August 2, 2024

Samsung Electronics Co., Ltd
% Matthew Wiggins
Sr. Director of Digital Health Commercialization
Samsung Research America Inc.
665 Clyde Avenue
Mountain View, California 94043

Re: K240909
Trade/Device Name: Samsung ECG App v 1.3 (ECG)
Regulation Number: 21 CFR 870.2345
Regulation Name: Electrocardiograph Software For Over-The-Counter Use
Regulatory Class: Class II
Product Code: QDA, QDB
Dated: July 3, 2024
Received: July 3, 2024

Dear Matthew Wiggins:

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 Shih 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.*

Submission Number *(if known)*

K240909

Device Name

Samsung ECG App v 1.3 (ECG)

Indications for Use *(Describe)*

The Samsung ECG app with IHRN is an over-the-counter (OTC) software-only, mobile medical application operating on a compatible Samsung Galaxy Watch and Phone for informational use only in adults 22 years and older. The app analyzes pulse rate data to identify episodes of irregular heart rhythms suggestive of atrial fibrillation (AFib) and provides a notification suggesting the user record an ECG to analyze the heart rhythm. The Irregular Heart Rhythm Notification Feature is not intended to provide a notification on every episode of irregular rhythm suggestive of AFib and the absence of a notification is not intended to indicate no disease process is present; rather the feature is intended to opportunistically acquire pulse rate data when the user is still and analyze the data when determined sufficient toward surfacing a notification.

Following this prompt, or based on the user's own initiative, the app is intended to create, record, store, transfer, and display a single channel ECG, similar to a Lead I ECG. Classifiable traces are labeled by the app as sinus rhythm, AFib, high heart rate (non-AFib), or AFib with high heart rate with the intention of aiding heart rhythm identification.

The app is not intended for users with other known arrhythmias, and it is not intended to replace traditional methods of diagnosis or treatment. Users should not interpret or take clinical action based on the device output without consultation of a qualified healthcare professional.

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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# K240909 - Samsung ECG App v1.3

## Applicant Information


**Manufacturer:** **Samsung Electronics Co., Ltd**
129, Samsung-ro, Yeongtong-gu, Suwon-si, Gyeonggi-do 16677, Korea

**Contact Person:** **Matthew Wiggins, Ph.D.**
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**Date Prepared:** July 3rd, 2024

## Device Information

**Trade/Device Name:** Samsung ECG App v1.3

**Classification:**
- QDA - Electrocardiograph software for over-the-counter use (21 CFR 870.2345)
- QDB - Photoplethysmograph Analysis Software For Over-The-Counter Use (21 CFR 870.2790)

**Predicate Device:**
- Primary: Samsung ECG Monitor App with Irregular Heart Rhythm Notification Feature (K230292)

**Reference Device**
- Apple ECG 2.0 App (K201525)

## Device Description

The Samsung ECG App v1.3 is a software as a medical device (SaMD) that consists of a pair of mobile medical apps: one app on a compatible Samsung wearable and the other on a compatible Samsung phone, both general-purpose computing platforms.

When enabled, the wearable application of the SaMD uses a wearable photoplethysmography (PPG) sensor to background monitor cardiac signals from the user. The application examines beat-to-beat intervals and generates an irregular rhythm notification indicative of atrial fibrillation (AFib). Upon receiving an irregular rhythm notification or at their discretion, the user can record a single-lead ECG using the same wearable. The wearable application then calculates the average heart rate from the ECG recording and produces a rhythm classification. The wearable application also securely transmits the data to the ECG phone application on the paired phone. The phone application shows a time-stamped irregular rhythm notification history with heart rate information; ECG measurement history; and generates a PDF file of the ECG signal, which the user can share with their healthcare provider.

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**Intended Use/Indications for Use**

The subject device's indications for use include the new classifiable ECG rhythms, High heart rate and Atrial fibrillation with high heart rate, while maintaining its background AFib monitoring and on-demand ECG classification intended uses. The updated indications for use are provided below.

