July 9, 2026

Synergen Technology Labs, LLC
Udara Karasnagoda
Quality and Regulatory Manager
2626 Cole Ave.
Suite 429
Dallas, Texas 75204

Re: K252978
Trade/Device Name: ScioCardio ECG Analysis Platform
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK, DPS
Dated: May 29, 2026
Received: May 29, 2026

Dear Udara Karasnagoda:

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 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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,

KIMBERLY N. CROWLEY -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

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)*
K252978

Device Name
ScioCardio ECG Analysis Platform

Indications for Use *(Describe)*
The ScioCardio ECG Analysis Platform is intended for use by healthcare professionals or trained personnel in healthcare facilities for the assessment of cardiac rhythms and arrhythmias using ECG data in adults aged 22 years and older.

The ScioCardio ECG Analysis Platform supports analyzing ECG data recorded from the ScioCardio ECG transmitter (K171019).

The ScioCardio ECG Analysis platform provides ECG signal processing and analysis including QRS complex detection, beat classification, and rhythm analysis. The reports include beat-by-beat analysis, heart rate measurement, and rhythm analysis.

The ScioCardio ECG Analysis Platform is not intended for use in life-supporting or sustaining systems, or for real-time ECG monitoring or alarm functions.

Interpretation results provided by the ScioCardio are not intended to be the sole means of diagnosis and are offered as an advisory aid to be used alongside clinician review, ECG patterns, patient history, clinical indications, and other diagnostic data.

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.

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1. 510(K) SUMMARY

Prepared in accordance with the requirements of 21 CFR 807.92

2. SUBMITTER INFORMATION [807.92(A)(1)]

Applicant	Synergen Technology Labs LLC
Submitter / Primary Contact Person	Udara Karasnagoda
Submitter / Primary Contact Person email info	udara.k@synergentl.com
Secondary Contact Person	Sameer Jareen
Secondary Contact Person email info	sameer.j@synergentl.com
Date Prepared	05/27/2026

3. DEVICE INFORMATION [807.92(A)(2)]

Trade Name	ScioCardio ECG Analysis Platform
Common Name	Electrocardiograph
Classification	21 CFR§870.2340
Device Class	Class II
Product Code	DPS
Subsequent Product Code	DQK

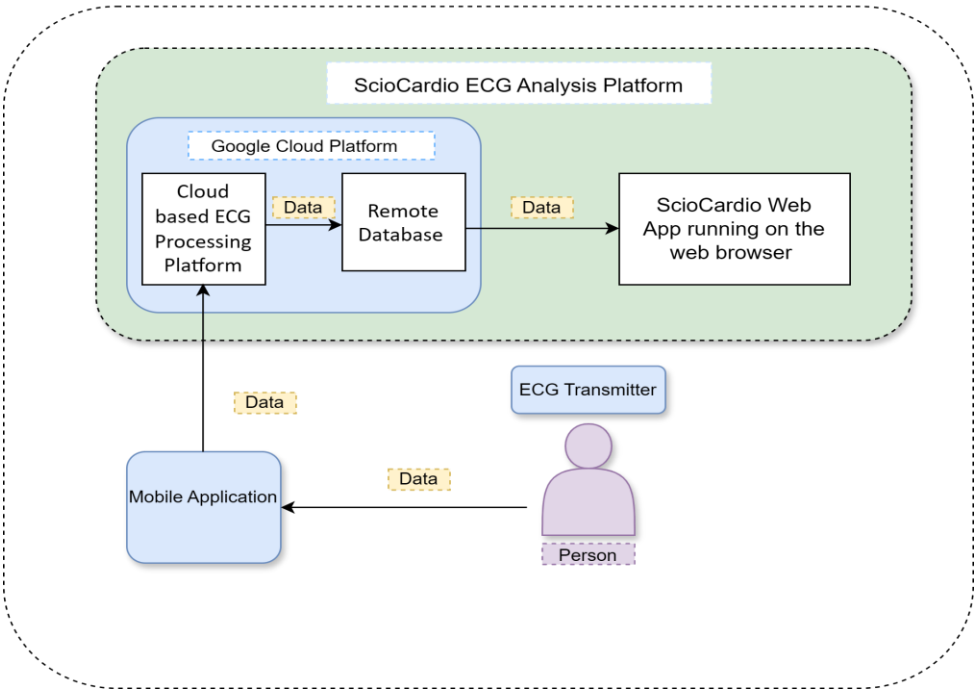
4. Predicate Information [807.92(a)(3)]

