August 4, 2020

Samsung Electronics Co., Ltd
Matthew Wiggins, Ph.D.
Director, Medical Device Team
665 Clyde Avenue
Mountain View, California 94043

Re: K201168
Trade/Device Name: Samsung ECG Monitor Application
Regulation Number: 21 CFR 870.2345
Regulation Name: Electrocardiograph software for over-the-counter use
Regulatory Class: Class II
Product Code: QDA
Dated: July 14, 2020
Received: July 15, 2020

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

Jennifer Shih
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201168

Device Name
Samsung ECG Monitor Application

Indications for Use *(Describe)*
The Samsung ECG Monitor Application is an over-the-counter (OTC) software-only, mobile medical application operating on a compatible Samsung Galaxy Watch and Phone. The app is intended to create, record, store, transfer, and display a single channel electrocardiogram (ECG), similar to a Lead I ECG, for informational use only in adults 22 years and older. Classifiable traces are labeled by the app as either atrial fibrillation (AFib) or sinus rhythm with the intention of aiding heart rhythm identification; it is not intended to replace traditional methods of diagnosis or treatment. The app is not intended for users with other known arrhythmias and 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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SAMSUNG

Samsung ECG Monitor Application
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 770-596-1765 m.wiggins@samsung.com
Date Prepared:	August 4th, 2020

Device Information

Proprietary Name:	Samsung ECG Monitor Application
Common Name:	ECG Monitor App
Classification:	QDA - Electrocardiograph software for over-the-counter use (21 CFR 870.2345)
Predicate Device:	Apple ECG App (DEN180044)

Device Description

The Samsung ECG Monitor Application consists of a pair of mobile medical apps: one on a compatible Samsung wearable and the other on a compatible Samsung phone. The compatible Samsung wearable application captures bioelectrical signals from the user and generates single lead ECG signals, calculates average heart rate and classifies the rhythm. The wearable application securely transmits the obtained data to the phone application on the paired phone device. The phone application shows the ECG measurement history and generates the PDF file for the received ECG signals which can be shared by the user.

Intended Use/Indications for Use

The Samsung ECG Monitor Application is an over-the-counter (OTC) software-only, mobile medical application operating on a compatible Samsung Galaxy Watch and Phone. The app is intended to create, record, store, transfer, and display a single channel electrocardiogram (ECG), similar to a Lead I ECG, for informational use only in adults 22 years and older. Classifiable traces are labeled by the app as either atrial fibrillation (AFib) or sinus rhythm with the intention of aiding heart rhythm identification; it is not intended to replace traditional methods of diagnosis or treatment. The app is not intended for users with other known arrhythmias and 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 predicate and the subject device have an equivalent intended use,
- The operating principle and specifications are equivalent, and
- Clinical and Usability validation testing, as well as bench testing, show performance equivalence and bring up no new safety or effectiveness questions.

A more detailed comparison of the devices is provided below in ***Table 1***.

Table 1. Technological Comparison

Specification	Predicate SaMD Apple ECG App (DEN 180044)	Samsung ECG Monitor App	Difference
Indications for Use	The ECG app is a software-only mobile medical application intended for use with the Apple Watch to create, record, store, transfer, and display a single channel electrocardiogram (ECG) similar to a Lead I ECG. The ECG app determines the presence of atrial fibrillation (AFib) or sinus rhythm on a classifiable waveform. The ECG app is not recommended for users with other known arrhythmias. The ECG app is intended for over-the-counter (OTC) use. The ECG data displayed by the ECG app is intended for informational use only. The user is not intended to interpret or take clinical action based on the device output without consultation of a qualified healthcare professional. The ECG waveform is meant to supplement rhythm classification for the purposes of discriminating AFib from normal sinus rhythm and not intended to replace traditional methods of diagnosis or treatment. The ECG app is not intended for use by people under 22 years old.	The Samsung ECG Monitor Application is an over-the-counter (OTC) software-only, mobile medical application operating on a compatible Samsung Galaxy Watch and Phone. The app is intended to create, record, store, transfer, and display a single channel electrocardiogram (ECG), similar to a Lead I ECG, for informational use only in adults 22 years and older. Classifiable traces are labeled by the app as either atrial fibrillation (AFib) or sinus rhythm with the intention of aiding heart rhythm identification; it is not intended to replace traditional methods of diagnosis or treatment. The app is not intended for users with other known arrhythmias and users should not interpret or take clinical action based on the device output without consultation of a qualified healthcare professional.	Equivalent
Patient population	Adults not previously diagnosed with other known arrhythmias	Adults not previously diagnosed with other known arrhythmias	Equivalent
Prescription Use/OTC	OTC	OTC	Equivalent

