January 12, 2023

Garmin International, Inc.
Travis Johnson
Product and Strategy Director, Medical Devices
1200 East 151st Street
Olathe, Kansas 66062

Re: K221774
Trade/Device Name: Garmin ECG App
Regulation Number: 21 CFR 870.2345
Regulation Name: Electrocardiograph Software For Over-The-Counter Use
Regulatory Class: Class II
Product Code: QDA
Dated: December 9, 2022
Received: December 9, 2022

Dear Travis Johnson:

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)*
K221774

Device Name
Garmin ECG App

Indications for Use *(Describe)*
The Garmin ECG app is a software-only, mobile medical application intended for use with compatible Garmin smartwatches to create, record, store, transfer, and display a single-channel electrocardiograph similar to a Lead I ECG. The ECG app determines the presence of atrial fibrillation (AFib) or sinus rhythm (SR) 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 SR, and it is not intended to replace traditional methods of diagnosis or treatment.

The ECG app is not intended for use by people under 22 years old.

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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GARMIN.

K221774 - 510(k) Summary

This summary of 510(k) substantial equivalence information is submitted in accordance with the requirements of 21 C.F.R. § 807.92.

1 Submitter

Applicant	Garmin International, Inc. 1200 East 151st Street Olathe, KS, 66062
Contact Person	Travis Johnson Product and Strategy Director, Medical Devices Phone: 913-440-2624 Email: travis.johnson@garmin.com
Date Prepared:	June 17th, 2022

2 Device Names and Classifications

Subject Device:

Name of Device	Garmin ECG App
Common Name	ECG App
Classification Name	Electrocardiograph Software for Over-the-Counter Use
Regulation Number	21 C.F.R. § 870.2345
Product Code	QDA
Regulatory Class	Class II

Predicate Device:

Predicate Manufacturer	Apple Inc.
Predicate Trade Name	Apple ECG App
Predicate 510(k)	DEN180044

3 Device Description

The Garmin ECG App (ECG App) is a software-only, mobile medical application that has two components: (1) the Watch ECG App for compatible Garmin smartwatches ("Watch" or "Watches"), and (2) the Smartphone ECG App included within Garmin's consumer health and fitness application ecosystem, Garmin Connect. Garmin Connect allows users to store, manage, and share their respective health and fitness data.

The ECG App is intended to create, record, store, transfer, and display a single lead ECG signal similar to a Lead I ECG. The Watch ECG App acquires and analyzes the single lead ECG signal from electrodes built into each Watch and detects the presence of atrial fibrillation (AFib) or normal sinus rhythm (SR) in the adult wearer of the Watch. The Watch ECG App then calculates the average heart rate and displays that value, along with the rhythm classification result, to the

user on the Watch screen. The user may annotate the result by choosing from a provided list of symptoms.

Optionally, and only when directed by the user, the Watch ECG App can securely transmit the result to the Smartphone ECG App for the purposes of storing and viewing a history of ECG App results. The user may also export ECG App results as a PDF for easy sharing.

4 Indications for Use

The Garmin ECG app is a software-only, mobile medical application intended for use with compatible Garmin smartwatches to create, record, store, transfer, and display a single-channel electrocardiograph similar to a Lead I ECG. The ECG app determines the presence of atrial fibrillation (AFib) or sinus rhythm (SR) 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 SR, and it is not intended to replace traditional methods of diagnosis or treatment.

The ECG app is not intended for use by people under 22 years old.

5 Comparison of Predicate and Subject Device Technological Characteristics

The predicate and subject devices have equivalent indications for use. The devices have equivalent technological characteristics and operating principles. Clinical, usability, and bench testing show performance equivalence and raise no new questions of safety or effectiveness. Table 1 provides a detailed comparison of the devices.

Specification	Garmin ECG App (Subject Device)	Apple ECG App – DEN180044 (Predicate Device)
Manufacturer	Garmin International, Inc.	Apple Inc.
Device Classification	Class II	Class II
FDA Product Code	QDA	QDA
Regulation Number	21 C.F.R. § 870.2345	21 C.F.R. § 870.2345
Type of Use	OTC	OTC
Patient population	Adults 22 years or older	Adults 22 years or older

Specification	Garmin ECG App (Subject Device)	Apple ECG App – DEN180044 (Predicate Device)
Indications for Use	The Garmin ECG app is a software-only, mobile medical application intended for use with compatible Garmin smartwatches to create, record, store, transfer, and display a single-channel electrocardiograph similar to a Lead I ECG. The ECG app determines the presence of atrial fibrillation (AFib) or sinus rhythm (SR) 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 SR, and it is 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 Apple 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 (AF) 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 AF 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.
Principle of Operation	The ECG app acquires the electrical potential between electrodes built into compatible Garmin smartwatches. After acquisition, the ECG app analyzes the signal, generates an ECG waveform, and classifies the rhythm to display to the user.	The ECG app acquires the electrical potential difference between electrodes built into the Apple Watch. After acquisition, the ECG app analyzes the signal, generates an ECG waveform, and classifies the rhythm to display to the user.
Mechanism of Action	While at rest, users complete circuit with skin contact from two fingers on smartwatch bezel while wearing the smartwatch on their wrist.	While at rest, users completes circuit with skin contact from a single finger on a button on the side of device.
Smartwatch 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 bezel where the fingers are 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 digital crown where the finger is placed.

