November 17, 2023

Masimo Corporation
Sindura Penubarthi
Associate Director, Regulatory Affairs
52 Discovery
Irvine, California 92618

Re: K232512
Trade/Device Name: Masimo W1
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS, DQA, DXH
Dated: October 23, 2023
Received: October 23, 2023

Dear Sindura Penubarthi:

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 (the 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 available 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.

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).

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Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 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

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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.

Submission Number *(if known)*

K232512

Device Name

Masimo W1

Indications for Use *(Describe)*

Masimo W1™ and the integrated Masimo W1 module are intended for the spot-check determination of Heart Rate using a single-channel electrocardiogram (ECG). The Masimo W1 and the integrated Masimo W1 module records, stores, transfers, and displays the single-channel ECG for the manual interpretation of heart rate. It is worn on the wrist and also provides other continuous parameters technologies (e.g., pulse oximetry).

The Masimo W1™ and the integrated Masimo W1 module are also intended for the spot-checking of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR). The Masimo W1 and the integrated Masimo W1 Module are indicated for adults 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary
K232512

Submitter and Address of Manufacturing Facility:	Masimo Corporation 52 Discovery Irvine, CA 92618 Phone: (949) 297-7000 FAX: (949) 297-7592
Date:	November 17, 2023
Contact:	Sindura Penubarthi Associate Director, Regulatory Affairs Masimo Corporation Phone: (949) 396-4041
Trade Name:	Masimo W1
Common Name:	Electrocardiograph
Classification Regulation/ Product Code:	21 CFR 870.2340, Class II/DPS
Additional Product Codes:	DQA DXH
Establishment Registration Number:	3011353843
Reason for Premarket Notification:	New Device
Predicate Device:	K201456 – Withings Scan Monitor
Reference Device:	K221260 – CSF-3

1.0 Device Description

The Masimo W1 is a watch that incorporates the W1 Module, which is the device that is responsible for the physiological signal detection and algorithm in providing the supported parameters. The module incorporates ECG functionality for Heart Rate Monitoring and Masimo SET Pulse Oximetry technology so that it can provide both ECG (Heart Rate parameter) and Masimo SET Pulse Oximetry parameters. The parameter output from the W1 Module is displayed on the touchscreen watch interface.

As part of the Masimo W1 watch, the Masimo W1 Module is integrated into the Masimo W1 watch platform, which consists of a typical IT hardware platform to enable other non-medical smart watch features (e.g., step counting, walking, running, fall detection and rise to wake).

See Table 1 below for the Masimo W1 Specifications.

Table 1 - Specifications	
Feature	**Specifications**
Continuous Display of Parameter Data	Yes
User Interface	Touchscreen

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Table 1 - Specifications	
Feature	**Specifications**
Performance Specifications	
SpO2, No Motion/ Low Perfusion (70-100%)	2% adults
Pulse Rate, No Motion (25-240 bpm)	3 bpm adults
Heart Rate (25-240 bpm)	≤ 5 bpm adults
Electrical Specifications	
Battery	Internal Rechargeable Li-Ion
Mechanical Specifications	
Size	40 mm (1.57”)
Display Type	Touchscreen
Weight	54 g (including watchband)
Environmental Specifications	
Operating Temperature	0 to 35 °C (32 to 95°F)
Operating Humidity	10% to 95% RH (non-condensing)
Storage/Transport Temperature	-20°C to 60°C (-4°F to 140°F)
Storage/Transport Humidity	10% to 95% RH (non-condensing)
Classification per IEC 60601-1	
Electrical Safety	IEC 60601-1
EMC	IEC 60601-1-2
Electrical Isolation Type	Internally Powered
Applied Part Type	CF Applied Part
Ingress Protection	IP24
Mode of Operation	Continuous

2.0 Intended Use/ Indications for Use

Masimo W1™ and the integrated Masimo W1 module are intended for the spot-check determination of Heart Rate using a single-channel electrocardiogram (ECG). The Masimo W1 and the integrated Masimo W1 module records, stores, transfers, and displays the single-channel ECG for the manual interpretation of heart rate. It is worn on the wrist and also provides other continuous parameters technologies (e.g., pulse oximetry).

