April 3, 2025

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

Re: K243305
Trade/Device Name: Masimo W1
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS, DQA, DXH, QDA
Dated: February 25, 2025
Received: February 25, 2025

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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)*

K243305

Device Name

Masimo W1

Indications for Use *(Describe)*

Masimo W1™ and the integrated Masimo W1 Module are intended to record, store and transfer single-channel electrocardiogram (ECG) rhythms. The Masimo W1 also displays ECG rhythms, and the Masimo W1 Module detects the presence of atrial fibrillation. The Masimo W1 and the integrated Masimo W1 Module are intended for use by healthcare professionals, patients with known or suspected heart conditions, and health-conscious individuals.

Masimo W1 Module ECG software is an over-the-counter (OTC) software that operates on the Masimo W1 Module that can be used with compatible watches (e.g., Masimo W1). The software is intended to create, record, store, transfer, and display a single channel electrocardiogram (ECG) for informational use only in adults 22 years and older. It supports the classification of either atrial fibrillation (AFib) or sinus rhythm with the intention of aiding heart rhythm identification; it is not intended to replace traditional methods of diagnosis or treatment. The software is not intended for users with other known arrhythmias and users should not interpret or take clinical action based on the device output without consultation of a qualified healthcare professional.

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.

MASIMO CORPORATION
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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:	April 2nd 2025
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, QDA
Establishment Registration Number:	3011353843
Reason for Premarket Notification:	Update to add Atrial Fibrillation (AFib) Classification Feature
Primary Predicate:	K240229 – Masimo W1
Secondary Predicate:	K201456 - Withing Scan Monitor
Tertiary Predicate	K201168 – Samsung ECG Monitor

1 Device Description

The Masimo W1 is a watch that incorporates the Masimo W1 Module, which is the device that is responsible for the physiological signal detection and algorithm used to support the different parameters. The Masimo W1 Module incorporates spot check ECG functionality and Masimo SET Pulse Oximetry technology so that it can provide both ECG and Masimo SET pulse oximetry parameters. As part of this submission, Masimo is requesting clearance for an automated atrial fibrillation "AFib" Classification Feature that is used to analyze the single channel ECG waveform.

The parameter outputs from the Masimo W1 Module are communicated and displayed on the watch screen so that the data can be viewed and recorded. Masimo W1 also supports wireless communication of monitored data to a compatible smart device application. The sharing of the parameter data to the applications allows the 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 - Specifications	
Feature	**Specifications**
Continuous Display of Parameter Data	Yes
Performance Specifications	
SpO2, No Motion/ Low Perfusion (70-100%)	2% Arms adults

510(k) Summary

Table 1-1 - Specifications	
Feature	**Specifications**
Pulse Rate (25-240 bpm)	3 bpm Arms adults
Heart Rate (25-240 bpm)	≤5 bpm adults
ECG Rhythm Classifications	Atrial Fibrillation, Sinus Rhythm
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 Indications for Use

Masimo W1™ and the integrated Masimo W1 Module are intended to record, store and transfer single-channel electrocardiogram (ECG) rhythms. The Masimo W1 also displays ECG rhythms, and the Masimo W1 Module detects the presence of atrial fibrillation. The Masimo W1 and the integrated Masimo W1 Module are intended for use by healthcare professionals, patients with known or suspected heart conditions, and health-conscious individuals.

Masimo W1 Module ECG software is an over-the-counter (OTC) software that operates on the Masimo W1 Module that can be used with compatible watches (e.g., Masimo W1). The software is intended to create, record, store, transfer, and display a single channel electrocardiogram (ECG) for informational use only in adults 22 years and older. It supports the classification of either atrial fibrillation (AFib) or sinus rhythm with the intention of aiding heart rhythm identification; it is not intended to replace traditional methods of diagnosis or treatment. The software is not intended for users with other known arrhythmias and users should not interpret or take clinical action based on the device output without consultation of a qualified healthcare professional.

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.

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3 Technological Characteristics

Principle of Operation

There were no changes made to the principles of operation from the previously cleared features of the Masimo W1 under K240229. However, as part of this submission, an AFib Classification Feature is added that expands upon the principles of operation for the ECG feature.

Electrocardiogram (ECG)

Same as under K240229, the ECG feature on Masimo W1 relies on the principle that the electrical signals can be detected as the heart contracts and relaxes during each cardiac cycle allowing for the estimation of heart rate (HR). The depolarization and repolarization of the heart muscle creates electrical signals that are propagated for recording on the skin surface at the wrist.