Predicate(s)	CardioLogs Holter Platform, (K212112)

5. Device Description [807.92(a)(4)]

The ScioCardio ECG Analysis Platform is made up of:

- A web interface which provides tools to view, analyze and review ECGs
- A cloud database to store the incoming ECG records and the analysis results
- An automated cloud based proprietary ECG interpretation algorithm to process and analyze ECG signals (Lead II) to provide supportive information for arrhythmia detection in ECG signals



ScioCardio ECG Analysis Platform is only intended to analyze ECG recordings performed on adults.

The ScioCardio ECG Analysis Platform is compatible with ScioCardio ECG transmitter (K171019) which use wet electrodes which gives the Lead II output, provided that their ECG signal output conforms to the technical input requirements outlined in Table 1 below.

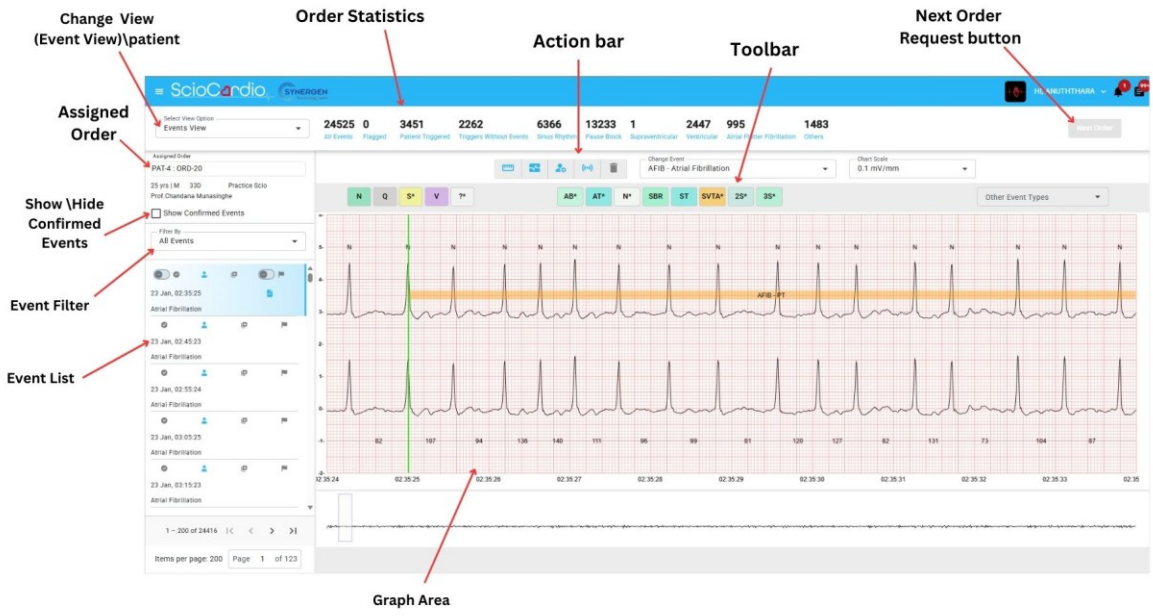


Figure 2: Enlarged View of the Web Application

ScioCardio ECG Analysis platform provides beat-by-beat ECG signal processing and analysis, QRS detection, Ventricular Ectopic Beat detection, interval measurement, heart rate, and rhythm analysis. The backend application is established in the cloud and accessed through an internet connection and a web browser to perform ECG analysis and generate reports.