> *The Samsung ECG with IHRN 2.0 is an over-the-counter (OTC) software-only, mobile medical application operating on a compatible Samsung Galaxy Watch and Phone for informational use only in adults 22 years and older. The app analyzes pulse rate data to identify episodes of irregular heart rhythms suggestive of atrial fibrillation (AFib) and provides a notification suggesting the user record an ECG to analyze the heart rhythm. The Irregular Heart Rhythm Notification feature is not intended to provide a notification on every episode of irregular rhythm suggestive of AFib and the absence of a notification is not intended to indicate no disease process is present; rather the feature is intended to opportunistically acquire pulse rate data when the user is still and analyze the data when determined sufficient toward surfacing a notification.*
>
> *Following this prompt, or based on the user's own initiative, the app is intended to create, record, store, transfer, and display a single channel ECG, similar to a Lead I ECG. Classifiable traces are labeled by the app as sinus rhythm, AFib, high heart rate (non-AFib), or AFib with high heart rate with the intention of aiding heart rhythm identification.*
>
> *The app is not intended for users with other known arrhythmias, and it is not intended to replace traditional methods of diagnosis or treatment. Users should not interpret or take clinical action based on the device output without consultation of a qualified healthcare professional.*

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**Comparison of Technological Characteristics**

The ECG function of the subject device is substantially equivalent to the predicate and reference devices. Using the dry electrodes on the Galaxy Watch wearable, the user can record an on-demand ECG recording, similar to Lead I ECG, without requiring a physician visit. This function enables users to easily and more frequently record their ECG, and consult with their qualified healthcare provider. The updates to the ECG function primarily consist of expansion of classifiable ECG heart rates up to 150 beats per minutes, consistent with the reference Apple ECG 2.0 App (K201525).

The IHRN function of the subject device, including user workflow, sensor and algorithm function, and device output remains substantially equivalent to the predicate device, where it uses Photoplethysmograph (PPG) technology to extract rhythm information and notify the user when consistent tachograms are classified as a rhythm suggestive of Atrial Fibrillation.

A more detailed comparison between the subject device, the predicate device (Samsung ECG Monitor App with IHRN Feature, K230292), and the reference device (Apple's ECG 2.0 App, K201525) is provided in ***Table 1***.