The Masimo W1 Module ECG software can also analyze these electrical signals for signs of AFib. To detect AFib, the software relies on the understanding that AFib rhythms are defined as "irregularly irregular" heartbeat patterns.

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:

- 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

There were no changes to the mechanism of action for the Masimo W1 from the previous clearance under K240229.

The Masimo W1 still achieves its intended effect through the integrated Masimo W1 Module that provides both the electrical and optical sensing technology and parameter algorithms. The Masimo W1 Module is integrated into the Masimo W1 watch so that the sensing components contact the skin on the wrist. 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 recording 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 and determines the rhythm classification (e.g., Sinus Rhythm, Atrial Fibrillation).

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The Masimo SET pulse oximetry-based parameters are supported by the Masimo W1 Module's optical sensing components located on the bottom of the module that contacts the skin on the wrist. The Masimo W1 Module continuously detects and processes the optical signals that change with the transmission of LED light into the wrist tissue. The Masimo 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. 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 Predicate and Subject Device

The subject device, Masimo W1 with AFib Classification Feature, and the predicate device, Masimo W1 (K240229), have the following key similarities:

- Both devices have similiar intended use.
- Both devices rely on the same principles of operation.

The subject device, Masimo W1 with AFib Classification Feature, and the predicate device, Masimo W1 (K240229), have the following key difference:

- The subject device is provided with an AFib Classification Feature.

The key difference between the subject device and predicate device is the addition of the AFib Classification Feature. The intended use of this feature is substantially equivalent to the predicate devices. To support there are no technological characteristic differences that raise different questions of safety and effectiveness, clinical performance data of the AFib classification feature is provided as part of this submission. The test results support the substantial equivalence of the subject device.

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510(k) Summary

Feature 510(k) Number	Masimo W1 Subject Device	Masimo W1 Primary Predicate (K240229)	Withing Scan Monitor Secondary Predicate (K201456)	Samsung ECG Monitor Tertiary Predicate (K201168)	Comparison to Primary Predicate
General Information					
Classification	Class II, Electrocardiograph	Class II, Electrocardiograph	Class II, Electrocardiograph	Class II, Electrocardiograph software for Over-The-Counter Use	Same.
Regulation/ Product Code	21 CFR 870.2340, Class II/ DPS	21 CFR 870.2340, Class II/ DPS	21 CFR 870.2340, Class II/ DPS	21 CFR 870.2345, Class II/ QDA	Same.
Additional Product Code(s)	DQA DXH QDA	DQA DXH	DQA DXH	QDA	The subject device includes an additional product code QDA to support atrial fibrillation classification feature. The addition of the product code is the same as the tertiary predicate device that has the same intended use
Intended Use	Masimo W1™ and the integrated Masimo W1 module are intended to record, store and transfer single-channel electrocardiogram (ECG) rhythms	The Masimo W1 and the integrated Masimo W1 module records, stores, transfers, and displays the single-channel electrocardiogram (ECG).	The Scan Monitor is intended to record, store and transfer single-channel electrocardiogram (ECG) rhythms.	The app is intended to create, record, store, transfer, and display a single channel electrocardiogram (ECG).	Same.
Indications for Use	Masimo W1 also displays ECG rhythms, and the Masimo W1 Module detects the presence of atrial fibrillation.	The Masimo W1 and the integrated Masimo W1 module records, stores, transfers, and displays the single-channel	The Scan Monitor also displays ECG rhythms and detects the presence of atrial fibrillation (when the monitor	The Samsung ECG Monitor Application is an over-the-counter (OTC) software-only, mobile medical	Different. The subject device is also indicated for an atrial fibrillation classification feature. The indication for the AFib feature of the subject device is similar to the secondary