The ScioCardio ECG Analysis Platform's algorithm is designed for electrocardiogram (ECG) beats and rhythm detection and classification. The ScioCardio algorithm uses a combination of standard signal processing techniques, clinically established ruleset, and Machine Learning (ML) algorithms. It uses the ML components to classify QRS complexes into 3-beat classes (beat type labelling) and to detect atrial fibrillation (AFIB) in the ECG segments. The algorithm also uses clinically established rules to identify arrhythmias using heart rate and beat patterns. The ECG analysis platform uses standard signal processing techniques to filter out noise from the raw ECG data. The algorithms used in the platform are modularized based on the functionality and input dependencies.

The ScioCardio algorithm accepts input ECG data sampled at 250 Hz using Lead II electrode configurations. It utilizes bio-signal processing techniques, clinically established rulesets, and machine learning technology to achieve high performance. The algorithm uses supervised machine learning techniques for beat classification and AFIB

arrhythmia detection. The machine learning algorithms do not contain continuous learning, and the models are "frozen" before release.

The ScioCardio ECG Analysis Platform is intended for use by qualified healthcare professionals or trained personnel for the assessment of arrhythmias using ECG data in subjects of 22 years and older. The product supports analyzing ECG data recorded from ScioCardio ECG transmitter (K171019).

The compatible recorded ECG must meet the following requirements:

Table 1

Parameter	**ScioCardio ECG Transmitter (K171019)**
Displayed lead	Lead II
Lead positioning (adult)	RA: infraclavicular right chest below right clavicle; LL: left lower torso at left anterior axillary line above iliac crest; tolerance ±3 cm.
ADC resolution	16-bit
Input range / max input	10 mV p-v signal over a +/- 300 mV DC
Input-referred noise	7 µVpp
Common Mode Rejection Ratio (CMRR) (50/60 Hz)	100 dB
Device sampling frequency (Output)	250 Hz
Internal/ source sampling	250 Hz

Digital passband	0.05–40 Hz
Supported electrode types	Wet Silver (Ag) / Silver Chloride (AgCl) ECG electrodes with conductive gel
Operating Conditions	Temperature 0–40 °C Relative Humidity 10% to 95% (non-condensing)
Input impedance	10 MΩ
Continuous lead-off detection	Real-time alert and flag
Skin preparation & use	Clean/dry skin; shave if needed; avoid lotions; replace wet gel electrodes every 24 hours

ScioCardio 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. The ScioCardio ECG Analysis Platform is not for use in life supporting or sustaining systems or ECG monitor and alarm devices.

6. INDICATIONS FOR USE [807.92(A)(5)]

The ScioCardio ECG Analysis Platform is intended for use by healthcare professionals or trained personnel in healthcare facilities for the assessment of cardiac rhythms and arrhythmias using ECG data in adults aged 22 years and older.

The ScioCardio ECG Analysis Platform supports analyzing ECG data recorded from the ScioCardio ECG transmitter (K171019).

The ScioCardio ECG Analysis platform provides ECG signal processing and analysis including QRS complex detection, beat classification, and rhythm analysis. The reports include beat-by-beat analysis, heart rate measurement, and rhythm analysis.

The ScioCardio ECG Analysis Platform is not intended for use in life-supporting or sustaining systems, or for real-time ECG monitoring or alarm functions.

Interpretation results provided by the ScioCardio are not intended to be the sole means of diagnosis and are offered as an advisory aid to be used alongside clinician review, ECG patterns, patient history, clinical indications, and other diagnostic data.

7. SUBSTANTIAL EQUIVALENCE

Cardiologs Holter Platform (**K212112**) has been selected as the Predicate Device for the ScioCardio ECG Analysis Platform. Predicate device have similar intended uses and technological characteristics to the subject device, making it suitable for establishing substantial equivalence for the subject device in this 510(k) submission.

