August 8, 2024

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

Re: K240229
Trade/Device Name: Masimo W1
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS, QDA, DXH
Dated: July 12, 2024
Received: July 12, 2024

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).

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240229

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 the spot-checking of other continuous parameters (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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MASIMO CORPORATION
52 Discovery
Irvine, CA 92618

510(k) Summary

Submitter and Address of Manufacturing Facility:	Masimo Corporation 52 Discovery Irvine, CA 92618 Phone: (949) 297-7000 FAX: (949) 297-7592
Date:	January 26, 2024
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 Code:	DQA, DXH
Establishment Registration Number:	3011353843
Reason for Premarket Notification:	Addition of Bluetooth connectivity to Masimo W1
Predicate Device:	K232512 – Masimo W1

1 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 W1 Module incorporates ECG functionality and Masimo SET Pulse Oximetry technology so that it can provide both ECG parameters and Masimo SET pulse oximetry parameters.

As part of this submission, Bluetooth connectivity has been added to the Masimo W1 to support the wireless communication of monitored data to a compatible smart device application, such as the Masimo SafetyNet. The sharing of the parameter data to applications like the Masimo SafetyNet allows for users to see and track their data using their smart phones. Smart phone applications can also help to share information to caregivers and healthcare professionals.

The Masimo W1 specifications are provided in Table 1-1 below:

Table 1-1 Masimo W1 Specifications

Feature	**Specifications**
Remote Access to Parameter Data	Yes
Supported Communication	Wireless
Types of Wireless Communication	Bluetooth
Communication Security	Encryption
Continuous Display of Parameter Data	Yes
Performance Specifications	
SpO2, No Motion/ Low Perfusion (70-100%)	2% adults
Pulse Rate (25-240 bpm)	3 bpm adults

510(k) Summary

Table 1-1 Masimo W1 Specifications	
Feature	**Specifications**
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 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 the spot-checking of other continuous parameters (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 Technological Characteristics

Principle of Operation

There were no changes made to the principles of operation of the subject device, Masimo W1, from the previous clearance under K232512.

Pulse oximetry-based parameters

The Masimo W1 still relies on Masimo SET pulse oximetry, which relies on the Beer-Lambert law and the following principles of pulse oximetry to provide estimates of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate:

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- 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.

Electrocardiogram (ECG)

The ECG feature on Masimo W1 still 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 the electrical signals that are propagated so that they can be detected at the skin surface of the wrist.

Mechanism of Action for Achieving the Intended Effect

There were no changes to the mechanism of action of the Masimo W1 from the previous clearance under K232512, except for the addition of Bluetooth connectivity.

The Masimo W1 still achieves its intended effect through the integrated W1 Module that provides both the electrical and optical sensing technology and parameter algorithms. The W1 Module is integrated into the Masimo 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 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 monitored parameters are then continuously updated and displayed on the watch so that it can be viewed, recorded, and/or transferred. As part of this submission, the Masimo W1 is also provided with Bluetooth connectivity to support the wireless communication of the monitored data to a smart device application for supplemental display. 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 Discussion of Similarities and Differences Between Primary Predicate and Subject Device

Similarities and Differences between Primary Predicate and Subject Device

The subject device, Masimo W1, and the predicate device, Masimo W1 (K232512), have the following key similarities:

510(k) Summary

- 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, Masimo W1 (K232512), have the following key differences:

- The subject device is provided with Bluetooth connectivity.

Between the subject device and the predicate device, they have the same intended use with a technological difference. The technological difference from the predicate device is that the subject device is provided with Bluetooth connectivity to support the wireless communication of monitored data to a compatible smart device application. To support the addition of the Bluetooth connectivity does not raise different questions of safety and effectiveness, testing was conducted. The testing supported there were no significant differences in the safety of the subject device as compared to the predicate device.

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510(k) Summary

Table 4-1 Comparison between subject and predicate device			
Feature **510(k) Number**	**Masimo W1** **Subject Device**	**Masimo W1** **Predicate Device** **(K232512)**	**Comparison to Predicate Device**
General Information			
Classification	Class II, Electrocardiograph	Class II, Electrocardiograph	Same
Regulation, Product Code	21 CFR 870.2340, Class II/DPS	21 CFR 870.2340, Class II/DPS	Same
Additional 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.	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.	Same
Technological Characteristics			
Principles of Operation	The W1 Module software analyzes the patterns in the ECG waveform to determine manual interpretation of Heart Rate.	The W1 Module software analyzes the patterns in the ECG waveform to determine manual interpretation of Heart Rate.	Same

510(k) Summary

Table 4-1 Comparison between subject and predicate device			
Feature **510(k) Number**	**Masimo W1** **Subject Device**	**Masimo W1** **Predicate Device** **(K232512)**	**Comparison to Predicate Device**
	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 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.	
Supported Measured Parameters	HR, SpO2, PR	HR, SpO2, PR	Same
Supported Calculated features	Pi	Pi	Same
Supported Communication	Wireless	N/A	Different. Subject device is provided with wireless communication (Bluetooth). Testing is provided to support substantial equivalence.
Wireless Type	Bluetooth	N/A	Different. Subject device is provided with Bluetooth connectivity to share data.

