April 8, 2022

Fitbit Inc
Randy Parry
Senior Regulatory Affairs Specialist
199 Fremont Street 14th Floor
San Francisco, California 94105

Re: K212372
Trade/Device Name: Fitbit Irregular Rhythm Notifications
Regulation Number: 21 CFR 870.2790
Regulation Name: Photoplethysmograph Analysis Software For Over-The-Counter Use
Regulatory Class: Class II
Product Code: QDB
Dated: March 8, 2022
Received: March 9, 2022

Dear Randy Parry:

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,

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)*
K212372

Device Name

Fitbit Irregular Rhythm Notifications

Indications for Use *(Describe)*

The Fitbit Irregular Rhythm Notifications is a software-only mobile medical application that is intended to be used with compatible consumer wrist-worn products to analyze pulse rate data to identify episodes of irregular heart rhythms suggestive of atrial fibrillation (AFib) and provide a notification to the user.

The Fitbit Irregular Rhythm Notifications is intended for over-the-counter (OTC) use. It 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 Fitbit Irregular Rhythm Notifications is intended to opportunistically surface a notification of possible AFib when sufficient data are available for analysis.

These data are only captured when the user is still. Along with the user's risk factors, the Fitbit Irregular Rhythm Notifications can be used to supplement the decision for AFib screening. The Fitbit Irregular Rhythm Notifications is not intended to replace traditional methods of diagnosis or treatment.

The Fitbit Irregular Rhythm Notifications has not been tested for and is not intended for use in people under 22 years of age. It is also not intended for use in individuals previously diagnosed with AFib.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) X Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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VII. 510(K) Summary

1. Submitter Information:

Fitbit LLC
199 Fremont Street, 14th Floor
San Francisco, CA 94105

Contact Person: Randy Parry
Phone: (415) 985-4778
Email: parran@google.com
Date Prepared: March 8, 2022

2. Subject Device Information

Name of Device: Fitbit Irregular Rhythm Notifications
Common or Usual Name: Irregular Rhythm Analysis Software
Classification Name: Photoplethysmograph Analysis Software For Over-The-Counter Use
Regulatory Class: Class II
Product Code: QDB - 21 CFR 870.2790

3. Predicate Device

Apple Inc., Irregular Rhythm Notification Feature (DEN180042)

4. Indications for Use

The Fitbit Irregular Rhythm Notifications is a software-only mobile medical application that is intended to be used with compatible consumer wrist-worn products to analyze pulse rate data to identify episodes of irregular heart rhythms suggestive of atrial fibrillation (AFib) and provide a notification to the user.

The Fitbit Irregular Rhythm Notifications is intended for over-the-counter (OTC) use. It 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 Fitbit Irregular Rhythm Notifications is intended to opportunistically surface a notification of possible AFib when sufficient data are available for analysis.

These data are only captured when the user is still. Along with the user's risk factors, the Fitbit Irregular Rhythm Notifications can be used to supplement the decision for AFib screening. The Fitbit Irregular Rhythm Notifications is not intended to replace traditional methods of diagnosis or treatment.

The Fitbit Irregular Rhythm Notifications has not been tested for and is not intended for use in people under 22 years of age. It is also not intended for use in individuals previously diagnosed with AFib.

5. Device Description

Intended Use

The Fitbit Irregular Rhythm Notifications feature is a software as a medical device (SaMD). The Fitbit Irregular Rhythm Notifications feature analyzes pulse rate data to identify heart rhythms that are consistent with atrial fibrillation (AFib) and if identified, provide a notification to the user.

Technological Characteristics

The Fitbit Irregular Rhythm Notifications consists of an algorithm that classifies pulse rate data, and a mobile application run within the Fitbit app that serves as the user interface (UI) and device display.

The Fitbit Irregular Rhythm Notifications leverages pulse rate data collected from compatible commercially available, general purpose wrist-worn products (e.g., smartwatch or fitness tracker). Photoplethysmograph (PPG) sensors consist of light-emitting diodes (LED) and photodiodes that detect changes in blood flow of a user's vasculature at any given moment. When the heart beats, it sends a pressure wave through the vasculature causing a blood flow increase. By monitoring the fluctuations the consumer wrist-worn products can measure pulse rate data. When the user is still the sensor detects when individual pulses reach the periphery (i.e., wrist) and measures beat-to-beat intervals.

If the analyzed data are consistent with signs of atrial fibrillation, a notification indicating that a heart rhythm showing signs suggestive of AFib will be displayed to the user. The Fitbit Irregular Rhythm Notifications will only surface a notification of a heart rhythm showing signs of AFib once in a 24-hour period.

The Fitbit Irregular Rhythm Notifications mobile app functions within the Fitbit consumer application and is run on a compatible, user-provided general purpose mobile computing product (e.g., smartphone or tablet). The Fitbit Irregular Rhythm Notifications mobile app serves as the display/user interface for the Fitbit Irregular Rhythm Notifications.

