January 17, 2019

Verily Life Sciences LLC
Shilpa Mydur
Sr. Principal, Regulatory Affairs
269 E Grand Avenue
South San Francisco, California 94080

Re: K182456
Trade/Device Name: Study Watch
Regulation Number: 21 CFR 870.2920
Regulation Name: Telephone Electrocardiograph Transmitter And Receiver
Regulatory Class: Class II
Product Code: DXH, DPS
Dated: December 20, 2018
Received: December 20, 2018

Dear Shilpa Mydur:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jessica E. Paulsen -S

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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)*
K182456

Device Name
Study Watch

Indications for Use *(Describe)*
The Study Watch is intended to record, store, transfer, and display single-channel electrocardiogram (ECG) rhythms. The Study Watch is intended for use by healthcare professionals, adult patients (22 years or older) with known or suspected heart conditions, and health conscious individuals.

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 –Study Watch

Date Prepared:	January 11, 2019
Submitter:	Verily Life Sciences LLC
Official Contact:	Shilpa Mydur Sr. Principal, Regulatory Affairs 269 E Grand Ave South San Francisco, CA 94080, USA Telephone: +1-415-736-0652 Fax: +1650-618-1499 E-Mail: smydur@google.com
Proprietary Name:	Study Watch
Common Name:	Telephone Electrocardiograph Transmitter and Receiver
Classification:	Class II Medical Device Regulation Number: 21 CFR 870.2920 Product Code: DXH, DPS
Predicate Device:	AliveCor Kardia Band (K171816)
Reason For Submission:	New Device

Indications for Use

The Study Watch is intended to record, store, transfer, and display single-channel electrocardiogram (ECG) rhythms. The Study Watch is intended for use by healthcare professionals, adult patients (22 years or older) with known or suspected heart conditions, and health conscious individuals.

Device Description

The Study Watch is a miniaturized physiological data monitoring device that is intended to record, store, transfer and display single-channel electrocardiogram (ECG) rhythms. 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 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 60-second ECG measurement. 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 device, the ECG measurements are securely transferred to Verily's cloud server and are viewed by the HCP using a web portal. 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 (used to transfer data from the watch to the cloud), a Cradle, and the web portal.

Substantial Equivalence Discussion

The Study Watch has the following similarities to the previously cleared predicate device:

- Similar Intended Use
- Similar Technological Characteristics
- Similar Performance Specifications

A comparative summary of the technological characteristics of the Study Watch with the predicate device AliveCor Kardia Band (K171816) is presented below:

Characteristic	AliveCor Kardia Band (K171816)	Study Watch (New Device)
Indications for Use	The Kardia Band System is intended to record, store and transfer single-channel electrocardiogram (ECG) rhythms. The Kardia Band System also displays ECG rhythms and detects the presence of atrial fibrillation and normal sinus rhythm (when prescribed or used under the care of a physician). The Kardia Band System is intended for use by healthcare professionals, adult patients with known or suspected heart conditions, and health conscious individuals.	The Study Watch is intended to record, store, transfer, and display single-channel electrocardiogram (ECG) rhythms. The Study Watch is intended for use by healthcare professionals, adult patients (22 years or older) with known or suspected heart conditions, and health conscious individuals.
Product Code	DXH, DPS	DXH, DPS
Mechanism of Action	User completes circuit with skin contact and hardware transmits audio signal to MCP to convert and display ECG waveform	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
Where Used	Mobile/active users at rest (ambulatory)	Same
Anatomical Sites	Left hand fingers to right wrist or vice versa	Same
Data Acquisition: Frequency Response	0.5 Hz – 40 Hz	0.16 Hz – 40 Hz
ECG Channels	Single Channel	Same
Resolution	16 bit	Same
Sample Rate	300 Samples/Second	240 Samples/Second

Memory Capacity	Essentially unlimited due to real-time transmission to MCP memory (size of ECG file is miniscule – kilobytes compared to device memory capacity – gigabytes)	512 MB
Number of ECG Leads	Single lead, 2 sensing electrodes	Single lead, 2 sensing electrodes and 1 right-leg drive (RLD) electrode
Power Supply: Battery Battery Life	1 Lithium Manganese Dioxide Coin Cells 100 hours operational	1 Lithium Polymer Rechargeable Battery 112 Hours Per Full Charge
User Interface: Primary Lead Data Acquisition Hardware Software Interface	Lead I, Left to Right Ultrasonic acoustics Apple Watch Band and Sensor Apple iOS based software and Apple WatchOS based software	Same USB Study Watch Study Watch Graphical User Interface, Web Portal
Physical Specs: Dimensions Weight	24.5 x 24.5 x 6.5 mm 9 grams	42.6 x 42.3 x 11 mm 22 grams (without watch band)
Prescribed	Prescription and OTC	Prescription
Environmental: Operating Temp Storage Temp	10 to 40 degrees C -20 to 60 degrees C	-5 to 40 degrees C -25 to 70 degrees C
Communications	Ultrasonic Acoustics acquired by watch	USB via Study Hub

