January 17, 2020

Verily Life Sciences LLC
Richard Stewart
Head of Regulatory Affairs
269 E Grand Avenue
South San Francisco, California 94080

Re: K192415
Trade/Device Name: 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: December 4, 2019
Received: December 6, 2019

Dear Richard Stewart:

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 W. Shih -S

Jennifer Shih
Assistant Director (Acting)
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

Masimo Ex. 1029
IPR Petition - US D883,279

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)*
K192415

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 Irregular Pulse Monitor is indicated for use in professional healthcare facility environments, while worn as a wrist watch.

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.

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Masimo Ex. 1029
IPR Petition - US D883,279

510(k) Summary

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

Date Prepared:	January 17, 2020
Submitter:	Verily Life Sciences LLC
Official Contact:	Richard M. Stewart, Ph.D. Head of Regulatory Affairs 269 East Grand Ave South San Francisco, CA 94080, USA Telephone: (650) 379-5200 Fax: +1 650-618-1499 E-Mail: rmstewart@verily.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:	Primary: Study Watch (K182456) Secondary: FibriCheck (K173872)
Reason For Submission:	New Device

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 in professional healthcare facility environments, while worn as a wrist watch.

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 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 60-second ECG measurement. The patient is able to capture an ECG rhythm on-demand by navigation to the ECG menu, in response to a daily ECG reminder, or 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 wave form.

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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

Study Watch with Irregular Pulse Monitor is substantially equivalent to the selected primary predicate Study Watch (K182456) and secondary predicate FibriCheck (K173872) in terms of intended use, fundamental scientific technology and operating principle as it relates to K182456 and indication for use and the primary modes of data collection as it relates to K173872. Specifically, both the proposed and primary predicate are intended to record, store, transfer, and display single-channel ECG rhythms in adults with known or suspected heart conditions. Also, both the proposed and secondary predicate are specifically indicated to detect irregular pulse in adults with a diagnosis of, or are susceptible to, AF. Similar to the primary 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 primary 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 primary predicate Study Watch (K182456) and secondary predicate FibriCheck (K173872).

Table 1. Predicate Device Comparison Table

Manufacturer	**Verily Life Sciences, LLC**	**Verily Life Sciences, LLC**	**Qompium**
Model Name	**Study Watch w/ Irregular Pulse Monitor**	**Study Watch**	**FibriCheck**
510(k) Number	**Proposed Device: Kxxxxxx**	**Primary Predicate: K182456**	**Secondary Predicate: K173872**
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 in professional healthcare facility environments, while worn as a wrist watch.	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 with known or suspected heart conditions, and health conscious individuals.	FibriCheck is indicated for self-testing by patients who have been diagnosed with, or are susceptible to developing, atrial fibrillation and who would like to monitor and record their heart rhythms on an intermittent basis.
Prescription Device for Home Use	No	Yes	Yes
Regulation Number	21 CFR 870.2920	21 CFR 870.2920	21 CFR 870.2920
Device Classification Name	Telephone Electrocardiograph Transmitter And Receiver	Telephone Electrocardiograph Transmitter And Receiver	Telephone Electrocardiograph Transmitter And Receiver
Product Code	DXH, DPS	DXH, DPS	DXH

