February 25, 2025

Fitbit
Dinesh Puppala
Regulatory Affairs Lead
215 Fremont Street
San Francisco, California 94105

Re: K242967
Trade/Device Name: Loss of Pulse Detection
Regulation Number: 21 CFR 870.2790
Regulation Name: Photoplethysmograph Analysis Software For Over-The-Counter Use
Regulatory Class: Class II
Product Code: SDY
Dated: September 25, 2024
Received: September 26, 2024

Dear Dinesh Puppala:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 W. Shih -S

Jennifer 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242967

Device Name

Loss of Pulse Detection

Indications for Use *(Describe)*

Loss of Pulse Detection is a software-only mobile medical application that is intended to be used with compatible consumer wrist-worn products to analyze pulse data to identify loss of pulse events and provide audio, visual, and haptic alerts to the user.

If the user remains unresponsive to these alerts, Loss of Pulse Detection will attempt to prompt a call to emergency services through the user's connected compatible hardware, such as a smartphone or smartwatch.

Loss of Pulse Detection is intended for over-the-counter (OTC) use. It is not intended to provide a notification on every loss of pulse event and the absence of an alert is not intended to indicate that no such event has occurred; rather the Loss of Pulse Detection is intended to opportunistically surface an alert of possible loss of pulsatility when sufficient data are available for analysis.

These data are only captured when the user is still. Loss of Pulse Detection is not intended to replace traditional methods of diagnosis, treatment, or monitoring.

Loss of Pulse Detection 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 a high risk for sudden cardiac death such as those with coronary artery disease, cardiomyopathy and/or unexplained syncope/fainting.

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.

510(K) Summary

1. **Submitter Information:**

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Contact Person:
Dinesh Puppala
Regulatory Affairs Lead
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Email: puppalad@google.com
Date Prepared: Feb 19, 2025

2. **Subject Device Information**

Name of Device: Loss of Pulse Detection
Common or Usual Name: Loss of Pulse Detection
Classification Name: Photoplethysmograph Analysis Software For Over-The-Counter Use
Regulatory Class: Class II
Product Code: SDY - 21 CFR 870.2790

3. **Predicate Device**

Fitbit Irregular Rhythm Notifications
(K212372)

4. **Indications for Use**

Loss of Pulse Detection is a software-only mobile medical application that is intended to be used with compatible consumer wrist-worn products to analyze pulse data to identify loss of pulse events and provide audio, visual, and haptic alerts to the user.

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These data are only captured when the user is still. Loss of Pulse Detection is not intended to replace traditional methods of diagnosis, treatment, or monitoring.

Loss of Pulse Detection 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 a high risk for sudden cardiac death such as those with coronary artery disease, cardiomyopathy and/or unexplained syncope/fainting.

5. Device Description

Intended Use

Photoplethysmograph analysis software for over-the-counter use. A photoplethysmograph analysis software device for over-the-counter use analyzes photoplethysmograph data and provides information for identifying loss of pulse. This device is not intended to provide a diagnosis.

Technological Characteristics

The Loss of Pulse detection SaMD is intended to be used for the detection of loss of pulse using photoplethysmography (PPG) and accelerometer sensors present in a wrist worn consumer wearable device. Upon detection of loss of pulse, when the smartwatch is worn, the feature will prompt haptic and audio alerts and notifications to the user and prompt the user's compatible hardware to call emergency services if the user is unresponsive to the notifications and alerts. This is an opt-in feature and will be off by default.

The Loss of Pulse detection SaMD comprises a software component that resides on the compatible consumer wearable device (from here on referenced as a "smartwatch") and a user facing mobile application that resides on general purpose compatible consumer mobile devices such as a smartphone (from here on referenced as "Smartphone"). The software component on the smartwatch analyzes pulse data collected by photoplethysmography (PPG) and accelerometry sensors from qualified smartwatch, using an algorithm employing digital signal processing (DSP) and features-based machine learning based on a convolutional neural network (CNN) to detect possible loss of pulse events.

Summary of Substantial Equivalence

	Subject Device **Loss of Pulse Detection** **K242967**	**Predicate Device** **Fitbit Irregular Rhythm Notification** **K212372**	**Equivalence Discussion**
Intended Use	Photoplethysmograph analysis software for over-the-counter use. A photoplethysmograph analysis software device for over-the-counter use analyzes photoplethysmograph data and provides information for identifying loss of pulse. This device is not intended to provide a diagnosis.	Photoplethysmograph analysis software for over-the-counter use. A photoplethysmograph analysis software device for over-the-counter use analyzes photoplethysmograph data and provides information for identifying irregular heart rhythms. This device is not intended to provide a diagnosis.	Same

