July 19, 2022

Verily Life Sciences LLC
Dinesh Puppala
Regulatory Affairs Specialist
269 East Grand Avenue
South San Francisco, California 94080

Re: K213357
Trade/Device Name: Study Watch with Irregular Pulse Monitor (Home), Study Watch with Irregular Pulse Monitor
Regulation Number: 21 CFR 870.2920
Regulation Name: Telephone Electrocardiograph Transmitter And Receiver
Regulatory Class: Class II
Product Code: DXH, DPS
Dated: July 18, 2022
Received: July 18, 2022

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 (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)*
K213357

Device Name
Study Watch with Irregular Pulse Monitor

Indications for Use *(Describe)*
The Study Watch with Irregular Pulse Monitor is indicated for use by adult patients (22 years and older) who have been diagnosed with, or are susceptible to developing, atrial fibrillation enabling them to monitor and record their heart rhythms. Study Watch is also intended to record, store, transfer, and display single-channel electrocardiogram (ECG) rhythms.

The Study Watch is intended for prescription use only.

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.

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510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Date Prepared:	July 15, 2022
Submitter:	Verily Life Sciences LLC
Official Contact:	Dinesh Puppala Senior Regulatory Affairs Specialist 269 East Grand Ave South San Francisco, CA 94080, USA Telephone: (650)-267-1263 E-mail: puppalad@google.com
Proprietary Name:	Study Watch with Irregular Pulse Monitor
Common Name:	Telephone Electrocardiograph Transmitter and Receiver
Classification:	Class II Medical Device Regulation Number: 21 CFR 870.2920 Product Code: DXH, DPS
Predicate Device:	Study Watch with Irregular Pulse Monitor (K192415)
Reason For Submission:	Additional or Expanded Indications Interoperability with ZEUS System (Zio Watch), an iRhythm Technologies, Inc. software system

Indications for Use

The Study Watch with Irregular Pulse Monitor is indicated for use by adult patients (22 years and older) who have been diagnosed with, or are susceptible to developing, atrial fibrillation enabling them to monitor and record their heart rhythms. Study Watch is also intended to record, store, transfer, and display single-channel electrocardiogram (ECG) rhythms.

The Study Watch with Irregular Pulse Monitor is intended for prescription use only.

Device Description

The Study Watch with Irregular Pulse Monitor is a miniaturized physiological data monitoring device that is intended to record, store, transfer and display single-channel electrocardiogram (ECG) rhythms. The Study Watch with Irregular Pulse Monitor is intended to notify the user in the event of an irregular pulse, such as atrial fibrillation (AF), and recommend acquisition of an ECG. The device utilizes a band and proprietary watch that incorporates two dedicated sensing electrodes to obtain a single-channel ECG measurement. In practice, a healthcare professional (HCP) may prescribe the Study Watch with Irregular Pulse Monitor to a patient and recommend the capture and transmission of one or more ECG rhythms on a daily basis for analysis by the HCP. The patient uses prompts provided on the graphical user interface (GUI) of the watch to collect a real-time 45-second ECG measurement. The patient is able to capture an ECG rhythm on-demand by navigation to the ECG menu, upon receipt of an irregular pulse notification. While an animated ECG waveform is briefly displayed on the GUI of the watch, the patient will not have direct access to the collected waveform. Using the provided charging dock (Cradle) and Verily's Study Hub or Watch App, the ECG measurements are securely transferred to Verily's cloud server and are viewed by the HCP using a web portal. Additionally, data may be securely transferred to interoperable devices for further analysis. The web portal is solely intended for use by the HCP to view time-stamped ECG waveforms collected by the patient and does not include any analysis features. Collectively, the Study Watch consists of the wearable watch and band, the Study Hub or Watch app (used to transfer data from the watch to the cloud), a Cradle, and the web portal.

Irregular Pulse Monitoring Algorithm

The Irregular Pulse Monitoring Algorithm is responsible for processing PPG-based data collected by the Study Watch device to provide detection of irregular pulses over the patient's wear period. The algorithm operates on a continuous basis by analyzing - once every 15 minutes - the prior 15-minutes of PPG-based data to detect the presence of an irregular rhythm, such as AF.