510(k) Summary

Feature 510(k) Number	Masimo W1 Subject Device	Masimo W1 Primary Predicate (K240229)	Withing Scan Monitor Secondary Predicate (K201456)	Samsung ECG Monitor Tertiary Predicate (K201168)	Comparison to Primary Predicate
	The Masimo W1 and the integrated Masimo W1 Module are intended for use by healthcare professionals, patients with known or suspected heart conditions, and health-conscious individuals. Masimo W1 Module ECG software is an over-the-counter (OTC) software that operates on the Masimo W1 Module that can be used with compatible watches (e.g., Masimo W1). The software is intended to create, record, store, transfer, and display a single channel electrocardiogram (ECG) for informational use only in adults 22 years and older. It supports the classification of either atrial fibrillation (AFib) or sinus rhythm with the intention of aiding heart rhythm identification; it is not intended to replace traditional methods of	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.	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.	application operating on a compatible Samsung Galaxy Watch and Phone. The app is intended to create, record, store, transfer, and display a single channel electrocardiogram (ECG), similar to a Lead I ECG, for informational use only in adults 22 years and older. Classifiable traces are labeled by the app as either atrial fibrillation (AFib) or sinus rhythm with the intention of aiding heart rhythm identification; it is not intended to replace traditional methods of diagnosis or treatment. The app is not intended for users with other	and tertiary predicate devices under the same intended use.

510(k) Summary

Feature 510(k) Number	Masimo W1 Subject Device	Masimo W1 Primary Predicate (K240229)	Withing Scan Monitor Secondary Predicate (K201456)	Samsung ECG Monitor Tertiary Predicate (K201168)	Comparison to Primary Predicate
	diagnosis or treatment. The software is not intended for users with other known arrhythmias and users should not interpret or take clinical action based on the device output without consultation of a qualified healthcare professional. 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.			known arrhythmias and users should not interpret or take clinical action based on the device output without consultation of a qualified healthcare professional.	
Technological Characteristics					
Principles of Operation	The ECG feature on Masimo W1 relies on the principle that the electrical signals can be detected as the heart contracts and	The ECG feature on Masimo W1 still relies on the principle that the electrical signals can be	The iECG software analyzes the patterns in the ECG waveform to determine different	Unavailable.	Same.

510(k) Summary

Feature 510(k) Number	Masimo W1 Subject Device	Masimo W1 Primary Predicate (K240229)	Withing Scan Monitor Secondary Predicate (K201456)	Samsung ECG Monitor Tertiary Predicate (K201168)	Comparison to Primary Predicate
	relaxes during each cardiac cycle allowing for the estimation of heart rate (HR). The depolarization and repolarization of the heart muscle creates electrical signals that are propagated for recording on the skin surface at the wrist. The Masimo W1 Module ECG software can also analyze these electrical signals for signs of AFib. To detect AFib, the software relies on the understanding that AFib rhythms are defined as "irregularly irregular" heartbeat patterns. 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	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. The Masimo SET pulse oximeter technology relies on the Beer-Lambert law and the following principles of pulse oximetry: • Oxyhemoglobin (oxygenated blood) and	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.		

510(k) Summary

Feature 510(k) Number	Masimo W1 Subject Device	Masimo W1 Primary Predicate (K240229)	Withing Scan Monitor Secondary Predicate (K201456)	Samsung ECG Monitor Tertiary Predicate (K201168)	Comparison to Primary Predicate
	arterial hemoglobin (SpO2) and pulse rate: • 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.	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 Pulse Oximetry	SpO2, PR	SpO2, PR	SpO2, PR	N/A	Same.

510(k) Summary

Feature 510(k) Number	Masimo W1 Subject Device	Masimo W1 Primary Predicate (K240229)	Withing Scan Monitor Secondary Predicate (K201456)	Samsung ECG Monitor Tertiary Predicate (K201168)	Comparison to Primary Predicate
Parameters					
Supported Measured ECG Parameters	HR	HR	HR, HRV	HR	Same.
Supported Rhythm Classifications	Atrial Fibrillation, Sinus Rhythm	N/A	Atrial Fibrillation, Sinus Rhythm	Atrial Fibrillation, Sinus Rhythm	Different. The subject device provides an Atrial Fibrillation classification feature similar to the secondary and tertiary predicate devices. Testing is provided to support the substantial equivalence.
Supported Calculated features	Pi	Pi	N/A	N/A	Same.
Lead	A single channel ECG, similar to Lead 1 ECG.	A single channel ECG, similar to Lead 1 ECG.	A single channel ECG, similar to Lead 1 ECG.	A single channel ECG, similar to Lead 1 ECG.	Same.
Performance specifications					
SpO2, (70-100%)	2%, adults (No Motion/ Low Perfusion)	2%, adults (No Motion/ Low Perfusion)	3%, adults (No Motion)	N/A	Same.
Pulse Rate (25-240 bpm)	3 bpm	3 bpm	Not supported	N/A	Same.
Heart Rate (25-240 bpm)	5 bpm	5 bpm	Not Known	N/A	Same.
Rhythm Classification	Atrial Fibrillation Sensitivity: 99.3%	N/A	Atrial Fibrillation Sensitivity: 96.3%	Atrial Fibrillation Sensitivity: 98.1%	AFib feature is being added. The performance has been evaluated to be