The subject device, ScioCardio ECG Analysis Platform, and the predicate device is software-based solutions designed for ECG signal analysis and arrhythmia detection to aid healthcare professionals in cardiac assessment. Both devices process, analyze, and display ECG data to assist qualified healthcare professionals or trained personnel in clinical interpretation; they do not provide diagnostic conclusions or active monitoring functions.

The subject device has the same intended use as the predicate device. Both device are intended to process ECG data to detect the presence of arrhythmias. These analysis outputs represent potential findings to be reviewed and interpreted by qualified healthcare professionals or trained personnel. The subject device and predicate devices both process and analyze recorded ECGs, with results that are stored, transferred, and displayed. None of the devices provide alarms or real-time patient monitoring.

The subject device includes all the analytical outputs of the predicate device and introduces additional analysis outputs within the same general intended use. The ScioCardio device's arrhythmia detection functionalities, like the predicate device, are prescription features. The subject device is indicated for adults aged 22 years and older, whereas the Cardiologs Holter Platform includes both adult and pediatric populations. This difference does not raise new safety or effectiveness questions.

Therefore, the ScioCardio ECG Analysis Platform has the same intended use and similar technological characteristics as the predicate device. Any differences do not raise different questions of safety or effectiveness. Performance testing confirms that ScioCardio meets its performance specifications and is as safe and effective as the predicate device for their intended use. Thus, ScioCardio is substantially equivalent to the predicate device.

Comparison of Technological Characteristics with the Predicate Device [807.92(a)(6)]			
Feature	**Synergen Technology Labs** **ScioCardio ECG Analysis Platform** **(Subject Device)**	**CardioLogs Holter Platform, K212112** **(Predicate Device I)**	**Comparison**
Product Code	DPS, Electrocardiograph DQK, Programmable Diagnostic Computer	DPS, Electrocardiograph DQK, Computer, Diagnostic, Programmable	Same
Regulation	21 CFR§870.2340, Electrocardiograph Class II	21 CFR§870.2340 , Electrocardiograph Class II	Same

Indications for use	The ScioCardio ECG Analysis Platform is intended for use by healthcare professionals or trained personnel in healthcare facilities for the assessment of cardiac rhythms and arrhythmias using ECG data in adults aged 22 years and older. The ScioCardio ECG Analysis Platform supports analyzing ECG data recorded from ambulatory ScioCardio ECG transmitter (K171019) The ScioCardio ECG Analysis platform provides ECG signal processing and analysis including QRS complex detection, beat classification, and rhythm analysis. The reports include beat-by-beat analysis, heart rate measurement, and rhythm analysis. The ScioCardio ECG Analysis Platform is not intended for use in life-supporting or sustaining systems, or for real-time ECG monitoring or alarm functions. Interpretation results provided by the ScioCardio are not intended to be the sole means of diagnosis and are offered as an advisory aid to be used alongside clinician review, ECG patterns, patient	The Cardiologs Platform (Also known as Cardiologs Holter Platform) is intended for use by qualified healthcare professionals for the assessment of arrhythmias using ECG data in the adult and pediatric population. 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 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 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 Platform is not for use in life supporting or sustaining systems or ECG monitor and Alarm devices.	Same users, Same intended use Subject device is for 22 years and older vs pediatric and adult (18 years and older), considered same for adults. Contains a subset of the predicate's intended patient population. Both provide signal processing and analysis, QRS detection, beat classification, and rhythm analysis. The signal analysis and detection may differ in specific sub classifications but are similar in intended use as an adjunct intended to facilitate healthcare decision-making in conjunction with the physician's knowledge of ECG patterns Both do not produce alarms, are not intended for active patient monitoring, or as life supporting / sustaining purposes.

	history, clinical indications, and other diagnostic data.	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 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.	Predicate device (CardioLogs Holter Platform) support ECG data from multiple lead configurations including **12-lead and ambulatory ECG recordings**, whereas the **ScioCardio ECG Analysis Platform supports ECG recordings from the ScioCardio ECG transmitter** . The difference in ECG input configuration reflects the subject device's focus on **limited-lead ambulatory rhythm analysis** rather than multi-lead diagnostic acquisition. Differences in ECG lead configuration (ScioCardio ECG transmitter vs 12-lead), patient population, and integration scope do not raise new questions of safety or effectiveness.