Manufacturer	Verily Life Sciences, LLC	Verily Life Sciences, LLC	Qompium
Model Name	**Study Watch w/ Irregular Pulse Monitor**	**Study Watch**	**FibriCheck**
510(k) Number	**Proposed Device: Kxxxxxx**	**Primary Predicate: K182456**	**Secondary Predicate: K173872**
Target Population	Adults diagnosed with, or are susceptible to developing, atrial fibrillation	Adults with known or suspected heart conditions, and health conscious individuals.	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)	Finger (PPG)
Where Used	Mobile/active users at rest (ambulatory)	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 device for continuous recording of physiological and environmental data. The 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.	Same as proposed device.	FibriCheck obtains waveform via Mobile Platform camera and displays signal in real time on the Mobile Platform device with an arrhythmia index. Text display (green, amber, or blue) indicates heart regularity or irregularity. All tests are stored.
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.	**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. **ECG:** Same as proposed device.	**PPG:** Uses optical camera of a mobile device to collect photoplethysmogram data (PPG data). FibriCheck receives data from the Mobile Platform device, from which the waveform is directly created. The irregularity is indicated with a text indicator.
User Interface	Patient: Study Watch HCP: Web Portal	Same as proposed device	Patient: Mobile Computing Platform / Web application
Principles of Operation	PPG data collection (to detect irregular pulse) ECG: acquisition (for rhythm)	PPG data collection (to measure heart rate) ECG: Same as proposed device.	PPG data collection (to detect irregular pulse)
Recording length	60 Seconds	Same as proposed device.	Same as proposed device.
Irregular Pulse Performance	Sensitivity: 85% Specificity: 96%	N/A	Sensitivity: 96% Specificity: 97%

The differences in technological characteristics associated with the proposed device in comparison to the primary predicate (K182456) and secondary predicate (K173872) have been evaluated through performance testing for target population and there are no new questions of safety and effectiveness. Therefore, the proposed device is substantially equivalent to the predicate devices.

Non-Clinical Performance Data

Performance Testing Bench

Design validation and verification activities were performed for the Study Watch with Irregular Pulse Monitor as a result of the risk analysis assessment and product requirements. Hardware verification completed for the Study Watch with Irregular Pulse Monitor covers performance assessment for the PPG sensor, battery life and memory capacity.

The Firmware verification includes test cases for performance assessment associated with ECG feature per K182456 as well as performance associated with the Irregular Pulse Monitoring feature. Testing completed follows the same software verification approach for the FW as to what was provided in the predicate device Study Watch K182456.

Successfully completed bench performance testing demonstrates the Study Watch with Irregular Pulse Monitor is substantially equivalent to the predicate device for the specified intended use.

Performance Testing Human Factors

The 510(k)-cleared Study Watch per K182456 underwent a human factors assessment demonstrating that the Study Watch is substantially equivalent to the predicate device for the specified intended use (for the ECG feature). This previously completed human factors assessment per K182456 is still applicable as there are no changes to user interface or how the ECG waveform is displayed. Additional human factors assessments were conducted to assess that the system as it relates to the Study Watch with Irregular Pulse Monitor meets user needs and that the Instructions for Use (IFU) support the effective use of the system including specific risk management measures. Two formative studies assessed the instructions for two user groups: Study Watch users and Web Portal users (HCP) and demonstrate that IFU for the Study Watch with Irregular Pulse Monitor can be well comprehended by users, supporting the effective use of the irregular pulse notification feature.

Clinical Performance Data

Clinical performance testing was conducted to demonstrate that Study Watch with Irregular Pulse Monitor generates data that meet the clinical requirements for irregular pulse monitoring in target patients. Specifically, the primary clinical study collected Study Watch PPG waveform (Test) data in clinic from patients with a history of AF and applied the PPG-based Irregular Pulse Monitor algorithm, using contemporaneous Holter ECG (Reference) data as ground truth. The presented data include the primary endpoints [per-interval sensitivity 0.85 (0.79-0.90) and specificity 0.96 (0.93-0.99)] showing that the PPG-based Irregular Pulse Monitor algorithm exceeds the pre-specified per-interval performance thresholds for sensitivity and specificity for continuous monitoring. This study demonstrates that the Study Watch with Irregular Pulse Monitor is substantially equivalent to primary predicate Study Watch (K182456) and secondary predicate FibriCheck (K173872) and substantially equivalent to 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 substantially equivalent to the predicate device for the specified intended use. This testing in addition to the comprehensive comparison to the primary predicate Study Watch (K182456) and secondary predicate FibriCheck (K173872) demonstrate the Study Watch with Irregular Pulse Monitor is substantially equivalent to the named predicate devices for the specified intended use.