The major differences between the Study Watch and the AliveCor Kardia Band are as follows:

- **Indications for Use:** The Indications for Use statement for Study Watch is not identical to that of the predicate device. The intended use of the predicate device includes detection of atrial fibrillation and normal sinus rhythm based on a system analysis of the collected ECG waveform. These analysis features are not present in the Study Watch, and the proposed device is solely intended to record, store, transfer and display ECG waveforms. The Study Watch patient uses the device to record and transfer ECG waveforms to the healthcare provider, but does not have direct access to independently view these data. Accordingly, the Study Watch is only intended for prescription use.

- **Data Collection:** The Study Watch features a band and proprietary watch that incorporates two dedicated sensing electrodes to enable single-channel ECG measurement. The first of the sensing electrodes is positioned on the top of the watch, and the other sensing electrode is at the bottom of the watch contacting the user's wrist. When the user wears the watch on one wrist and contacts the top of the watch with the other hand, an acquisition loop is created and an ECG measurement is generated. The watch also includes a third electrode known as a right-leg drive (RLD) electrode which functions to reduce electrical interference from the environment to improve signal quality. The predicate device functions similarly to acquire ECG data from two sensing electrodes on a proprietary watch band, but does not incorporate the RLD electrode. The addition of the RLD electrode does not affect the stated intended use or fundamental scientific technology of the proposed device.

- **Data Transmission:** The Study Watch uses a system whereby ECG data is collected by the wearable watch and is then transferred to Verily's Study Hub device via a USB connection to the included charging dock (Cradle). The data are then transferred from the Study Hub to Verily's cloud server for storage using the Study Hub and are then viewed by the HCP using a web portal. The predicate device uses a system that transfers the ECG signal from its electrodes to mobile medical application on the Apple Watch to be analyzed and presented directly to the user.

- **User Access:** For the Study Watch, the ECG data is collected by the patient, but is only viewable in its final form by an HCP using the web portal. The predicate device enables viewing of the ECG waveform data by the patient using a dedicated mobile medical application.

The differences in technological characteristics have been evaluated through performance testing and do not raise any new questions of safety and effectiveness, and therefore the proposed device is substantially equivalent to the predicate device.

Non-Clinical Performance Data

Design validation and verification activities were performed for the Study Watch as a result of the risk analysis assessment and product requirements. Testing included validation of specifications related to software development, sensor performance, stability and material properties. All tests confirmed that the product met the predetermined acceptance criteria. In particular, non-clinical performance testing demonstrated that the Study Watch is substantially equivalent to the predicate device when taking into account its intended use.

The Study Watch was designed and tested in accordance with the applicable requirements in relevant FDA guidance documents and international standards including:

- ISO 14971 (2012): Medical Devices - Application of Risk Management to Medical Devices.
- IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 60601-1:2005 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

- IEC 60601-2-47:2012/ (R)2016 Medical electrical equipment - Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems.
- IEC 62133 Battery Safety Testing
- IEC 62304:2006 Medical device software -- Software life cycle processes
- ISO 10993-1:2009 Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
- ISTA 2A (2011): Partial Simulation Performance Tests (Packaging). Packaged-Products 150 lb (68 kg) Or Less.

Clinical Performance Data

Clinical performance testing was conducted to demonstrate that the Study Watch generates data that meets the clinical quality requirements for an accurate ECG waveform display. The presented data shows qualitative clinical equivalence and inter-beat interval Bland-Altman analysis with Bias of 1.2ms and 95% limits-of-agreement <20ms when compared to industry-standard 12-lead ECG device. The study is sufficient to draw a conclusion of substantial equivalence based on meeting qualitative and quantitative acceptance criteria. In addition, a human factors assessment was conducted to identify errors associated with the use of the Study Watch that could lead to patient harm and to assess the effectiveness of specific risk management measures. This study demonstrated that the Study Watch is safe and effective for the specified intended use.

Conclusion

The information in this submission demonstrates that the Study Watch is substantially equivalent to the cited predicate device. The non-clinical and clinical data support the safety and effectiveness of the device and demonstrate that Study Watch should perform as intended in the specified use conditions.