October 8, 2020

Apple Inc.
Luke Olson
Regulatory Affairs Associate
One Apple Park Way
Cupertino, California 94015

Re: K201525
    Trade/Device Name: ECG 2.0 App
    Regulation Number: 21 CFR 870.2345
    Regulation Name: Electrocardiograph Software for Over-The-Counter Use
    Regulatory Class: Class II
    Product Code: QDA
    Dated: September 8, 2020
    Received: September 9, 2020

Dear Luke Olson:

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 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: 06/30/2023

See PRA Statement below.

510(k) Number *(if known)*
K201525

Device Name
ECG 2.0 App

Indications for Use *(Describe)*
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), sinus rhythm, and high heart rate (no detected AF with heart rate 100-150 bpm) 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 sinus rhythm and 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.

Section 5

510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR §807.92:

5.1 Submitter

Applicant	Apple Inc. One Apple Park Way Cupertino, CA 95014
Submission Correspondent	Luke Olson Regulatory Affairs Associate Phone: (408) 608-2001 Email: luke_olson@apple.com
Contact	David Amor Sr Manager, Quality and Regulatory Affairs Phone: (786) 546-1806 Email: damor@apple.com
Date Prepared	October 6, 2020

5.2 Device Names and Classifications

Subject Device:

Name of Device	ECG App (2.0)
Classification Name	Electrocardiograph Software For Over-The-Counter Use, 21 CFR 870.2345
Regulatory Class	Class II
Product Code	QDA
510(k) Review Pannel	Cardiovascular

Predicate Device:

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

5.3 Device Description

The ECG 2.0 app comprises a pair of mobile medical apps - one on Apple Watch and the other on the iPhone.

The ECG Watch app analyzes data collected by the integrated electrical sensors on a compatible Apple Watch to generate an ECG waveform similar to a Lead I, calculate average heart rate, and provide a rhythm classification to the user for a given 30 second session. When a user opens the ECG Watch app while wearing the Watch on one wrist, and places the finger of the opposite hand on the digital crown, they are completing the circuit across the heart which begins a recording session.

Once the recording session is complete, the ECG Watch app performs signal processing, feature extraction and rhythm classification to generate a session result.

The resulting classification and average heart rate for the session, along with educational information, will be displayed to the user within the ECG Watch app.

The ECG iPhone app contains the on-boarding and educational materials that a user must review prior to taking an ECG reading. The ECG iPhone app is included in the Health App, which allows users to store, manage, and share health and fitness data, and comes pre-installed on every iPhone. The ECG 2.0 app expands the classifiable heart range, introduces new classification results, and introduces minor, non-user-facing algorithm updates. These changes will be reflected in both the Apple Watch app, and also on the corresponding iPhone app within the Health App.

5.4 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), sinus rhythm, and high heart rate (no detected AF with heart rate 100-150 bpm) 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 sinus rhythm and 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.

5.5 Comparison with the Predicate Device

Item	Subject Device	Predicate Device
	ECG 2.0 App	**ECG App**
Manufacturer	Apple Inc.	Apple Inc.
Submission Reference	K201525	DEN180044

Item	Subject Device	Predicate Device
	ECG 2.0 App	**ECG App**
Intended Use	An electrocardiograph software device for over-the-counter use creates, analyzes, and displays electrocardiograph data, and can provide information for identifying cardiac arrhythmias. This device is not intended to provide a diagnosis.	An electrocardiograph software device for over-the-counter use creates, analyzes, and displays electrocardiograph data, and can provide information for identifying cardiac arrhythmias. This device is not intended to provide a diagnosis.
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), sinus rhythm, and high heart rate (no detected AF with heart rate 100-150 bpm) 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 sinus rhythm and 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 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 2.0 app acquires platform sensor data from Apple Watch. After acquisition, the ECG 2.0 app algorithms process and classify the signal and display the classification to the user.	The ECG app acquires platform sensor data from Apple Watch. After acquisition, the ECG app algorithms process and classify the signal and display the classification to the user.

