



October 5, 2021

Withings SA
Debreuil Xavier
Product Director
2 rue Maurice Hartmann
Issy-Les-Moulineaux, 92130
France

Re: K201456
Trade/Device Name: Scan Monitor
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS, DXH, DQA
Dated: October 4, 2021
Received: October 4, 2021

Dear Debreuil Xavier:

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

Indications for Use

510(k) Number (if known)

K201456

Device Name

Scan Monitor

Indications for Use (Describe)

Scan Monitor is intended to record, store and transfer single-channel electrocardiogram (ECG) rhythms. The Scan Monitor also displays ECG rhythms and detects the presence of atrial fibrillation (when the monitor is prescribed or used under the care of a physician). The Scan Monitor is intended for use by healthcare professionals, patients with known or suspected heart conditions and health-conscious individuals.

The Scan Monitor is also indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (%SpO₂). The Scan Monitor is intended for spot-checking of adult patients in hospitals, clinics, long-term care facilities, and homes.

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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1. Submitter

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Contact Person: Xavier Debreuil
Prepared: July 23, 2021

2. Device

Trade Name of the Device: Withings Scan Monitor on the Scan Watch

Model: HWA09

Common or usual name/Classification name: Transmitters and Receivers, Electrocardiograph, Telephone (Product Code: DXH; 21 C.F.R. 870.2920); Oximeter (Product Code: DQA, 21 C.F.R. 870.2700)

Regulatory Class: Class II

Predicate Device: AliveCor, Inc. AliveCor Heart Monitor (K140933)

Reference Devices:

- AmZetta Technologies Private Limited B.O.L.T Pulse Oximeter (K182401)
- Oxitone Medical Ltd. Oxitone 1000 (K163382)

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3. Indications for use

The Scan Monitor is intended to record, store and transfer single-channel electrocardiogram (ECG) rhythms. The Scan Monitor also displays ECG rhythms and detects the presence of atrial fibrillation (when the monitor is prescribed or used under the care of a physician). The Scan Monitor is intended for use by healthcare professionals, patients with known or suspected heart conditions and health-conscious individuals.

The Scan Monitor is also indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (SpO₂). The Scan Monitor is intended for spot-checking of adult patients in hospitals, clinics, long-term care facilities and homes.

4. Device Description

The Scan Monitor is a wearable, Bluetooth-connected wrist-worn watch that records two medical measurements—heart activity (electrocardiogram (ECG)) and oxygen saturation (SpO₂)—as well as other measurements including step count, sleep cycles, running, biking, and walking. The Scan Monitor has a companion mobile application called Health Mate. The Scan Monitor is available in two sizes, 38 mm and 42 mm, which have different watch faces but are otherwise identical.

The Scan Monitor has two stainless steel electrodes integrated on the back case of the watch and are always in contact with the skin. One of these two electrodes is used to obtain a reference signal and reduce the noise on the ECG signal. A third electrode is accessible by the free hand (the hand that does not wear the device) on the top of the device.

The Scan Monitor classifies ECG signals as follows:

- Normal Sinus Rhythm;
- Atrial Fibrillation;
- Inconclusive;
- Noisy.

The SpO₂ measurements are obtained by a photoplethysmograph sensor located at the back-case of the product. This sensor is composed of three LEDs (green, red, and infrared) and two photodiodes (one large band and one with a green filter). The Scan Monitor is validated for an SpO₂ range of 70% to 100% and an SpO₂ range between 85% to 100% is displayed on the gauge.

All measurements obtained by the Scan Monitor are available in the companion Health Mate app.

5. Substantial Equivalence

The Scan Monitor has the same intended use and indications for use for its core medical functionalities as the selected predicate device and the two selected reference devices. Specifically, the Scan Monitor performs both of its medical functions through two embedded sensors, which (1) record single-channel electrocardiogram (ECG) rhythms that can then be stored and transferred, and (2) measure functional oxygen saturation of arterial hemoglobin (%SpO₂), which can then be displayed to the user or clinician. Similarly, the predicate and reference devices measure heart activity and SpO₂ through sensors embedded in a hardware device, which interface with connected software to enable display, transfer, and storage of the collected data.

The minor technical differences are supported by nonclinical and clinical testing and do not raise different questions of safety or effectiveness, because the fundamental purpose and method of use of the device, and the nature and severity of potential risks associated with such use, remain the same. Thus, the subject device is substantially equivalent.

6. Software verification and validation testing

The companion Health Mate mobile application presents a moderate level of concern, and the appropriate software verification and validation testing was conducted in accordance with FDA's Guidance for the Content of Premarket Submission for Software Contained in Medical Devices (May 11, 2005).

7. Performance Testing

Biocompatibility Testing

The patient contacting materials of the Scan Monitor have been evaluation in accordance with the ISO 10993-1 and the FDA guidance "Use of International Standard ISO 10993-1, Biological evaluation of medical devices- Part 1: Evaluation and testing within a risk management process". The Scan Monitor was found to be non-cytotoxic, non-sensitizing, and non-irritating.

Non Clinical Testing

The Scan Monitor was found to meet all requirements for the following standards:

- ANSI/AAMI ES60601-1: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005).IEC 60601-1-2: Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance -- Collateral Standard: Electromagnetic disturbances -- Requirements and tests.
- IEC 60601-1-11: Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.
- ANSI/AAMI EC57: Testing and reporting performance results of cardiac rhythm and ST-segment measurement algorithms.

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Clinical Testing

Two clinical studies were conducted to validate the ECG and the SpO2 features.

The ECG quality and clinical performance of the Scan Monitor software for the detection of atrial fibrillation and normal sinus rhythm was evaluated as a prospective, multicentric, comparative, cross-over study. The results of the clinical study (n=262) demonstrated that the Scan Monitor achieved a sensitivity of 96.3% and a specificity of 100% (lower bound of 95% confidence interval 89.4% and 96.7% respectively) in detecting atrial fibrillation.

The SpO2 functionality of the Scan Monitor was also validated in accordance with IEC 80601-2-61:2017, Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment, and FDA's Guidance "*Pulse Oximeters- Premarket Notification Submission 510(k): Guidance for Industry and Food and Drug Administration Staff*". The clinical study results (n=15) demonstrated that the device met the acceptance criteria set forth in FDA's guidelines and ISO 80601-2-61. Further, the results of this study showed that the subject device has a comparable performance to the chosen reference device (Oxitone 1000).

Usability Testing

The Scan Monitor was found to be as safe and effective for the intended users, uses, and use environments as the predicate device.

8. Conclusion

The Withings Scan Monitor has the same intended use and similar technological characteristics and principles of operation as its predicate device. The minor technological differences between the Scan Monitor and its predicate and reference devices raise no new or different questions of safety or effectiveness. Performance data demonstrate that the Scan Monitor is as safe and effective as the primary predicate and reference devices. Therefore, the Scan Monitor is substantially equivalent.