Summary of Technological Characteristics and Substantial Equivalence

Table 7.1 Summary of Technological Characteristics and Substantial Equivalence

	Subject Device **Fitbit Irregular Rhythm Notifications**	**Predicate Device** **Apple - Irregular Rhythm Notification**
Intended Use	Analyze pulse rate gathered from PPG pulse rate data to identify episodes of irregular heart rhythms suggestive of atrial fibrillation (AFib) and provide a notification to the user.	Analyze pulse rate gathered from PPG pulse rate data to identify episodes of irregular heart rhythms suggestive of atrial fibrillation (AFib) and provide a notification to the user.

Indications for Use	The Fitbit Irregular Rhythm Notifications is a software-only mobile medical application that is intended to be used with compatible consumer wrist-worn products to analyze pulse rate data to identify episodes of irregular heart rhythms suggestive of atrial fibrillation (AFib) and provide a notification to the user. The Fitbit Irregular Rhythm Notifications is intended for over-the-counter (OTC) use. It 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 Fitbit Irregular Rhythm Notifications is intended to opportunistically surface a notification of possible AFib when sufficient data are available for analysis. These data are only captured when the user is still. Along with the user's risk factors, the Fitbit Irregular Rhythm Notifications can be used to supplement the decision for AFib screening. The Fitbit Irregular Rhythm Notifications is not intended to replace traditional methods of diagnosis or treatment. The Fitbit Irregular Rhythm Notifications has not been tested for and is not intended for use in people under 22 years of age. It is also not intended for use in individuals previously diagnosed with AFib.	The Irregular Rhythm Notification Feature is a software-only mobile medical application that is intended to be used with the Apple Watch. The feature analyzes pulse rate data to identify episodes of irregular heart rhythms suggestive of atrial fibrillation (AFib) and provides a notification to the user. The feature is intended for over-the-counter (OTC) use. It 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 surface a notification of possible AFib when sufficient data are available for analysis. These data are only captured when the user is still. Along with the user's risk factors, the feature can be used to supplement the decision for AFib screening. The feature is not intended to replace traditional methods of diagnosis or treatment. The feature has not been tested for and is not intended for use in people under 22 years of age. It is also not intended for use in individuals previously diagnosed with AFib.
Mechanism of Operation	Software-only mobile medical application that uses inputs from compatible consumer wrist-worn PPG sensors to analyze pulse rate data to identify episodes of irregular heart rhythms suggestive of AFib.	Software-only mobile medical application that uses inputs from wrist-worn Apple Watch PPG sensors to analyze pulse rate data to identify episodes of irregular heart rhythms suggestive of AFib.
Device Classification	Class II	Class II

FDA Product Code and Regulatory Classification	QDB - 870.2790 Photoplethysmograph analysis software for over-the-counter use	QDB - 870.2790 Photoplethysmograph analysis software for over-the-counter use
Anatomical Site	Wrist-worn compatible consumer product with PPG sensors.	Wrist-worn Apple Watch with PPG Sensors
Patient Population	Individuals (22 years or older)	Individuals (22 years or older)
Data storage	Pulse rate data stored locally on wrist-worn product until transmission to a server.	Pulse rate data stored locally on wrist-worn product until transmission to a server.
Prescription/OTC	OTC	OTC
User interface	Mobile application run within the Fitbit consumer app.	Mobile application run within the iPhone Apple Health App.
Use Method	Collects and analyzes tachograms during periods of stillness or sleep using input from PPG sensors.	Collects and analyzes a one-minute tachogram approximately every 4 hours using input from PPG sensors.
Limiting Factors	Motion, hand and finger movements, dark tattoos on the wrist, inadequate blood flow. Does not continuously monitor for signs of AFib. A lack of notification does not indicate an absence of AFib.	Motion, hand and finger movements, dark tattoos on the wrist, inadequate blood flow. Does not continuously monitor for signs of AFib. A lack of notification does not indicate an absence of AFib.
Results of algorithm	Tachograms are classified as having signs of AFib, no signs of AFib or unanalyzable. Notification of a heart rate that shows signs consistent with atrial fibrillation.	Tachograms are classified as either irregular rhythm or not AFib. Notification of a heart rate that shows signs consistent with atrial fibrillation.
History of events	History of events consistent with AFib viewable in the mobile application.	History of events consistent with AFib viewable in the mobile application.
Compatible devices	Consumer wrist-worn products with PPG sensors (e.g., smartwatch or fitness tracker) that have been qualified for use with Fitbit Irregular Heart Rhythm Notifications Fitbit Sense Fitbit Versa Fitbit Versa Lite Fitbit Inspire 2	Apple Watch with PPG sensors (series 1 and later).