Lead	A single channel electrocardiogram (ECG) similar to a Lead I ECG.	A single channel electrocardiogram (ECG) similar to a Lead I ECG.	Equivalent
ECG duration	30 seconds	30 seconds	Equivalent
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)	Equivalent
Heart Rate	Yes	Yes	Equivalent
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 digital crown 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	Placement of the finger electrode on the top button of the Samsung watch vs. the predicate's digital crown.
Platforms	Wearable: Apple Watch with watch OS Phone: Apple iPhones with iOS	Wearable: Samsung Galaxy Watch running Tizen OS Phone: Samsung Galaxy phones with Android OS	Different hardware and OS for both wearable and phone platforms, both offering similar communications and sensor capabilities and features.
User Interface	• Apple watch screen for initiating spot checks, viewing signal during acquisition (user engagement feature, not diagnosis quality), delivering rhythm classification, and capturing symptoms • Phone screen for viewing and sharing ECG spot check results, viewing	• Samsung wearable screen for initiating spot checks, viewing signal during acquisition (user engagement feature, not diagnosis quality), delivering rhythm classification, and capturing symptoms • Phone screen for viewing and sharing ECG spot check results, viewing	Equivalent

	historic data and PDF report including recorded ECG and algorithmic rhythm classification	historic data and PDF report including recorded ECG and algorithmic rhythm classification	
Algorithms	• ECG Lead I Rhythm Classification for Sinus Rhythm, Atrial Fibrillation, Inconclusive (includes poor recording), High/Low Heart Rate • Heart Rate	• ECG Lead I Rhythm Classification for Sinus Rhythm, Atrial Fibrillation, Inconclusive, Poor Recording (for low quality or other reasons) • Heart Rate	All rhythms classified are the same as the predicate device except: • Predicate device classifies low signal quality as *Inconclusive- Poor Recording* while Samsung classifies it as *Poor Recording*. • Predicate device has a *High/Low Heart Rate* classification, whereas Samsung device outputs *Inconclusive* in this case. Both devices provide Heart Rate.
Rhythm Classification Performance	Atrial Fibrillation Sensitivity: 98.3% Sinus Rhythm Specificity: 99.6%	Atrial Fibrillation Sensitivity: 98.1% Sinus Rhythm Specificity: 100%	Equivalent

Performance Data

The following clinical, usability, and bench testing was conducted with the Samsung Galaxy Watch Active2, showing the SaMD meets predetermined acceptance criteria to demonstrate safety, effectiveness, and substantial equivalence to the previously cleared Apple ECG App device. No new safety issues were found during this testing.

- Clinical validation showing non-inferiority to the predicate in clinical performance in terms of
  - ECG signal quality sufficiency
  - Rhythm classification accuracy
- Human Factors Validation
- IEC 60601-2-47 ECG Database Testing
- Heart Rate Accuracy Bench Testing
- SW Verification Testing

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

- ECG Signal Quality and Lead Detection Bench Testing
- Platform Interface SW Testing (for both platforms)
- Platform Interface HW 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

The Samsung ECG Monitor App was proven to be non-inferior to the predicate in terms of rhythm classification accuracy and ECG signal quality sufficiency. No adverse events were observed.

The study enrolled 544 subjects, among whom 268 were AFib patients, 261 had sinus rhythm (SR), and 15 had other arrhythmias. The ECG App algorithm detection of AFib and SR was compared to cardiologists' read of 12-lead ECG reference strip. Among the recordings where the algorithm output a rhythm classification, AFib was correctly indicated with 98.1% sensitivity (95%CI: 96.3%, 99.9%) and 100% specificity (95% CI: 100%, 100%) in the Samsung ECG Monitor App, while the predicate showed 99.6% sensitivity (95% CI: 98.7%, 100%) and 99.6% specificity (95% CI: 98.8%, 100%) in the comparison study. As a result, the sensitivity and specificity of the Samsung ECG Monitor App were within the pre-determined non-inferiority margin, thus the primary endpoint was met.

The ratio of readings that were deemed inconclusive (or unclassifiable) by the Samsung ECG Monitor App when the truth was either AFib or SR was 2.9% (95% CI: 1.1%, 4.7%) while the predicate was 2.2% (95% CI: 0.7%, 3.7%), which met the non-inferiority margin.

To assess the signal quality of the ECG Monitor App recording, cardiologists' interpretation of the ECG Monitor App strips was compared to the paired reference 12-lead ECG. Cardiologists were able to interpret 98.5% (95% CI: 97.4%, 99.5%) of ECG recordings on the Samsung ECG Monitor App and 99.4% (95% CI: 98.8%, 100%) on the predicate App. The results showed good concordance between the interpretation of the ECG Monitor App strip and the reference 12-lead ECG, 99.4% (95%CI: 98.7%,

100%) on Samsung ECG Monitor App and 99.8% (95%CI: 99.4%, 100%) on the predicate ECG App. Both of the interpretation and agreement met the pre-determined non-inferiority margin.

To further assess the ECG waveform accuracy, a total of 140 subjects (AFib cohort: 70, SR cohort: 70) were randomly selected for fiducial point annotation. Three blinded, independent ECG technicians marked the fiducial points for key ECG features (QRS amplitude, RR interval, QRS duration, PR interval) in comparison between the ECG Monitor App strip and the reference 12-lead ECG. The key ECG features of Samsung ECG Monitor App were all within non-inferiority margin with statistical significance. Thus the secondary endpoints were met.

Conclusion

The Samsung ECG Monitor Application is substantially equivalent to the Apple ECG App (DEN180044). The devices have the same intended use, the same key technological characteristics, and the same signal acquisition capabilities. In a clinical testing, the Samsung ECG Monitor app demonstrated that it is non-inferior to the predicate in quantitative ECG measurement and rhythm analysis accuracy.