distinct locations, encompassing healthy individuals, patients in critical care settings, and patients with known arrhythmias. The datasets represented a broad spectrum of ECG morphologies, including sinus rhythm, bradycardia, tachycardia, atrial arrhythmias, conduction abnormalities, drug-induced QTc prolongation, and clinically relevant T-wave, U-wave, and T-U wave fusion morphology.

Software-generated QT, QRS, and HR/RR measurements were compared against annotations performed by board-certified cardiologists with excellent agreement.

Standard ECG Test Databases (defined by IEC 60601-2-47)

The IEC 60601-2-47 standard references three datasets for testing: MIT-BIH Normal Sinus Rhythm dataset, AHA database, and MIT-BIH Noise Stress Test dataset. The testing included QRS sensitivity and positive predictivity results and the Heart Rate/RR root mean square error (RMSE) and RMSE Percent (%) using established metrics.

Testing on IEC 60601-2-47 reference ECG databases demonstrated effective beat-segment/QRS detection as well as heart rate/R-R interval estimation performance.

Common Standards for Electrocardiography (CSE) Database (defined by IEC 60601-2-25)

Performance testing in accordance with IEC 60601-2-25 was conducted using ECG recordings containing CSE reference measurements. Global QT interval and QRS duration measurements demonstrated excellent agreement with manual CSE reference measurements.

Conclusion
Based on the results of the nonclinical and clinical performance testing, the SafeBeat Rx App is substantially equivalent to the predicate device with respect to intended use, technological characteristics, and performance.

These results demonstrate that the device performs as well as or better than the predicate and that any differences in technological characteristics do not raise new questions of safety or effectiveness compared to the predicate. Therefore, the SafeBeat Rx is at least as safe and effective as the legally marketed predicate device, as required by 21 CFR 807.92(b)(3).