The Masimo W1™ and the integrated Masimo W1 module are also intended for the spot-checking of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR). The Masimo W1 and the integrated Masimo W1 Module are indicated for adults in hospitals, clinics, long-term care facilities, and homes.

3.0 Technological Characteristics

Principle of Operation

Electrocardiogram (ECG)

The ECG feature on Masimo W1 relies on the principle that the electrical signals can be detected as different parts of the heart contract and relax during a cardiac cycle allowing the detection of heart activity and for the estimation of heart rate (HR). The change in polarization of the heart muscles creates electrical signals that are propagated so that they can be detected at the skin surface of the wrist.

Pulse Oximetry-Based Parameters

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The Masimo SET pulse oximeter technology relies on the Beer-Lambert law and the following principles of pulse oximetry:

- Oxyhemoglobin (oxygenated blood) and deoxyhemoglobin (non-oxygenated blood) differ in their absorption of red and infrared light (spectrophotometry).

- The amount of arterial blood in tissue changes with your pulse (photoplethysmography). Therefore, the amount of light absorbed by the varying quantities of arterial blood changes as well.

Mechanism of Action for Achieving the Intended Effect

The Masimo W1 watch achieves its intended effect through the integrated Masimo W1 Module that provides both the electrical and optical sensing technology and parameter algorithms. The W1 Module is integrated into the W1 watch so that the sensing components contact the skin on the wrist. The top of the watch is provided with an electrical sensing pad that is contacted by the two fingers on the opposing hand. Contacting the electrical sensing pad allows for the detection of the ECG signal when the ECG feature is activated on the watch touchscreen. Once the ECG feature is activated, it detects and calculates the heart rate.

The Masimo SET pulse oximetry-based parameters are supported by the W1 Module's optical sensing components located on the bottom of the module that contacts the skin on the wrist. The W1 Module continuously detects and processes the optical signals that change with the transmission of LED light into the wrist tissue. The W1 Module utilizes multiple wavelengths of light and advanced signal processing techniques to isolate the arterial signal from other static factors (e.g., skin pigment) to establish the ratio used in the estimation of the SpO2. The pulse rate is determined by the periodic changes in the photoplethysmograph (PPG). The parameters are then continuously updated and displayed on the watch so that it can be viewed, recorded, and/or transferred. The use of the Masimo W1 watch can be discontinued by taking off the watch or deactivating the continuous parameters from the watch's touchscreen.

4.0 Summary of Technological Characteristics of Subject Device Compared to Predicate Device

Similarities and Differences between Predicate and Subject Device

The subject device, Masimo W1, and the predicate device, Scan Monitor (K201456), have the following key similarities:

- Both devices have the same intended use;
- Both devices rely on the same principles of operation;
- Both devices are indicated for the same population of prescription and OTC users;

The subject device, Masimo W1, and the predicate device, Scan Monitor (K201456), have the following key differences:

- The subject device does not support ECG rhythm classifications (e.g., AFib);
- The subject device continuously updates pulse oximetry parameter data.

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The subject device and predicate devices were found to have the same intended use without any technological differences that raise different questions of safety and effectiveness.

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Feature 510(k) Number	Masimo W1 Subject Device	Withings Scan Monitor Primary Predicate (K201456)	Comparison to Predicate Device
General Information			
Classification Regulation/ Product Code	21 CFR 870.2340, Class II/DPS	21 CFR 870.2340, Class II/DPS	Same
Product Code(s)	DQA DXH	DQA DXH	Same
Indications for Use	Masimo W1™ and the integrated Masimo W1 module are intended for the spot-check determination of Heart Rate using a single-channel electrocardiogram (ECG). The Masimo W1 and the integrated Masimo W1 module records, stores, transfers, and displays the single-channel ECG for the manual interpretation of heart rate. It is worn on the wrist and also provides other-continuous parameters technologies (e.g., pulse oximetry). The Masimo W1™ and the integrated Masimo W1 module are also intended for the spot-checking of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR). The Masimo W1 and the integrated Masimo W1 Module are indicated for adults in hospitals, clinics, long-term care facilities, and homes.	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.	Similar. The subject device has similar indications as the predicate for ECG HR and Pulse Oximetry
	Technological Characteristics		