Indications for Use	Loss of Pulse Detection is a software-only mobile medical application that is intended to be used with compatible consumer wrist-worn products to analyze pulse data to identify loss of pulse events and provide a notification to the user. If the user remains unresponsive to these alerts, Loss of Pulse Detection will attempt to prompt a call to emergency services through the user's connected compatible hardware, such as a smartphone or smartwatch. Loss of Pulse Detection is intended for over-the-counter (OTC) use. It is not intended to provide a notification on every loss of pulse event and the absence of a notification is not intended to indicate no disease process is present; rather the Loss of Pulse Detection is intended to opportunistically surface a notification of possible pulselessness when sufficient data are available for analysis. These data are only captured when the user is still. Loss of Pulse Detection is not intended to replace traditional methods of diagnosis or treatment. Loss of Pulse Detection 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	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.	Similar Both devices are software-only mobile medical applications intended for use with compatible consumer wrist-worn products. They both utilize PPG analysis software to identify potential irregular heart rhythms, analyze pulse data, and provide notifications to the user if an irregular heart rhythm is detected. Neither device is intended to provide a diagnosis or monitor the outcome of their alerts. Additionally, both devices are intended for users over 22 years old and are not intended for individuals with pre-existing cardiac conditions.

	previously diagnosed with a high risk for sudden cardiac death such as those with coronary artery disease, cardiomyopathy and/or unexplained syncope/fainting.		
Use Environment	Home/General Use	Home/General Use	Same Both are intended for home use.
Anatomical Site	Wrist-worn consumer wearable with PPG sensors.	Wrist-worn consumer wearable with PPG sensors.	Same Both use consumer grade wrist-worn devices to gather signals from PPG sensors.
User interface	Mobile application run within the Pixel watch consumer app.	Mobile application run within the Fitbit consumer app	Same Both devices include a mobile application component that is run within a consumer application on the user's mobile device (smartphone). This mobile application serves the purpose of the User Interface for both devices.
Use Method	Collects and analyzes pulse data during periods that meet input signal quality requirements (including stillness in the recent past) using input from PPG sensors.	Collects and analyzes tachograms (based on pulse data) during periods of stillness or sleep using input from PPG sensors.	Similar Both devices analyze sensor data from the PPG sensor and only analyze data that meet input signal quality requirements. Stillness is part of both devices' input signal quality requirements. Both devices limit the analysis window to time periods relevant to the irregular heart rhythm being detected. The use of the term "tachogram" by the predicate device refers to subsets of the PPG sensor data cropped to approximate individual R-R intervals, and does not meaningfully alter the use method, as both the

			subject and predicate devices use signal processing algorithms to analyze PPG sensor data. Both devices are passive background screening tools and users cannot initiate readings. Both devices opportunistically surface a notification to the user.
Limiting Factors	Motion, hand, and finger movements during pulseless period; tattoos on the wrist; inadequate blood flow. Does not continuously monitor for signs of loss of pulse A lack of notification does not indicate an absence of an underlying loss of pulse	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.	Same Both devices have similar limiting factors. Both devices are not intended for continuous monitoring. A lack of notification does not indicate an absence of an irregular rhythm for both devices.
Compatible devices	Consumer wrist-worn products with PPG sensors (e.g., smartwatch) that have been qualified for use with the Loss of Pulse Detection feature	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	Same Both devices are compatible with qualified wrist worn products with PPG sensors that have been qualified for use with the respective feature. The subject device is compatible with a subset of consumer wrist-worn products on which the predicate is qualified (i.e., smartwatches).
Principles of Operation	Pulse rate data is gathered from a consumer wrist-worn device. The algorithm analyzes the data and classifies it as having signs of an irregular heart rhythm, loss of pulse, or no signs thereof. When signs of loss of pulse are detected, a notification is surfaced to the user.	Pulse rate data gathered from a consumer wrist-worn device is uploaded to a server. The algorithm analyzes the data and classifies it as having signs of AFib or no signs of AFib. When signs of AFib are detected a notification is surfaced to the user through the mobile	Similar Both devices have the same basic principle of operation, with nonmaterial differences stemming from the particular irregular pulse rhythm that is intended to be detected. Both devices analyze pulse data

		application.	from consumer wrist-worn devices. Apparent differences such as algorithmic analysis on the watch in the subject device and the server on the predicate have no material impact on safety or effectiveness. Both devices opportunistically surface notifications to the user if an irregular pulse rhythm is detected.

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:

Algorithm Development

The Loss of Pulse Detection algorithm identifies potential loss of pulse events. The algorithm includes a machine learning component that consists of a convolutional neural network, which analyzes data from photoplethysmography (PPG) and accelerometer sensors. The algorithm was developed on a dataset consisting of over one hundred thousand hours of free-living data across hundreds of participants who experienced no loss of pulse events and 99 participants who experienced simulated loss of pulse events induced by an arterial occlusion model. The dataset used for model development was split at the participant level into training, validation, and held-out test sets The Loss of Pulse Detection algorithm was trained on the training split and evaluated on the validation set. When algorithm development was complete, the algorithm was locked and the algorithm was evaluated on the held-out test set. The training, validation, and test splits used for development included data from diverse participants with varied age, sex, BMI, and skin tone.

Bench Testing/Non-Clinical Testing

The Loss of Pulse Detection utilizes signals derived from compatible consumer grade wrist-worn products. The wrist-worn products were qualified for use with the software to ensure that the data provided could meet signal attribute and quality requirements necessary for heart rhythm analysis and detect adequate PPG signal quality. Bench testing included 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 Loss of Pulse Detection that were derived from the wrist-worn products. Qualification testing was repeated for all qualified wrist-wearable products. The algorithm was tested to ensure that it accepted and rejected data correctly and that it can correctly analyze the input data.