Comparison of Technological Characteristics with the Predicate Device [807.92(a)(6)]			
Feature	**Synergen Technology Labs** **ScioCardio ECG Analysis Platform** **(Subject Device)**	**CardioLogs Holter Platform, K212112** **(Predicate Device I)**	**Comparison**
Target population	Adults (over 22)	Adults and pediatric	Same for adults
Components	Software only	Software only	Same
Software Functionalities	An interface that provides tools to process and analyze ECGs through various algorithms The automated proprietary ECG algorithms provide supportive information for ECG diagnosis. The library can be accessed by directly connecting to the ScioCardio Application Programming Interface	An interface that provides tools to process and analyze ECGs through various algorithms The automated proprietary ECG algorithms provide supportive information for ECG diagnosis. The library can be accessed by directly connecting to the CardioLogs Application Programming Interface	Same functionality class; subject device includes user interface.
Compatible ECG Devices	ScioCardio ECG transmitter (K171019)	Compatible devices	Same

Comparison of Arrhythmia detection: ScioCardio Platform vs. the predicate device				
Output (Arrhythmia)	**Subject Device**	**Predicate Device**	**Difference?**	**Scientific/Clinical Rationale**
Atrial Fibrillation (AFIB)	Yes	Yes	No	The Subject device and Predicate device provide Afib classification output
Ventricular Tachycardia (VT)	Yes	Yes	No	The Subject device and Predicate device provide VT classification output
Pause (PSE)	Yes	Yes	No	The Subject device and Predicate device provide PSE classification output
Sinus Bradycardia (SBR)	Yes	Yes	No	The Subject device and Predicate device provide SBR classification output
Sinus Tachycardia (ST)	Yes	Yes	No	The Subject device and Predicate device provide ST classification output
Ventricular Bigeminy (B)	Yes	Yes	No	The Subject device and Predicate device provide B classification output
Ventricular Trigeminy (T)	Yes	Yes	No	The Subject device and Predicate device provide T classification output

Atrioventricular Block (second-degree, third-degree, advanced high-grade AV block)	No	Yes	Yes	The subject device does not detect AV blocks, which is beyond the intended use of the subject device.

8. PERFORMANCE DATA [807.92(B)]

All necessary testing was conducted on ScioCardio ECG Analysis Platform to support a determination of substantial equivalence to the predicate device and the following performance data were provided.

8.1. STERILIZATION & SHELF-LIFE TESTING

Not Applicable (Standalone Software)

8.2. BIOCOMPATIBILITY TESTING

Not Applicable (Standalone Software)

8.3. ELECTRICAL SAFETY AND ELECTROMAGNETIC COMPATIBILITY (EMC)

Not Applicable (Standalone Software)

8.4. SOFTWARE VERIFICATION AND VALIDATION TESTING (INCLUDING ALGORITHM PERFORMANCE)

Software Verification and Validation Testing has been conducted according to the following standards that are the same standards utilized by the predicate:

- ANSI AAMI IEC 62304:2006/A1:2016 Medical Device Software - Software Life Cycle Processes [Including Amendment 1 (2016)]
- Medical electrical equipment - Part 2-47:2012 - Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems
- ANSI AAMI EC57:2012 Testing and reporting performance results of cardiac rhythm and ST-segment measurement algorithms

8.5. MECHANICAL AND ACOUSTIC TESTING

Not Applicable (Standalone Software)

8.6. ANIMAL STUDY

Animal performance testing was not required to demonstrate the safety and effectiveness of the device.