Specification	Garmin ECG App (Subject Device)	Apple ECG App – DEN180044 (Predicate Device)
Anatomical Sites	Left hand fingers to right wrist or vice versa on a consumer grade electronic.	Left hand fingers to right wrist or vice versa on a consumer grade electronic.
ECG Channels	A single channel electrocardiogram similar to a Lead I ECG.	A single channel electrocardiogram similar to a Lead I ECG.
Rhythm Classification Results	• Low Heart Rate (< 50 bpm) • Sinus Rhythm (50-100 bpm) • Atrial Fibrillation (50-120 bpm) • Inconclusive (Other) • Inconclusive - Poor Recording • High Heart Rate (> 120 bpm)	• Low Heart Rate (< 50 bpm) • Sinus Rhythm (50-100 bpm) • Atrial Fibrillation (50-120 bpm) • Inconclusive (Other) • Inconclusive - Poor Recording • High Heart Rate (> 120 bpm)
Platforms	Watch ECG App: Compatible Garmin Smartwatches running GarminOS Smartphone ECG App: Garmin Connect mobile application for Android and iOS smartphones	Watch ECG App: Compatible Apple Watch models running WatchOS Smartphone ECG App: Apple Health mobile application for iOS smartphones (iPhones)
Data storage	ECG data stored locally on smartwatch (Watch ECG App) until transmission to Smartphone ECG App.	ECG data stored locally on smartwatch (Watch ECG App) until transmission to Smartphone ECG App.
User Interface	Garmin watch screen for taking an ECG recording, viewing signal during acquisition (not diagnosis quality), providing rhythm classification, viewing average heart rate, and entering symptoms. Smartphone screen for: 1) ECG app activation; and 2) Secondary display of ECG app results and export of results as a PDF report that includes the ECG waveform and rhythm classification.	Apple watch screen for taking an ECG recording, viewing signal during acquisition (not diagnosis quality), providing rhythm classification, viewing average heart rate, and entering symptoms. Smartphone screen for: 1) ECG app activation; and 2) Secondary display of ECG app results and export of results as a PDF report that includes the ECG waveform and rhythm classification.
ECG Waveform Display	Similar to a Lead I ECG displayed as a PDF on the Smartphone ECG App.	Similar to a Lead I ECG displayed as a PDF on the Smartphone ECG App.
Clinical Performance	Atrial Fibrillation Sensitivity: 99.5% Sinus Rhythm Specificity: 100%	Atrial Fibrillation Sensitivity: 98.3% Sinus Rhythm Specificity: 99.6%

Table 1 – Comparison of Subject and Predicate Device Technological Characteristics

6 Performance Data

Garmin conducted all the necessary non-clinical and clinical performance testing on the ECG App to support a determination of substantial equivalence to the predicate device.

6.1 Non-Clinical Testing

Software Verification Testing
Garmin conducted software verification testing and provided documentation as recommended by FDA Guidance, "Content of Premarket Submissions for Software Contained in Medical Devices."

Human Factors Validation
Garmin conducted a human factors validation study to verify the ECG App is substantially equivalent for the intended users, uses, and use environments. Results demonstrated that users can correctly use the device by solely reading the device labeling, correctly interpret the device output, and understand when to seek medical care. This testing satisfies the FDA special controls established for the predicate device.

ECG Database Testing
In compliance with special controls established under 21 C.F.R. § 870.2345, Garmin conducted database testing using a previously adjudicated dataset as per ANSI/AAMI EC57:2012.

Platform Compliance
- Input Signal Quality Testing per IEC 60601-2-47:2012 Medical Electrical Equipment – Ambulatory ECG Systems
- Applicable RF and EMC requirements under ETSI EN 301 489-1 V2.2.3 (2019-11), 301 489-3 V2.1.1 (2019-03), and 301 489-17 V3.2.4 (2020-09) and FCC Part 15
- Thermal and Electrical safety requirements under IEC 62368-1:2014

6.2 Clinical Testing

The ECG App's ability to accurately detect AFib and sinus rhythms in an ECG recording was validated in a clinical study involving approximately 590 subjects. ECG app rhythm classifications were compared to 12-Lead ECG rhythm classifications performed by board-certified cardiologists. The ECG App was able to correctly identify AFib 99.5% of the time and correctly identify SR 100% of the time in the recordings that could be classified.

During this study, the ECG App determined 11.5% of recordings were inconclusive, including those which were deemed of too poor quality for analysis. When including these inconclusive recordings, the probability that the ECG App would return an AFib result for a subject in AFib was 86.5%, and 91.1% for a SR result for subjects in sinus rhythm. Real-world performance may have a higher rate of inconclusive and poor recording results.

Accuracy of the ECG App PDF reports was assessed by comparing to a simultaneously recorded standard Lead I ECG. Key characteristics of the ECG waveforms such as PR and RR intervals, QRS duration, location, and amplitude, and P wave presence and amplitude were compared and found to be statistically equivalent within an acceptable margin of error. Comparison of the board-certified cardiologists' rhythm classifications of simultaneously recorded 12-Lead ECG and ECG App recordings had 96% agreement. No adverse events were observed during the clinical study. The results of the clinical study demonstrated substantial equivalence with the predicate device.

7 Statement of Substantial Equivalence

The Garmin ECG App has the same indications for use and similar technological characteristics as its predicate Apple ECG app. The Garmin ECG App was assessed and evaluated through extensive non-clinical and clinical performance testing. The testing results demonstrate that the minor differences between the subject and predicate device do not raise new questions of safety and effectiveness and support a substantial equivalence determination. The Garmin ECG App is substantially equivalent to the Apple ECG app.