Software Testing Summary

The Loss of Pulse Detection presents a “Basic Documentation” Software Documentation Level based on the risks of device software function in the context of the device’s intended use as defined in FDA’s Guidance for the Content of Premarket Submissions for Device Software Functions (June 14, 2023) (Guidance Document). Testing of the mobile application demonstrates that the Loss of Pulse Detection feature adequately performs all the necessary functionalities including education/onboarding and generating user notifications when pulselessness is identified.

Human Factors Testing Summary

A Human Factors Validation Study was designed to evaluate the critical and noncritical tasks associated with the use of the device. The Human Factors Validation Study was performed using a simulated version of the Loss of Pulse Detection within the Pixel watch mobile app, representative of the final app. 19 users were recruited from the general population for the study, with the goal of recruiting at least 15 intended users. During the test session, each participant performed various tasks within representative, naturalistic use scenarios. These tasks included setup and onboarding, responding to an initial check-in, responding to an escalation, triggering emergency response services, and passive feature use. The first evaluation activity (setup and onboarding) included a self-selection component where participants indicated whether or not they are an intended Loss of Pulse Detection application user, resulting in 16 intended and 3 unintended users. Participants also performed a knowledge task to evaluate critical tasks that could not be evaluated during the simulated use scenarios.

During each evaluation activity, use errors, instances of moderator assistance, close calls, and difficulties were documented. Open-ended questions were used to collect participants’ subjective assessments of the root cause(s) associated with any such event and to collect participants’ feedback on the product’s use-safety. Data was consolidated and analyzed with a focus on events with the potential for serious harm (critical tasks). The human factors testing found that the loss of pulse detection feature was safe and effective for the intended users, uses, and use environments.

Real World Evidence Summary

Real-world evidence (RWE) indicates users are able to respond to haptic, audio, and visual feedback and de-escalate based solely on reading the device labeling. A sample of data from RWE shows that users clear >98% of notifications from the pre-phone call gates in real-world free-living conditions. There was, on average, 1 phone call placed by Loss of Pulse Detection in 75 person-years of real-world use.

Clinical Testing Summary

The Loss of Pulse Detection (LPD) software, intended for use with wrist-worn devices, was clinically validated in a study. The study aimed to evaluate the software's ability to detect loss of pulse events and initiate an emergency call.

A total of 135 participants were enrolled in one clinical study and 21 participants in another clinical study. The participants included a racially and ethnically diverse population, including adults of diverse sex and age. The results from the clinical validation study showed a sensitivity of 69.3% (95% CI: 64.3%, 74.1%)

across 135 users and a sensitivity of 64.5% (95% CI: 55.7% to 74.2%) after adjusting for performance after a simulated collapse. The specificity was analyzed using evaluable data from 131 participants from the first study. It showed a day-level specificity of 99.965% (95% CI 99.804, 99.999). A total of 5 adverse events were reported. No adverse events reported were related to the LPD software. Most adverse events were identified as possible anticipated risks in the study protocol, namely skin irritation from wearing a consumer wrist-worn device. Demographic characteristics of the study population are summarized in the table below.

	Clinical validation study (pulseless and pulsatile)	**Clinical validation study (pulseless)**
N	135	21
Age		
≤35	16.3% (22)	14.3% (3)
36–59	38.5% (52)	61.9% (13)
60+	45.2% (61)	23.8% (5)
Sex		
Female	60.7% (82)	47.6% (10)
Male	39.3% (53)	52.4% (11)
Monk skin tone		
1–4	40.7% (55)	28.6% (6)
5–6	35.6% (48)	66.7% (14)
7–8	20.7% (28)	4.8% (1)
9–10	3.0% (4)	0.0% (0)
Individual typology angle scale		
1	3.0% (4)	0.0% (0)
2	5.9% (8)	9.5% (2)
3	11.1% (15)	28.6% (6)
4	11.1% (15)	33.3% (7)
5	43.0% (58)	19.0% (4)
6	25.9% (35)	9.5% (2)
Body mass index		
<18.5	0.7% (1)	4.8% (1)

	Clinical validation study (pulseless and pulsatile)	Clinical validation study (pulseless)
18.5– <25	18.5% (25)	47.6% (10)
25– <30	27.4% (37)	38.1% (8)
≥30	53.3% (72)	9.5% (2)

7. Conclusion

The Loss of Pulse Detection and its predicate have the same Intended Use, similar Indications for Use, similar technological characteristics and principles of operation. The technological differences between the subject Loss of Pulse Detection and its predicate, Fitbit Irregular Rhythm Notifications, are in relation to the very specific formulation of the respective algorithms. However, any such differences do not raise new or different questions of safety or effectiveness. Moreover, testing and clinical data provided in the submission demonstrate that the subject device meets all Special Controls and operates in a manner that is as safe and effective as the predicate device. Therefore, Loss of Pulse Detection is considered substantially equivalent to the predicate device.