***Table 1***. Technological Comparison of Subject Device, Predicate Device, and Reference Device

| | **Subject Device: Samsung ECG App v1.3** | **Predicate Device: Samsung ECG Monitor App with IHRN Feature (K230292)** | **Reference Device: ECG 2.0 App (K201525)** | **Differences and Discussion** |
|---|---|---|---|---|
| **Key Platform Sensor (ECG)** | Lead I Electrocardiogram (ECG) acquired from the dorsal side of the wrist to the opposing hand's finger, which is placed on the watch body. | Lead I Electrocardiogram (ECG) acquired from the dorsal side of the wrist to the opposing hand's finger which is placed on the watch body. | A single channel electrocardiogram (ECG) similar to a Lead I ECG. Taken from electrodes on the back of the watch on one had to the digital crown where the finger is placed | Identical to the Predicate Device. |
| **Key Platform Sensor (IHRN)** | Green wavelength PPG on the back side of the watch for contact with the dorsal side of the wrist. | Green wavelength PPG on the back side of the watch for contact with the dorsal side of the wrist. | N/A | Identical to the Predicate Device. |
| **Platform(s)** | • Samsung Galaxy Watch5 wearable running Wear OS version 4.0.<br>• Galaxy phones with Android 9 (Pie). | • Samsung Galaxy Watch4 wearable or later running Wear OS version 4.0.<br>• Samsung Galaxy phones with Android 9 (Pie) and beyond | • Apple Watch Series 4 with watch OS 7.0 or later<br>• Apple iPhone 6s with iOS 14 or later | Substantially equivalent to the Predicate Device. |
| **User Interface** | • Wearable screen for initiating ECG recording, viewing signal during acquisition (user engagement feature, not diagnostic quality), delivering rhythm classification, and capturing user reported symptoms<br>• Phone screen for viewing and sharing ECG recoding results and PDF report including recorded ECG and algorithmic rhythm classification<br>• Phone screen for onboarding and education materials | • Wearable screen for initiating ECG recording, viewing signal during acquisition (user engagement feature, not diagnostic quality), delivering rhythm classification, and capturing user reported symptoms.<br>• Phone screen for viewing and sharing ECG recoding results and PDF report including recorded ECG and algorithmic rhythm classification<br>• Phone screen for onboarding and education materials | • Apple watch screen for initiating spot checks, viewing signal during acquisition (user engagement feature, not diagnostic quality), and delivering rhythm classification and capturing symptoms<br>• Phone screen for viewing and sharing ECG spot check results, viewing historic data and PDF report including recorded ECG and algorithmic rhythm classification | Substantially equivalent to the Predicate Device for ECG and IHRN function. |
| **Rhythm Classification Results** | • ECG Lead I Rhythm Classification for Sinus rhythm, Atrial fibrillation, **Atrial fibrillation with high heart rate, High heart rate (non-AF), Inconclusive (inc. heart rate out of range), or Poor recording**<br>• ECG signal quality assessment for sufficient for analysis<br>• Average heart rate | • ECG Lead I Rhythm Classification for Sinus rhythm, Atrial fibrillation, **Inconclusive (heart rate out of range), or Poor recording (poor signal quality)**<br>• ECG signal quality assessment for sufficient for analysis<br>• Average heart rate | • ECG Lead I Rhythm Classification for Sinus Rhythm, Atrial Fibrillation, High heart rate, Inconclusive, Poor Recording<br>• Heart Rate High/Low Indicator | Substantially equivalent to the Reference Device.<br>Due to expanded heart rate range in the subject device, new classifications for high heart rate (≥100 BPM and ≤ 150 BPM) are created [high heart rate (non-AFib), and AFib with high heart rate]. |

| | Subject Device:<br>Samsung ECG App v1.3 | Predicate Device:<br>Samsung ECG Monitor App with IHRN Feature (K230292) | Reference Device:<br>ECG 2.0 App (K201525) | Differences and Discussion |
|---|---|---|---|---|
| **ECG Rhythm Classification Performance** | HR 50-150 BPM<br>• Sinus rhythm<br>▪ Specificity: 98.7% (95% CI 94.0%, 97.8%)<br>• Atrial Fibrillation<br>▪ Sensitivity: 96.0% (95% CI 94.0% 97.8%)<br>HR 100-150 BPM<br>• Sinus rhythm<br>▪ Specificity: 96.3% (95% CI 93.5% 98.9%)<br>• Atrial fibrillation<br>▪ Sensitivity: 93.6% (95% CI 88.5% 97.5%) | • Sinus rhythm (HR 50-100 BPM)<br>▪ Specificity: 100% (95% CI 100%, 100%)<br>• Atrial fibrillation (HR 50-120 BPM)<br>▪ Sensitivity: 98.1% (95% CI 96.3%, 99.9%)<br><br>Note: ECG performance was established in K201168 and maintained in K230292 as the ECG capability is equivalent between devices. | HR 50-150 BPM<br>• Sinus Rhythm<br>▪ Specificity: 99.3% (95% CI 98.4%, 100%)<br>• Atrial Fibrillation<br>▪ Sensitivity: 98.5% (95% CI 97.3%, 99.6%)<br>HR 100-150 BPM<br>• Sinus Rhythm<br>▪ Specificity: 83% (95% CI 77.8%, 88%)<br>• Atrial Fibrillation<br>▪ Sensitivity: 90.7% (95% CI 86.7%, 94.6%) | AF sensitivity and SR specificity with all heart rate and high heart rate is substantially equivalent to the Reference Device's point estimate level and lower confidence bound performance.<br>The IHRN function's performance has not changed from the Predicate Device. |

**Performance Data**

The following clinical, usability, and bench testing were conducted, showing that the updated ECG function of the subject SaMD meets predetermined acceptance criteria to demonstrate safety, effectiveness, and substantial equivalent to the reference Apple ECG 2.0 App. No new safety issues were found during this testing.