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Feature 510(k) Number	Masimo W1 Subject Device	Withings Scan Monitor Primary Predicate (K201456)	Comparison to Predicate Device
Principles of Operation	The W1 Module software analyzes the patterns in the ECG waveform to determine manual interpretation of Heart Rate. The Masimo SET pulse oximeter technology relies on the Beer-Lambert law and the following principles of pulse oximetry: • Oxyhemoglobin (oxygenated blood) and deoxyhemoglobin (non-oxygenated blood) differ in their absorption of red and infrared light (spectrophotometry). • The amount of arterial blood in tissue changes with your pulse (photoplethysmography). Therefore, the amount of light absorbed by the varying quantities of arterial blood changes as well.	The iECG software analyzes the patterns in the ECG waveform to determine different types of known heart activity (e.g., Heart Rate, Atrial Fibrillation). Scan Monitor pulse oximetry technology relies on the differential absorption by blood of red (660nm) and infrared light (940nm) which relies on the Beer-Lambert law for the principles of pulse oximetry.	Similar. The subject device utilizes the same principles related to ECG and Pulse Oximetry.
Supported Measured Parameters	HR, SpO2, PR	HR, SpO2	Different. The subject device provides additional pulse oximetry-based features (i.e., PR). Testing is provided to support the PR performance.

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Feature 510(k) Number	Masimo W1 Subject Device	Withings Scan Monitor Primary Predicate (K201456)	Comparison to Predicate Device
Supported Calculated features	Pi	HRV, AFib Classification	Different. The subject device provides Pi. Testing is provided to support the Pi feature.
User Interface	Touchscreen	Touchscreen	Same
	Performance Specifications (Arms)		
SpO2 (70-100%)	2%, adults (No Motion/ Low Perfusion)	3%, adults (No Motion)	Different. Subject device includes performance testing to support improved specification.
Pulse Rate (25-240 bpm)	3 bpm	Not supported	Different. Subject device includes performance testing to support improved specification.
Heart Rate (25-240 bpm)	5 bpm	Not Known	Testing is provided to support the specification.
	Electrical Specifications		
Battery	Internal Rechargeable	Internal Rechargeable	Same
	Mechanical Specifications		
Watch Face Size	40 mm (1.57”)	38 mm or 42 mm	Similar. Testing is provided to support the substantial equivalence.
Weight	54 g (including watchband)	58 gms or 83gms	Similar. The weight difference is minor and is consistent with other marketed watches.
	Environmental Specifications		

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Feature 510(k) Number	Masimo W1 Subject Device	Withings Scan Monitor Primary Predicate (K201456)	Comparison to Predicate Device
Operating Temperature	0 to 35 °C (32 to 95°F)	-10 to 45 °C (14 to 113°F)	Similar. Testing is provided to support the specification.
Operating Humidity	10% to 95%, non-condensing	Not Known	Testing is provided to support the specification.
Storage/Transport Temperature	-20 to 60°C (-4 to 140°F)	-20 to 85°C (4 to 185°F)	Similar. Testing is provided to support the specification.
Storage/Transport Humidity	10% to 95%, non-condensing	Not Known	Testing is provided to support the specification.
	Classification per IEC 60601-1		
Electrical Safety	IEC 60601-1	IEC 60601-1	Same
EMC	IEC 60601-1-2	IEC 60601-1-2	Same
Ingress Protection	IP24	Not Known.	Testing is provided to support the specification.
Mode of Operation	Continuous	Continuous	Same

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5.0 Performance Data

The following non-clinical testing was provided to support the non-parameter specifications and the substantial equivalence of the subject device.