510(k) Summary

Table 4-1 Comparison between subject and predicate device			
Feature 510(k) Number	**Masimo W1 Subject Device**	**Masimo W1 Predicate Device (K232512)**	**Comparison to Predicate Device**
			Testing is provided to support substantial equivalence.
Communication Security	Encryption	N/A	Different. Subject device is provided with application layer encryption.
User Interface	Touchscreen	Touchscreen	Same
Performance Specifications			
SpO2, (70-100%)	2%, adults (No Motion/ Low Perfusion)	2%, adults (No Motion/ Low Perfusion)	Same
Pulse Rate (25-240 bpm)	3 bpm	3 bpm	Same
Heart Rate (25-240 bpm)	5 bpm	5 bpm	Same
Electrical Specifications			
Battery	Internal Rechargeable	Internal Rechargeable	Same
Mechanical Specifications			
Watch Face Size	40 mm (1.57”)	40 mm (1.57”)	Same
Weight	54 g (including watchband)	54 g (including watchband)	Same
Environmental Specifications			
Operating Temperature	0 to 35 °C (32 to 95°F)	0 to 35 °C (32 to 95°F)	Same
Operating Humidity	10% to 95%, non-condensing	10% to 95%, non-condensing	Same
Storage/Transport Temperature	-20 to 60°C (-4 to 140°F)	-20 to 60°C (-4 to 140°F)	Same
Storage/Transport Humidity	10% to 95%, non-condensing	10% to 95%, non-condensing	Same
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	IP24	Same

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510(k) Summary

Table 4-1 Comparison between subject and predicate device			
Feature **510(k) Number**	**Masimo W1** **Subject Device**	**Masimo W1** **Predicate Device** **(K232512)**	**Comparison to Predicate Device**
Mode of Operation	Continuous	Continuous	Same

510(k) Summary

5 Performance Data

As part of this submission, non-clinical testing was included to support the addition of the Bluetooth connectivity and the substantial equivalence of the subject device.

Performance Bench Testing

Bench testing for the Masimo W1 was included in this submission to support the addition of the Bluetooth capability.

Biocompatibility Testing

As there were no changes made to the patient contacting materials of the subject device, Masimo W1, from the previous clearance under K232512, no new biocompatibility testing was included in this submission.

Electromagnetic Compatibility, Electrical Safety, Environmental, Mechanical and Cleaning

As there were no hardware changes made to the subject device, Masimo W1, from the previous clearance under K232512, no new electrical safety, environmental, mechanical, and cleaning testing was included as part of this submission.

Software Verification and Validation Testing

Software verification and validation testing were conducted and provided as part of this submission as recommended by the FDA Guidance, *"Content of Premarket Submissions for Software Device Software Functions"*, June 2023 to support the addition of the Bluetooth connectivity.

The Masimo W1 software was found to fit 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.

Wireless Testing

The Masimo W1 is provided with Bluetooth connectivity to support the wireless communication of the monitored data. Wireless testing was conducted in accordance with the FDA Guidance, *"Radio-Frequency Wireless Technology in Medical Devices"*, August 14, 2013, to support the Bluetooth feature provided as part of the device.

Cybersecurity Testing

Cybersecurity documentation was provided as part of this submission in accordance with the FDA Guidance, *"Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions"*. The cybersecurity of the Masimo W1 was implemented using a risk-based approach using the NIST 800-30 framework.

Human Factors and Usability Testing

510(k) Summary

Usability testing has been conducted to support human factors and usability risks associated with the use of the Masimo W1 Bluetooth connectivity is acceptable. The human factors and usability process was conducted in accordance with the FDA Guidance, "*Applying Human Factors and Usability Engineering to Medical Devices*", February 3, 2016.

Clinical Testing

No clinical testing was needed to support the addition of the Bluetooth feature to the subject device.

6 Conclusion

Based on the data provided as part of this submission, the subject device, Masimo W1, was found to be substantially equivalent.