- Clinical Validation showing comparable clinical performance in terms of:
  - Subject-level ECG classification accuracy, measured by sensitivity and specificity, for all classifiable heart rates (50-150 beats per minute) and high heart rate (100-150 beats per minute)
  - ECG signal quality sufficiency
- Human Factors Validation
- IEC 60601-2-47 ECG Database Testing
- Heart Rate Accuracy Bench Testing
- Artifact Detection Bench Testing
- Software Verification Testing
- Labeling Verification Testing

In addition, testing was performed on the commercial platform, showing it meets all necessary specifications to safely and effectively host the subject SaMD. This included the following:

- ECG Signal Quality, Sampling Rate, Operating Conditions, and Lead Detection Bench Testing
- Platform Interface Software Testing (Android and WearOS)
- Platform Interface Hardware Testing
  - General safety tests: Electrical safety, electromagnetic compatibility, radio frequency emissions, material safety for skin contact, thermal safety for skin contact tests
  - Device robustness tests: Resistance to electrostatic discharge, water ingress and breakage tests

As the IHRN function of the subject device has not been functionally changed since the predicate device clearance as Samsung ECG Monitor App with IHRN Feature (K230292), clinical, human factors, and PPG confounder testing were not repeated.

**Clinical Study**

Our clinical validation testing results indicate that the ECG rhythm classification function of the Samsung ECG App v1.3 has comparable classification accuracy compared to the reference device. Classification accuracy is measured in sensitivity and specificity.

The updated ECG function was validated in a multi-center study with 1,013 subjects who were 22 years old or older. The subject demographics is summarized in **Table 2** below. The study enrolled 446 subjects diagnosed with AFib, 536 subjects without AFib, and 31 subjects diagnosed with another type of irregular rhythm. These enrolled subjects contributed to 453 AFib recordings (heart rate 50 to 150 BPM) and 691 Sinus rhythm recordings (heart rate 50 to 150 BPM) for the primary endpoint analysis.

***Table 2.*** Clinical Validation Testing Subject Demographics

| Parameter | Description | Percentage |
|---|---|---|
| Age | Mean | 57.6 |
| | Standard Deviation | 18.3 |
| Gender | Female | 46.1% |
| | Male | 53.9% |
| Ethnic Group | Hispanic or Latino | 6.4% |
| | Non-Hispanic or Latino | 93.6% |
| Race | American Indian or Alaska Native | 0.4% |
| | Asian | 2.2% |
| | Black or African American | 8% |
| | Pacific Islander | 0.2% |
| | Caucasian | 87.7% |
| | Other | 1.5% |

The ECG function accurately classified 435 out of the 453 AFib recordings with a sensitivity of 96.0% and classified 682 out of the 691 Sinus rhythm recordings with a specificity of 98.7%. There were no clinically meaningful difference in classification performance for age and gender demographic groups. The ECG App version 1.3 also produced visually interpretable waveforms in 98.7% of the cases. Furthermore, the key intervals (RR, PR, QRS) and R-wave amplitude of the waveforms were accurately measured when compared against the standard Lead I ECG.

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**Conclusion**

The subject device and combined predicate and reference devices have the same intended use, the same key technological characteristics, and the same signal-acquisition capabilities. In clinical testing, the Samsung's updated ECG function demonstrated that it has comparable ECG rhythm classification accuracy performance as the Apple ECG 2.0 App. Therefore, Samsung ECG v1.3 is substantially equivalent to the Samsung ECG Monitor App with IHRN Feature (K230292) and the Apple ECG 2.0 App (K201525).