May 2, 2023

Samsung Electronics Co., Ltd
% Matthew Wiggins
MPS-HSL Lab Head
Samsung Research America
665 Clyde Avenue
Mountain View, California 94043

Re: K230292
Trade/Device Name: Samsung ECG Monitor Application with Irregular Heart Rhythm Notification Feature
Regulation Number: 21 CFR 870.2790
Regulation Name: Photoplethysmograph Analysis Software For Over-The-Counter Use
Regulatory Class: Class II
Product Code: QDB, QDA
Dated: February 1, 2023
Received: February 2, 2023

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

for Shruti N. Mistry -S

Jennifer Shih 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230292

Device Name
Samsung ECG Monitor Application with Irregular Heart Rhythm Notification (IHRN) Feature

Indications for Use *(Describe)*
The Samsung ECG Monitor Application with Irregular Heart Rhythm Notification 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 either AFib or sinus rhythm 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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Samsung ECG Monitor Application with Irregular Heart Rhythm Notification Feature 510(k) Summary

Applicant Information

Manufacturer:	**Samsung Electronics Co., Ltd** 129, Samsung-ro, Yeongtong-gu, Suwon-si, Gyeonggi-do 16677, Korea
Contact Person:	**Matthew Wiggins, Ph.D.** Samsung Research America 665 Clyde Avenue, Mountain View, CA 94043 650-770-5804 m.wiggins@samsung.com
Date Prepared:	May 1st, 2023

Device Information

Proprietary Name:	Samsung ECG Monitor Application with Irregular Heart Rhythm Notification Feature
Common Name:	ECG Monitor App with IHRN Feature
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: Apple Irregular Rhythm Notification Feature (DEN180042) • Secondary: Samsung ECG Monitor App (K201168)

Device Description

The Samsung ECG Monitor App with Irregular Heart Rhythm Notification (IHRN) Feature 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 bio-photonic 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 device. 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.

Intended Use/Indications for Use

The subject device's indications for use are a combination of the predicate devices' indications (K201168 and DEN180042), reflecting its background AFib monitoring and ECG classification purposes. This combination did not change the use population or application of the device and yielded no new questions of safety or effectiveness. The indications for use are provided below.

> *The Samsung ECG Monitor Application with Irregular Heart Rhythm Notification 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 either AFib or sinus rhythm 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.*

Comparison of Technological Characteristics

The IHRN feature of the subject device uses Photoplethysmograph (PPG) technology to extract rhythm information. A PPG array on the back side of the Galaxy Watch wearable device, in contact with the dorsal side of the wrist, collects data as tachograms of specific frequencies. The algorithm classifies the collected tachogram as either AFib or Sinus. Accelerometer and other sensor data also inform the algorithm to exclude tachograms from classification due to noise. The user is then notified on the wearable when consistent tachograms are classified as AFib. The process of collecting tachograms, classifying them, and notifying the user of an irregular rhythm is functionally equivalent to the primary predicate device: Apple Irregular Rhythm Notification Feature (DEN180042).

A more detailed comparison between the IHRN Feature of the subject device and Apple's Irregular Rhythm Notification Feature is provided in ***Table 1***.

Table 1. Technological Comparison of IHRN Function

Specification	Samsung ECG Monitor App with IHRN Feature	Primary Predicate Apple IRN Feature (DEN180042)	Difference
Key Platform Sensor	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.	Equivalent The Apple and Samsung sensor functions in the same method.
Platform(s)	• Wearable: Samsung Galaxy Watch4 or later running Wear OS • Phone: Samsung Galaxy phones with Android OS	• Wearable: Apple Watch with watch OS • Phone: Apple iPhones with iOS	Equivalent Different hardware and OS for both wearable and phone platforms, both offering equivalent communications and sensor capabilities and features
User Interface	• Samsung wearable screen for notifying the user when irregular rhythm is detected • Phone screen for onboarding, turning the feature ON/OFF, and viewing notification history and historic data including time-stamped heart rate information	• Apple watch screen for notifying the user when irregular rhythm is detected • Phone screen for onboarding, turning the feature ON/OFF viewing details about the tachograms that resulted in notification, viewing historic data including time-stamped heart rate information	Equivalent Both user interfaces offer the same key functions.
Algorithms	• PPG signal quality assessment algorithm (includes motion rejection) • PPG-based algorithm to extract tachograms • Irregular rhythm detection algorithm to detect AFib using tachograms • Notification generation algorithm to let user know about presence of AFib based on successive positive tachograms	• PPG signal quality assessment algorithm (includes motion rejection) • PPG-based algorithm to extract tachograms • Irregular rhythm detection algorithm to detect AFib using tachograms • Notification generation algorithm to let user know about presence of AFib based on successive tachograms	Equivalent High level algorithm is based on the same premise and basic steps though the details regarding parameters and sampling periods are different.

Specification	Samsung ECG Monitor App with IHRN Feature	Primary Predicate Apple IRN Feature (DEN180042)	Difference
Notification Performance	**Subject Level:** • Sensitivity – 68% (95% CI:59.9%, 75.4%) • Specificity – 98.8% (95% CI:97.6%, 99.5%) **Tachogram level:** • PPV – 95.7% (95% CI: 94.7%, 96.7%)	**Subject Level:** • Sensitivity – 47.9% (95% CI:37.5%, 58.5%) • Specificity – 90.9% (95% CI:84.7%, 95.2%) **Tachogram Level:** • PPV - 66.6% (97.5% CI lower bound 63%)	Equivalent Samsung's subject-level endpoints are sensitivity and specificity to remove the positive/negative population dependence inherent to PPV, which the IRN predicate used. Samsung's algorithm performance is substantially equivalent to the predicate device at both subject level and tachogram level.