Algorithm Training

The algorithm was developed using machine learning techniques. The source of training data for the algorithm is continuous cardiac recordings from compatible cardiac monitors. The algorithm was trained using thousands of ECG data collected from iRhythm Technologies' Zio devices, which have undergone Certified Cardiographic Technician (CCT) review. In addition, the algorithm was tuned using PPG data intervals recorded from devices similar to the Study Watch.

Algorithm Validation

The Study Watch AF Detection At Home (NCT04546763) data consists of free-living, multi-day PPG recordings obtained from the Study Watch, along with ECG-based rhythm labels obtained from reference iRhythm Technologies Zio XT Patches worn simultaneously.

Recording device	Study Watch with Irregular Pulse Monitor
Channel	Wrist-based PPG
Recording Length	Up to 14 days
Environment	Ambulatory*
Demographics	Patients at least 22 years or older who are at risk of having an AF event, as determined by having a diagnosis of paroxysmal AF. Age: Median = 67 years; Range: 23-86 years Gender: 45.5% Female Regional Demographics (USA): Midwest: 8%, Mountain: 32%, West: 32%, Northeast: 14%, South: 13%

*In-clinic during enrollment

Substantial Equivalence Discussion

Study Watch with Irregular Pulse Monitor is substantially equivalent to the predicate Study Watch (K192415) as both the proposed and predicate are intended to record, store, transfer, and display single-channel ECG rhythms in adults with known or suspected heart conditions. Both devices are indicated to detect irregular pulse in adults with a diagnosis of, or are susceptible to, AF. Similar to the predicate device, the proposed device is classified as a Telephone Electrocardiograph Transmitter and Receiver in accordance with 21 CFR 870.2920, Product Code DXH, DPS. It is of importance to note that both the Study Watch with Irregular Pulse Notification and the predicate device use two (2) dedicated sensing electrodes to obtain a single-channel ECG measurement.

A comparative summary of the similarities and differences between the Study Watch with Irregular Pulse Monitor and the predicate Study Watch (K192415).

Table. Predicate Device Comparison Table

Topic	Proposed Device	Predicate Device
Manufacturer	Verily Life Sciences, LLC	Verily Life Sciences, LLC
Model Name	Study Watch with Irregular Pulse Monitor (Home)	Study Watch with Irregular Pulse Monitor
510(k) Number	Subject Device: K213357	Predicate: K192415
Intended Use/Indications for Use	The Study Watch with Irregular Pulse Monitor is indicated for use by adult patients (22 years and older) who have been diagnosed with, or are susceptible to developing, atrial fibrillation enabling them to monitor and record their heart rhythms. Study Watch is also intended to record, store, transfer, and display single-channel electrocardiogram (ECG) rhythms.	The Study Watch with Irregular Pulse Monitor is indicated for use by adult patients (22 years and older) who have been diagnosed with, or are susceptible to developing, atrial fibrillation enabling them to monitor and record their heart rhythms. Study Watch is also intended to record, store, transfer, and display single-channel electrocardiogram (ECG) rhythms. The Irregular Pulse Monitor is indicated for use in professional healthcare facilities.
Prescription Device for Home Use	Yes (Both Home use & In-clinic use)	No (Only In-clinic use)
Regulation Number	21 CFR 870.2920	21 CFR 870.2920
Device Classification Name	Telephone Electrocardiograph Transmitter And Receiver	Telephone Electrocardiograph Transmitter And Receiver
Product Code	DXH, DPS	DXH, DPS
Target Population	Adults diagnosed with, or are susceptible to developing, atrial fibrillation	Adults diagnosed with, or are susceptible to developing, atrial fibrillation
Anatomical Site	Left hand fingers to right wrist or vice versa (ECG); Wrist (PPG)	Left hand fingers to right wrist or vice versa (ECG); Wrist (PPG)
Where Used	Mobile/active users at rest (ambulatory)	Mobile/active users at rest (ambulatory)
Device Design	Study Watch is a wearable miniaturized physiological data monitoring and data collection	Study Watch is a wearable miniaturized physiological data monitoring and data collection