510(k) Summary

Feature 510(k) Number	Masimo W1 Subject Device	Masimo W1 Primary Predicate (K240229)	Withing Scan Monitor Secondary Predicate (K201456)	Samsung ECG Monitor Tertiary Predicate (K201168)	Comparison to Primary Predicate
Performance	Sinus Rhythm Specificity: 100%		Sinus Rhythm Specificity: 100%	Sinus Rhythm Specificity: 100%	substantially equivalent to the secondary and tertiary predicates.
Electrical Specifications					
Battery	Internal Rechargeable	Internal Rechargeable	Internal Rechargeable	N/A	Same.
Mechanical Specifications					
Watch Face Size	40 mm (1.57”)	40 mm (1.57”)	38 mm or 42 mm	N/A	Same.
Weight	54 g (including watchband)	54 g (including watchband)	58 g or 83g	N/A	Same.
Environmental Specifications					
Operating Temperature	0 to 35 °C (32 to 95°F)	0 to 35 °C (32 to 95°F)	-10 to 45 °C (14 to 113°F)	N/A	Same.
Operating Humidity	10% to 95%, non-condensing	10% to 95%, non-condensing	Not Known	N/A	Same.
Storage/Transport Temperature	-20 to 60°C (-4 to 140°F)	-20 to 60°C (-4 to 140°F)	-20 to 85°C (4 to 185°F)	N/A	Same.
Storage/Transport Humidity	10% to 95%, non-condensing	10% to 95%, non-condensing	Not Known	N/A	Same.
Classification per IEC 60601-1					
Electrical Safety	IEC 60601-1	IEC 60601-1	IEC 60601-1	N/A	Same.
EMC	IEC 60601-1-2	IEC 60601-1-2	IEC 60601-1-2	N/A	Same.
Ingress Protection	IP24	IP24	Not Known.	N/A	Same.
Mode of Operation	Continuous	Continuous	Continuous	N/A	Same.

510(k) Summary

5 Performance Data

As part of this submission, clinical and non-clinical testing was included to support addition of the Atrial Fibrillation Classification Feature.

Performance Bench Testing

Bench testing for the Masimo W1 was included in this submission to support the addition of the Atrial Fibrillation Classification Feature.

Biocompatibility Testing

As there were no changes made to the patient contacting materials of the subject device from the previous clearance under K240229, 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 from the previous clearance under K240229, 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 AFib detection feature.

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

As there were no changes made to the subject device from the previous clearance under K240229, no new wireless testing was included as part of this submission.

Cybersecurity Testing

As there were no changes made to the subject device wireless communication from the previous clearance under K240229, thus no new cybersecurity testing was included as part of this submission.

Human Factors and Usability Testing

Human factors testing demonstrated the acceptability of the human factors and usability risks.

510(k) Summary

Clinical Testing

To support the performance of the Masimo W1 with Atrial Fibrillation Classification Feature, clinical validation testing is provided as part of this submission.

Masimo W1 ECG AFib Classification feature Performance

Prospective clinical testing was conducted to validate the AFib Classification Feature on adult subjects from 4 different sites. The testing included subjects with wide range of age and BMI.
The breakdown of the performance results, including the 95% Confidence Interval, are provided below in Table 5-1.

Table 5-1

Performance Metrics	Performance Result
Sensitivity	99.3% [96.3%,100%]
Specificity	100% [97.8%, 100%]
PPV	100% [97.5%, 100%]
Unclassified Rate	5.0%
Noise Rate	1.7%

Masimo W1 ECG Waveform Quality Analysis

To assess the quality of Masimo W1 ECG waveform in adults, the ECG waveform was accessed qualitatively and quantitatively by comparing similarity between Masimo W1 and gold-standard 12 lead ECG as reference. The qualitative assessment found a 98% [95% CI: 96% -98%] agreement by qualified clinicians in the analysis of the Masimo W1 ECG waveforms to that of the reference Lead I of a gold-standard 12-lead ECG reference.

The quantitative analysis showed key ECG features (QRS amplitude and QRS width) of the Masimo W1 ECG waveforms were similar to Lead I of a gold-standard 12-lead ECG reference.

6 Conclusion

The data supported the substantial equivalence of the subject device.