September 11, 2020

Fitbit, Inc.
Shruti Rajagopalan
Medical Regulatory Compliance Manager
199 Fremont Street
San Francisco, California 94105

Re: K200948
Trade/Device Name: Fitbit 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: August 10, 2020
Received: August 11, 2020

Dear Shruti Rajagopalan:

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
Acting 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)*
K200948

Device Name
Fitbit ECG App

Indications for Use *(Describe)*

The Fitbit ECG App is a software-only mobile medical application intended for use with Fitbit wrist wearable devices to create, record, store, transfer, and display a single channel electrocardiogram (ECG) qualitatively similar to a Lead I ECG. The Fitbit ECG App determines the presence of atrial fibrillation (AFib) or sinus rhythm on a classifiable waveform. The AFib detection feature is not recommended for users with other known arrhythmias.

The Fitbit ECG App is intended for over-the-counter (OTC) use. The ECG data displayed by the Fitbit 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 Fitbit 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

Submitter	Fitbit, Inc 199 Fremont Ave, 14th Floor, San Francisco, CA 94105
Contact Person:	Shruti Rajagopalan
Phone:	408-242-2515
Email:	shruti.rajagopalan@fitbit.com
Date Prepared:	09 September 2020
Name of Device:	Fitbit ECG App
Common or Usual Name:	Heart Rhythm Assessment, ECG
Regulation Number:	21 CFR§870.2345
Regulation Name:	Electrocardiograph software for over-the-counter use
Regulatory Class:	Class II
Product Code:	QDA
Submission Number	K200948

Predicate Device Information:

Name of Device:	ECG App
Manufacturer:	Apple, Inc.
De Novo Petition Number:	DEN180044

Indications for Use

The Fitbit ECG App is a software-only mobile medical application intended for use with Fitbit wrist-wearable devices to create, record, store, transfer, and display a single channel

electrocardiogram (ECG) qualitatively similar to a Lead I ECG. The Fitbit ECG App determines the presence of atrial fibrillation (AFib) or sinus rhythm on a classifiable waveform. The AF detection function is not recommended for users with other known arrhythmias.

The Fitbit ECG App is intended for over-the-counter (OTC) use. The ECG data displayed by the Fitbit 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 Fitbit ECG App is not intended for use by people under 22 years old.

Device Description

The Fitbit ECG App is a software-only medical device used to create, record, display, store and analyze a single channel ECG. The Fitbit ECG App consists of a Device application ("Device app") on a consumer Fitbit wrist-worn product and a mobile application tile ("mobile app") on Fitbit's consumer mobile application. The Device app uses data from electrical sensors on a consumer Fitbit wrist-worn product to create and record an ECG. The algorithm on the Device app analyzes a 30 second recording of the ECG and provides results to the user. Users are able to view their past results as well as a pdf report of the waveform similar to a Lead I ECG on the mobile app.

Summary of Technological Characteristics

Table 1. Subject and Predicate Device Comparison

	Subject Device **Fitbit ECG App** **K200948**	**Predicate Device** **Apple ECG app** **DEN180044**
Indications for Use	The Fitbit ECG App is a software-only mobile medical application intended for use with Fitbit wrist-wearable devices to create, record, store, transfer, and display a single channel electrocardiogram (ECG) qualitatively similar to a Lead I ECG. The Fitbit ECG App determines the presence of atrial	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.

	fibrillation (AFib) or sinus rhythm on a classifiable waveform. The AFib detection feature is not recommended for users with other known arrhythmias. The Fitbit ECG App is intended for over-the-counter (OTC) use. The ECG data displayed by the Fitbit 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 Fitbit ECG App is not intended for use by people under 22 years old.	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.
Mechanism of Operation	Uses input from consumer wrist-worn devices to detect the electrical potential differences between the electrical sensors and generate an ECG waveform.	Uses input from consumer wrist-worn devices to detect electrical potential differences between the electrodes and the crown and generate an ECG waveform.
Device Classification	Class II	Class II
FDA Product Code and Regulatory Classification	QDA 21 CFR 870.2345	QDA 21 CFR 870.2345

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.
Patient population	Individuals (22 years or older)	Individuals (22 years or older)
Data storage	ECG data stored locally on wrist-worn device until transmission to a server.	ECG data stored locally on wrist-worn device until transmission to a server.
Prescription/OTC	OTC	OTC
ECG Channels	Single Channel, Lead I	Single Channel, Lead I
User Interface	Device app and Mobile app	Device app and Mobile app
Use Method	Record a 30 second ECG on the wrist-worn device and receive results determining the presence of Atrial Fibrillation or Normal Sinus Rhythm.	Record a 30 second ECG on the wrist-worn device and receive results determining the presence of Atrial Fibrillation or Normal Sinus Rhythm.
Results of the algorithm	Atrial Fibrillation Normal Sinus Rhythm Inconclusive	Atrial Fibrillation Normal Sinus Rhythm Inconclusive
ECG Waveform Display	Qualitatively similar to a Lead I ECG waveform displayed as a pdf on the Mobile app	Similar to a Lead I ECG displayed as a pdf on the Mobile app

Non-clinical Testing

All necessary performance testing was conducted on the Fitbit ECG App to support a determination of substantial equivalence to the predicate device. This testing included testing of input signal quality as per IEC 60601-2-47:2012 Medical Electrical Equipment - Ambulatory Electrocardiographic Systems. Testing was conducted using appropriate databases from ANSI/AAMI EC57:2012.

Human Factors Testing

Human Factors testing was performed to demonstrate that the user can correctly use the device by solely reading the device labeling and also correctly interpret the device output and understand when to seek medical care. This testing satisfies the special control requirements of the predicate device and provides evidence of substantial equivalence.

Clinical Testing

Clinical testing was performed similar to the predicate device. 475 subjects, with and without a known diagnosis of AFib, were recruited to participate across 9 US sites. Eligible subjects underwent a 10-second screening using a 12-lead ECG. Subjects with a known history of AFib were screened for AFib by a single qualified physician and assigned to the AFib cohort. Subjects without a known history of AFib were screened for NSR and assigned to the NSR cohort. Subsequently, subjects underwent a simultaneous 30-second 12-lead ECG and Fitbit ECG App test. The Fitbit ECG App software algorithm was able to detect AF with the sensitivity and specificity of 98.7% and 100%, respectively. The Fitbit ECG App's single lead waveform was deemed morphologically equivalent to the Lead I of a 12-Lead ECG waveform overall for 95.0% of AF and SR tracings reviewed qualitatively. The qualitative and quantitative results of the clinical study demonstrated substantial equivalence.

Conclusions

The Fitbit ECG App is similar in technological characteristics and has the same intended use as the Apple ECG app. Differences in technological characteristics have been evaluated through performance testing including the special controls requirements of the predicate which has shown that the minor technological differences between the Fitbit ECG App and the predicate device raise no new issues of safety or effectiveness. Bench and clinical data demonstrate that the Fitbit ECG App is substantially equivalent to the Apple ECG App.