July 21, 2023

Apple Inc.
Bonnie Wu
Regulatory Affairs Lead
One Apple Park Way
Cupertino, California 95014

Re: K231173
Trade/Device Name: Irregular Rhythm Notification Feature (IRNF)
Regulation Number: 21 CFR 870.2790
Regulation Name: Photoplethysmograph Analysis Software For Over-The-Counter Use
Regulatory Class: Class II
Product Code: QDB
Dated: April 25, 2023
Received: April 25, 2023

Dear Bonnie Wu:

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.

FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP). Under section 515C(b)(1) of the Act, a new premarket notification is not required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an

established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively. 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 systems (QS) regulation (21 CFR 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 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 W. Shih -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)*
K231173

Device Name
Irregular Rhythm Notification Feature (IRNF)

Indications for Use *(Describe)*
The IRNF 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.

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.

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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
Primary Correspondent	Bonnie Wu Regulatory Affairs Phone: (408) 974-0617 Email: bonnie_h_wu@apple.com
Secondary Correspondent	Luke Olson Regulatory Affairs Phone: (408) 609-2001 Email: luke_olson@apple.com
Date Prepared	June 23, 2023

5.2 Device Names and Classifications

Subject Device:

Name of Device	IRNF 2.0
Classification Name	Photoplethysmograph Analysis Software For Over-The-Counter Use, 21 CFR 870.2790
Regulatory Class	Class II
Product Code	QDB
510(k) Review Pannel	Cardiovascular

Predicate Device:

Predicate Manufacturer	Apple Inc.
Predicate Trade Name	IRNF 2.0
Predicate 510(k)	K212516

5.3 Device Description

IRNF 2.0 is comprised of a pair of mobile medical apps - One on Apple Watch and the other on the iPhone.

IRNF 2.0 is intended to analyze pulse rate data collected by the Apple Watch PPG sensor on Apple Watch Series 3-8, Series SE, and Apple Watch Ultra to identify episodes of irregular heart rhythms consistent with AFib and provides a notification to the user. It is a background screening tool and there is no way for a user to initiate analysis of pulse rate data. IRNF 2.0 iPhone App is part of the Health App, which allows users to store, manage, and share health and fitness data, and comes pre-installed on every iPhone.

IRNF 2.0 Watch App refers to the tachogram classification algorithm, confirmation cycle algorithm, and the AF notification generation. If an irregular heart rhythm consistent with AFib is identified, IRNF 2.0 Watch App will transfer the AFib notification to IRNF 2.0 iPhone App through HealthKit sync. In addition to indicating the finding of signs of AFib, the notification will encourage the user to seek medical care.

IRNF 2.0 iPhone App contains the on-boarding and educational materials that a user must review prior to enabling AFib notifications. IRNF 2.0 iPhone App is designed to work in combination with IRNF 2.0 Watch App and will display a history of all prior AFib notifications. The user is also able to view a list of times when each of the irregular tachograms contributing to the notification was generated.

5.4 Indications for Use

The IRNF 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.

5.5 Comparison of Technological Characteristics with the Predicate Device

The subject device is identical to the predicate device, having the same intended use, indications for use, and principles of operation as its predicate device. The technological characteristics of the subject device are identical to the predicate device, other than the implementation of a Predetermined Change Control Plan (PCCP) that specifies anticipated modifications to the IRNF

2.0 software and the methods that will be utilized to implement those modifications in a controlled manner such that the device is as safe and as effective as the predicate.

The PCCP includes a specific list of software modifications defining the region of potential changes that can be made to the algorithms in the device. The detailed description of the changes, associated requirements and test methods are summarized in the table below.

The PCCP includes an algorithm modification protocol describing the verification and validation activities that will support the proposed changes. The modification protocol incorporates impact assessment considerations and specifies requirements for data management, including data sources, collection, storage, and sequestration, as well as documentation and data re-use practices.

Specific test methods are specified in the PCCP to establish substantial equivalence relative to IRNF 2.0, and include sample size determination, analysis methods, and acceptance criteria. To help ensure validation test datasets are representative of the intended use population, each will meet minimum demographic requirements for age, sex, race, and skin tone derived from the demographics of the United States.

	Detailed List of Changes	Requirements	Test Method
Modifications to Tachogram Classification Algorithm	Adjust the numerical threshold at which a tachogram is classified as AF (operating point). While maintaining the same algorithm architecture and number of parameters, retrain algorithm with additional datasets	• No change to sensor input signal type • No change to output type • No change to confirmation cycle algorithm • No change to intended use of device • Can be fully verified/validated by requirements of the Modification Protocol and applicable Test Method	Substantial equivalence in sensitivity and specificity when compared to the performance of IRNF 2.0
Modifications to Confirmation Cycle Algorithm	Modification to the number of sequential tachograms that must be classified as irregular in a given time period to surface a notification Modification to the time period of confirmation cycle	• No change to input of confirmation cycle algorithm • No change to output type • No change to tachogram classification algorithm • No change to intended use of device • Can be fully verified/validated by requirements of the Modification Protocol and applicable Test Method	Substantial equivalence in positive predictive value relative to IRNF 2.0

In accordance with the PCCP, all algorithm modifications will be trained, tuned, and locked prior to release of the software to the field. The PCCP does not include provisions for implementation of adaptive algorithms that will continuously learn in the field. A procedure for Instructions for Use

updates has been established in order to inform users about algorithm changes implemented under this FDA authorized PCCP, including a summary of the changes and a characterization of algorithm performance, as well as the availability and compatibility of the feature. Apple will publish updated Instructions for Use on its website, and make them accessible within the Health App.

5.6 Conclusion

The subject device, IRNF 2.0, has the same intended use, indications for use, and principles of operation as its predicate device. The technological characteristics are identical with the exception of the implementation of a PCCP, and this difference does not raise new questions of safety and effectiveness. Thus, the subject device is substantially equivalent.