	device for continuous recording of physiological and environmental data. The watch features single-lead ECG capability and a PPG sensor among other sensors. The watch also includes an electronic circuit board, batteries, GUI that displays watch features and enables menu navigation.	device for continuous recording of physiological and environmental data. The watch features single-lead ECG capability and a PPG sensor among other sensors. The watch also includes an electronic circuit board, batteries, GUI that displays watch features and enables menu navigation.
Mechanism of Action	PPG: The Study Watch contains an optical sensor that collects the PPG waveform from blood flow and this PPG raw data is utilized for non-medical heart rate data as well as irregular pulse notification. ECG: User completes circuit with skin contact and hardware measures ECG waveform, which is stored and securely transferred to the cloud via the proprietary Study Hub. Additionally, data may be securely transferred to the cloud via Bluetooth and a mobile app.	PPG: The Study Watch contains an optical sensor that collects the PPG waveform from blood flow and this PPG raw data is utilized for non-medical heart rate data as well as irregular pulse notification. ECG: User completes circuit with skin contact and hardware measures ECG waveform, which is stored and securely transferred to the cloud via the proprietary Study Hub.
User Interface	Patient: Study Watch HCP: Web Portal	Patient: Study Watch HCP: Web Portal
Interoperability with third party ECG & PPG Analysis Software systems	Zio Watch (Branded Study Watch) is interoperable with the ZEUS System (iRhythm Technologies)	Not Interoperable with any third party systems
Principles of Operation	PPG data collection (to detect irregular pulse) ECG: acquisition (for rhythm)	PPG data collection (to detect irregular pulse) ECG: acquisition (for rhythm)
Recording Length	45 Seconds	60 Seconds
Irregular Pulse Performance (interval - level)	In-clinic Use: Sensitivity: 98.3% Specificity: 100.0%	In-clinic Use: Sensitivity: 85% Specificity: 96%

	Home Use: Sensitivity: 96.1% Specificity: 98.1%	

The differences in technological characteristics associated with the proposed device in comparison to the predicate (K192415) have been evaluated through performance testing for the target population and there are no new questions of safety and effectiveness. Therefore, the proposed device is substantially equivalent to the predicate device.

Non-Clinical Performance Data

Performance Testing Bench

Performance testing for the Study Watch with Irregular Pulse Monitor comprises verification and validation completed in a software environment using raw data collected via a prospective clinical study. Bench testing includes verification and validation of specifications related to software development and hardware sensor performance for the Study Watch with Irregular Pulse Monitor. All tests confirmed that the product met the predetermined acceptance criteria and that the features driving performance are substantially equivalent to those present in the specified predicate device.

Clinical Performance Data

Clinical validation performance testing was conducted to demonstrate that Study Watch with Irregular Pulse Monitor generates data that meets the clinical requirements for irregular pulse monitoring in target patients. Specifically, the prospective clinical study collected Study Watch PPG waveform (Test) data in a free-living (home use) setting from patients at risk of having AF and applied the PPG-based irregular pulse algorithm, using contemporaneous Zio Patch (Reference) ECG data as the ground truth. The presented data include the primary endpoints [per-interval sensitivity 96.1% (95% CI: 92.7 - 98.0) and specificity 98.1% (95% CI: 97.2 - 99.1)] showing that the PPG-based irregular pulse monitoring algorithm exceeds the pre-specified per-interval performance thresholds for sensitivity and specificity for continuous monitoring. This study demonstrated that the Study Watch with Irregular Pulse Monitor in a home use environment is substantially equivalent to the predicate Study Watch (K192415) and as safe and as effective as the predicate device for the specified intended use.

Conclusion

In summary, the comprehensive performance testing demonstrates that the Study Watch with Irregular Pulse Monitor is as safe and as effective as the predicate device for the specified intended use. This testing, in addition to the comprehensive comparison to the predicate Study Watch (K192415), demonstrates the Study Watch with Irregular Pulse Monitor is substantially equivalent to the named predicate device for the specified intended use.