8.7. CLINICAL STUDIES

Clinical testing was not required to demonstrate the safety and effectiveness of the ScioCardio ECG Analysis, substantial equivalence is based upon benchtop performance testing using controlled, known datasets.

9. NONCLINICAL TESTING SUMMARY [807.92(B)(1)]

Nonclinical testing, similar to that conducted to support the predicate devices, was conducted to assess algorithm performance and to verify that ScioCardio ECG Analysis Platform performs as intended.

Software verification and validation testing was conducted for the ScioCardio ECG Analysis Platform in accordance with FDA guidance and recognized consensus standards. Algorithm performance was evaluated using a combination of publicly available ECG databases and Synergen's proprietary datasets. To ensure robustness and clinical relevance, additional testing was performed using standard databases referenced in ANSI/AAMI EC57:2012 and ANSI/AAMI/IEC 60601-2-47:2012.

Comparative performance analysis was undertaken for algorithm outputs common to both the subject and predicate devices. ScioCardio's outputs demonstrated equivalent performance to those of the predicate device. The testing outcomes affirm that the ScioCardio ECG Analysis Platform meets its design specifications and intended use, supporting a conclusion of substantial equivalence to the predicate devices.

In addition, a human factors usability study was conducted in accordance with recommendations in IEC 62366-1:2015, "Medical devices - Part 1: Application of usability engineering to medical devices", and FDA Guidance, "Applying Human Factors and Usability Engineering to Medical Devices", issued February 3, 2016. The results of the study demonstrated that users can use the device and understands its outputs based on labeling, and further understand appropriate actions if symptoms are present, such as when to seek medical care.

The performance of ScioCardio, in terms of sensitivity, specificity and positive predictivity is provided in the table below.

Table 2 : ScioCardio Validation Summary

Arrhythmia	Sample Size		Performance		
	Records	Patients	Sensitivity	Specificity	Positive Predictivity
Atrial Fibrillation (AFIB)	341	320	98.61%	99.52%	96.55%
Sinus Tachycardia (ST)	630	602	94.32%	99.27%	97.89%
Sinus Bradycardia (SBR)	727	626	96.44%	99.21%	98.33%
Ventricular Tachycardia (VT)	410	402	98.60%	99.73%	97.92%
Ventricular Bigeminy (B)	276	259	97.48%	99.75%	98.06%
Ventricular Trigeminy (T)	270	248	98.61%	99.49%	95.70%
Pause (PSE)	199	183	99.76%	100.00%	97.92%

The ScioCardio ECG Platform was clinically validated using a diverse, statistically powered dataset of 2,850 ECG strips from 2,146 subjects, representing the intended ambulatory use population. All targeted arrhythmias were well-represented, with case counts exceeding minimum requirements to support reliable performance evaluation.

The system consistently met predefined acceptance criteria for sensitivity and specificity across all claimed rhythm types. These thresholds were informed by internal validation, performance of FDA cleared predicate device, and high-quality literature benchmarks. In addition, positive predictive value remained consistently high across rhythm classes.

Performance consistency was also demonstrated across key demographic subgroups, underscoring the generalizability of the algorithm. The validation process was conducted in accordance with the principles outlined in applicable regulatory standards and guidance, including ANSI/AAMI EC57:2012 and IEC 60601-2-47:2012.

These results support a determination of substantial equivalence to the identified predicate device.

10. CONCLUSIONS [807.92(B)(3)]

ScioCardio ECG Analysis Platform has the same intended use as the predicate device, and any differences in technological characteristics do not raise different questions of safety or effectiveness. Differences between the subject devices and the predicate device have been tested to ensure that the device meets its intended use. The results of nonclinical testing specifically demonstrate that ScioCardio ECG Analysis Platform meets its intended use which is equivalent to that of the predicate device. Therefore, ScioCardio ECG Analysis Platform is substantially equivalent to the predicate device.