Item	Subject Device	Predicate Device
	ECG 2.0 App	**ECG App**
ECG Session Classification Results	- Low Heart Rate (< 50 bpm) - Sinus Rhythm (50-99 bpm) - High Heart Rate (No AFib) (100-150 bpm) - Atrial Fibrillation (50-99 bpm) - Artial Fibrillation High Heart Rate (100-150 bpm) - Inconclusive - Poor Recording - High Heart Rate (> 150 bpm)	- Low Heart Rate (< 50 bpm) - Sinus Rhythm (50-100 bpm) - Atrial Fibrillation (50-120 bpm) - Inconclusive - Inconclusive - Poor Recording - High Heart Rate (> 120 bpm)
Clinical Application	The ECG 2.0 app is intended to supplement rhythm classification for the purposes of discriminating Afib from normal rhythms. The device is not intended to replace traditional methods or diagnosis.	The ECG app is intended to supplement rhythm classification for the purposes of discriminating Afib from normal rhythms. The device is not intended to replace traditional methods or diagnosis.
Compatibility with Intended Platforms	iOS version 14.0 WatchOS version 7.0 Apple Watch Series 4, Apple Watch Series 5 iPhone 6s - iPhone 11 models	iOS 12.1.1 - 14.0.1 WatchOS 5.1.2 - 7.0.1 Apple Watch Series 4, Apple Watch Series 5, Apple Watch Series 6 iPhone 5s - iPhone 11 models

Performance Data

Apple conducted all necessary clinical and non-clinical performance testing on the ECG 2.0 app to support a determination of substantial equivalence to the predicate device.

Non-Clinical Testing Summary

Apple conducted the necessary non-clinical testing on the ECG 2.0 app with passing results supporting a determination of substantial equivalence. Non-clinical testing conducted included the following:

- Software Verification Testing
  Software verification testing was conducted and documentation was provided as recommended by FDA's Guidance for Industry and Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate" level of concern.

- Human Factors Validation

Apple conducted a human factors validation study to verify the ECG 2.0 app is safe and effective for the intended users, uses, and use environments.

- ECG Database Testing per EC57

  In compliance with special controls established under 21 CFR 870.2345, Apple conducted database testing using a previously adjudicated dataset.
- Platform compliance with the following standards:
    - Thermal safety requirements under IEC-60950
    - Applicable RF and EMC requirements under EN 301-489-17 v 3.2.0 and FCC Part 15

Clinical Testing Summary

The ECG app's ability to accurately classify an ECG recording into AFib and sinus rhythm was extensively tested in a pivotal, prospective, multi-center clinical trial of approximately 546 subjects - 305 were enrolled in the Atrial Fibrillation cohort, 241 were enrolled in the normal sinus rhythm cohort. The mean age of enrolled subjects was 58. Rhythm classification of a 12-lead ECG by a cardiologist was compared to the rhythm classification of a simultaneously collected ECG from the ECG 2.0 app. The ECG app demonstrated 98.5% sensitivity in classifying AFib (HR 50-150 bpm) and 99.3% specificity in classifying sinus rhythm (HR 50-150 bpm) in classifiable recordings. Subgroup analysis indicated sensitivity ranged from 98.3% - 100% across all age groups, and specificity ranged from 99.0% - 100.0%. Specificity and sensitivity estimates were slightly higher for females (99.6% and 99.2%, respectively) than for males (99.1% and 98.3%, respectively). Specificity and sensitivity estimates for subjects identifying as White were 99.1% and 98.5%, respectively, and were 100.0% each for subjects identifying as Asian, Black or African American, and Other.

In addition, The morphology of the waveform was also tested in this clinical trial by visual assessment of the PQRST wave and R wave amplitude in comparison to a reference. The ECG 2.0 app produced a visually acceptable PQRST waveform with a pass rating of 100% compared to the reference waveform. Additionally, the total pass rating for R-wave amplitude assessment was 97.2% compared to the reference.

Conclusion

The Apple ECG 2.0 app is substantially equivalent to the Apple ECG app as they are identical with respect to intended use and share very similar technological characteristics. The differences in technological characteristics were assessed and testing through extensive non-clinical and clinical testing. The testing results demonstrate that the differences between the subject and predicate device do not raise new questions of safety and effectiveness. The Apple ECG 2.0 app is substantially equivalent to the Apple ECG app.