The on-demand ECG capability of Samsung ECG Monitor App with IHRN Feature has not been functionally changed since the original clearance as Samsung ECG Monitor App (K201168). A detailed comparison between the subject device's ECG function and the predicate Samsung ECG Monitor App is presented in ***Table 2***.

Table 2. Technological Comparison of ECG Function

Specification	Samsung ECG Monitor App with IHRN Feature	Secondary Predicate Samsung ECG Monitor App (K201168)	Difference
Lead	A single channel electrocardiogram (ECG) similar to a Lead I ECG.	A single channel electrocardiogram (ECG) similar to a Lead I ECG.	Same
ECG duration	30 seconds	30 seconds	Same
Rhythms detected	• Atrial Fibrillation (HR between 50-120 BPM) • Sinus rhythm (HR between 50 – 100 BPM) • Inconclusive (Any Other Rhythm and HR <50 BPM) OR (AFib and HR >120 BPM) OR (NOT SR or AFib and HR 50-100 BPM) OR (SR and HR >100 BPM)	• Atrial Fibrillation (HR between 50-120 BPM) • Sinus rhythm (HR between 50 – 100 BPM) • Inconclusive (Any Other Rhythm and HR <50 BPM) OR (AFib and HR >120 BPM) OR (NOT SR or AFib and HR 50-100 BPM) OR (SR and HR >100 BPM)	Same
Heart Rate	Yes	Yes	Same
Key Platform Sensor	A single channel electrocardiogram (ECG) similar to a Lead I ECG taken from electrodes on the back of the watch on one wrist and the top button where the finger is placed	A single channel electrocardiogram (ECG) similar to a Lead I ECG taken from electrodes on the back of the watch on one wrist and the top button where the finger is placed	Same
Algorithms	• ECG Lead I Rhythm Classification for Sinus Rhythm, Atrial Fibrillation, Inconclusive, Poor Recording (for low quality or other reasons) • Heart Rate	• ECG Lead I Rhythm Classification for Sinus Rhythm, Atrial Fibrillation, Inconclusive, Poor Recording (for low quality or other reasons) • Heart Rate	Same
Rhythm Classification Performance	• Atrial Fibrillation Sensitivity: 98.1% • Sinus Rhythm Specificity: 100%	• Atrial Fibrillation Sensitivity: 98.1% • Sinus Rhythm Specificity: 100%	Same

Performance Data

As the on-demand ECG capability of the subject device has not been functionally changed since the original clearance as Samsung ECG Monitor App (K201168), clinical, human factors, ECG database (IEC 60601-2-47), and ECG heart rate accuracy tests were not repeated.

The following clinical, usability, and bench testing were conducted, showing that the IHRN function of the subject SaMD meets predetermined acceptance criteria to demonstrate substantial equivalence to the previously cleared Apple Irregular Rhythm Notification device. No new safety issues were found during this testing.

- Clinical Validation showing non-inferiority to the predicate in clinical performance in terms of
    - Subject-level irregular rhythm notification accuracy, measured by sensitivity and specificity
    - Tachogram-level positive predictive value
- Human Factors Validation
- Bench Verification Testing covering potential confounder conditions
- Software Verification Testing
- Labeling Verification Testing

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

- Sensor Suite Testing
- Platform Interface Software Testing
- 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

Clinical Study

Our clinical validation testing results indicate that the PPG-based notification function of the Samsung ECG Monitor App with IHRN Feature has substantially equivalent classification accuracy compared to the predicate device. Classification accuracy is measured in sensitivity and specificity.

A total of 888 subjects were enrolled. All recruited subjects were at risk for AFib and had experienced symptoms such as palpitations lasting at least several minutes or a feeling of their heart beating quickly or irregularly while at rest. Subjects who did not have a previous diagnosis of AFib had risk factors for AFib with a CHADS2 score ≥2 or CHADS2VASc score ≥3. Of all enrolled subjects, 810 were included in the analyzable dataset for primary and secondary endpoints. All subjects wore a reference ECG patch and the watch simultaneously for approximately seven days. IHRN notifications were compared against clinician-adjudicated and cardiologist-reviewed patch ECG data. Samsung IHRN Feature's subject-level sensitivity is 68.0% (C.I. 60.5 – 75.5) and the specificity is 98.8% (C.I. 98.0 – 99.6).

Since irregular rhythm notifications are aggregates of several PPG tachograms, tachogram classification accuracy was also assessed during the study. 98 subjects who had an AFib episode(s)

over the span of an hour and 101 subjects who had less than an hour of AFib or no AFib were randomly selected by biostatisticians from all of the cardiologist-reviewed subjects. Up to 25 positive tachograms with reference ECG data were randomly selected from these subjects. Two board-certified cardiologists reviewed each reference ECG for annotation with a third cardiologist serving as tie-breaker. Based on this data, Samsung IHRN Feature's tachogram level positive predictive value is 95.7% (C.I. 94.7 – 96.7).

Conclusion

The subject device and combined predicate devices have the same intended use, the same key technological characteristics, and the same signal-acquisition capabilities. In clinical testing, the Samsung IHRN Feature demonstrated that it is capable of substantially equivalent irregular rhythm notification accuracy. Therefore, Samsung ECG Monitor App with Irregular Heart Rhythm Notification Feature is substantially equivalent to the Apple Irregular Rhythm Notification Feature (DEN180042) and the Samsung ECG Monitor App (K201168).