- Biocompatibility in accordance with ISO 10993-1
- EMC testing per IEC 60601-1-2
- Electrical safety testing per IEC 60601-1
- Environmental and Mechanical testing
- Cleaning Validation
- Software verification and validation testing per FDA Software Guidance
- Human Factors Usability testing per FDA Human Factors and Usability Guidance

The following are the list of standards that were used as part of the evaluation:

- IEC 60601-1:2005/2012
- IEC 60601-1-2:2014
- IEC 60601-1-6:2013
- IEC 60601-1-11:2015
- IEC 60601-2-27:2011
- IEC 60601-2-47:2012
- ISO 80601-2-61:2017
- ISO 10993-1:2018
- IEC 62304:2015
- IEC 62366-1:2015

Performance Bench Testing

Performance bench testing for the Masimo W1 is included in this submission to support both ECG HR and Pulse Oximetry based parameter performance.

Biocompatibility Testing

Biocompatibility testing in accordance with ISO 10993-1 is included as part of this submission to support the acceptability of the biocompatibility risks.

Electromagnetic Compatibility, Electrical Safety, Environmental, Mechanical and Cleaning

EMC testing was conducted in accordance with IEC 60601-1-2: 4.1 Edition and the electrical safety in accordance with the IEC 60601-1 standard. Environmental, mechanical, cleaning, and chemical resistance testing was also provided to support the substantial equivalence of the Masimo W1.

Software Verification and Validation Testing

Software verification and validation testing were conducted, and documentation was provided as

recommended by *FDA Guidance for the Content of Premarket Submissions for Software Device Software Functions, June 2023.* The software was found to fit in the category of products that would require Basic Documentation Level because the failure or latent flaw of the device software function would not present a hazardous situation with a probable risk of death or serious injury to either a patient, user of the device or others in the environment of use prior to the implementation of the risk controls. The software does not provide any data that is considered life supporting.

Human Factors Usability Testing

To support the usability of the Masimo W1, human factors and usability risks were evaluated to be acceptably mitigated in accordance with FDA Guidance*, Applying Human Factors and Usability Engineering to Optimize Medical Device Design,* dated February 3, 2016. The testing was found to support acceptability of the human factors and usability risks.

Clinical Performance Testing

To support the performance of the Masimo W1, clinical data is provided to support of the performance of the Masimo W1. To address potential concerns related to skin pigment discrepancies in pulse oximetry, the SpO2 clinical testing included 31 subjects with varying skin pigmentations measured using a color-based scale, Massey-Martin. The results separated by skin pigment supported the performance of the Masimo W1 across different skin tones.

The SpO2 performance testing was conducted in accordance with the ISO 80601-2-61. The prospective clinical study included 31 healthy volunteer subjects, including 13 light, 12 medium and 6 dark pigmented subjects, which exceeded the ISO 80601-2-61 minimum sample size requirements and the minimum number of dark pigmented subjects in accordance with the FDA Guidance for Pulse Oximeters. Subjects were classified as dark and light based upon their Massey-Martin scores, 1-3 classified as "Light", 4-6 classified as "Medium" and 7-10 as "Dark" or subjects with more skin pigment.

The overall performance was 1.62% Arms after adjusting for repeated measures. The results support the specification of 2% Arms across the range of 70%-100% SaO2. The breakdown of the performance for dark, medium, and light subjects is provided below.

Pigmentation	Bias	Precision	A_{RMS}	Adjusted Precision	Adjusted A_{RMS}	Adjusted LOA	Nsubj	Npairs
Dark (Massey 7-10)	0.37	1.64	1.68	1.78	1.82	[-3.14, 3.88]	6	329
Medium (Massey 4-6)	-0.26	1.58	1.60	1.65	1.67	[-3.49, 2.97]	12	724
Light (Massey 1-3)	0.56	1.41	1.51	1.48	1.58	[-2.34, 3.46]	13	831

To clinically validate the performance of the heart rate (HR) feature on the Masimo W1 watch, a prospective clinical study was conducted on 61 subjects where the spot-check HR measurements obtained

from the W1 module were compared to an FDA cleared ECG reference measurement. The testing supported the claimed heart rate performance and its substantial equivalence.

To clinically validate the ECG waveform quality of the Masimo W1, the ECG waveforms collected by the Masimo W1 were compared to Lead I of a gold standard reference of a 12-Lead ECG by three board certified cardiologists. The testing supported the acceptability of the detected ECG waveforms.

6.0 Conclusion

The data supported the substantial equivalence of the Masimo W1.