	Fitbit Charge 4	

6. Performance Data

Testing verifying the performance requirements of the subject device was conducted and is included in this premarket notification, the results of which support substantial equivalence. A summary of the testing is included below:

Bench Testing/Non-Clinical Testing

The Fitbit Irregular Rhythm Notifications utilizes signals derived from compatible consumer grade wrist-worn products. The wrist-worn products are qualified for use with the software to ensure that the data provided meet signal attribute and quality requirements necessary for heart rhythm analysis and to detect adequate PPG signal quality. Bench testing includes: product signal acquisition testing, aggressor testing for known challenge conditions potentially impacting the quality of PPG signal acquisition, and accuracy assessment of the inputs to the Fitbit Irregular Rhythm Notifications that are derived from the wrist-worn products. Qualification testing is repeated for all qualified wrist-wearable products. The algorithm is tested to ensure that it accepts and rejects data correctly and that it correctly analyzes the input data.

Software Testing Summary

The Fitbit Irregular Rhythm Notifications presents a “moderate” level of concern (LOC) as defined in FDA’s Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 11, 2005) (Guidance Document). The software components consist of the Irregular Rhythm Notifications algorithm, which resides/runs on Fitbit servers, and the mobile app used for on-boarding, education and display of notification results. Testing supports that the algorithm analyzes pulse rate data and classifies it as having signs of AFib, having no signs of AFib, or unanalyzable. Testing of the mobile application demonstrates that the Fitbit Irregular Rhythm Notifications mobile application adequately surfaces on-boarding/educational information, generates user notifications when the feature identifies an irregular rhythm suggestive of AFib, and facilitates viewing of that notification.

Human Factors Testing Summary

A human factors study was designed to evaluate the critical and noncritical tasks associated with the use of the device.
Human Factors Usability testing was performed using a simulated version of the Fitbit Irregular Rhythm Notifications mobile app, representative of the final app. There were a total of 30 subjects distributed into two (2) user groups:

- 15 active interest participants – adult laypeople (22 years and older) with active interest in AFib, defined as individuals who:
    - Have concern regarding AFib and have an active interest in monitoring potential AFib, and

    - Would use the app due to high interest
- 15 passive interest participants – adult laypeople (22 years and older) with passive interest in AFib, defined as individuals who:
    - Do not have concern regarding AFib and do not have an active interest in monitoring potential AFib, and
    - Might use the app due to casual or passing interest.

The Human Factors Validation demonstrated that the Fitbit Irregular Rhythm Notifications meets the special control requirements for human factors and usability testing that demonstrates the following:

a. The user can correctly use the device based solely on reading the device labeling.

b. The user can correctly interpret the device output and understand when to seek medical care.

Testing was also performed to assess consumers' ability to correctly self-select if the Irregular Rhythm Notifications app is intended for them. This testing involved 33 subjects, including both users for whom the app is intended, as well as persons outside the app's intended use population. The testing concluded that users can adequately self-select if the device is intended for them.

Clinical Testing Summary

A clinical study was conducted on the Fitbit Irregular Rhythm Notifications algorithm. This study recruited subjects from Fitbit's U.S. user population, inviting them to participate in a study. Upon consent, users had their PPG data analyzed for signs consistent with AFib by the algorithm. The users whose data showed signs of AFib were then instructed to schedule a telehealth visit with a clinician. Subjects still meeting the inclusion criteria were then provided with an ECG patch and directed to simultaneously wear both the ECG patch and their Fitbit wrist-wearable, PPG-equipped product for seven (7) consecutive days and nights. Data gathered from the ECG patch was analyzed by medical professionals to determine whether signs of AFib were present and was compared to the corresponding Fitbit algorithm output.

In the 225 subjects who received a positive algorithm detection while wearing the ECG patch, the algorithm's positive predictive value (PPV) was 98.2% (97.5% LCB: 96.4%) and supports that the subject Fitbit Irregular Rhythm Notifications is substantially equivalent to the predicate, Apple Inc. Irregular Rhythm Notification. A total of 2,094 adverse events were reported for 1,275 subjects. No adverse events reported were related to the Fitbit Irregular Rhythm Notifications software. Most adverse events were identified as possible risks in the study protocol, namely skin irritation from wearing a Fitbit or ECG patch, stress or anxiety from participating in the study, new information or diagnosis as the result of being in the study and combinations of multiple events.

7. Conclusion

The Fitbit Irregular Heart Rhythm Notifications is as safe and effective as the Apple - Irregular Rhythm Notification. Additionally, minor technological differences between the Fitbit

feature and its predicate do not raise different questions of safety or effectiveness compared to the predicate. The Fitbit Irregular Heart Rhythm Notifications has the same intended use, indications for use, underlying technological characteristics, and similar principles of operation as the predicate device. Based on the similarities and performance testing, the subject device, Fitbit Irregular Rhythm Notifications, is substantially equivalent to the predicate device.