



January 31, 2024

Masimo Corporation  
Kertana Shankar  
Regulatory Specialist II  
52 Discovery  
Irvine, California 92618

Re: K214115

Trade/Device Name: MightySat – OTC  
Regulation Number: 21 CFR 870.2700  
Regulation Name: Oximeter  
Regulatory Class: Class II  
Product Code: OLK  
Dated: September 19, 2022  
Received: September 20, 2022

Dear Kertana Shankar:

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

**Bradley Q. Quinn -S**

Bradley Quinn

Assistant Director

DHT1C: Division of Sleep Disordered

Breathing, Respiratory and

Anesthesia Devices

OHT1: Office of Ophthalmic, Anesthesia,

Respiratory, ENT and Dental Devices

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K214115

Device Name

MightySat-OTC

Indications for Use (Describe)

The Masimo MightySat-OTC is intended for the spot-checking of functional oxygen saturation of arterial hemoglobin (SpO<sub>2</sub>) and pulse rate (PR).

The Masimo MightySat-OTC is indicated for use with individuals 18 years and older who are well or poorly perfused under no motion conditions.

The Masimo MightySat-OTC is not intended for diagnosis or screening of lung disease and treatment decisions using the device should only be under the advice of a healthcare provider.

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 K214115

Submitter and Address of Manufacturing Facility:	Masimo Corporation 52 Discovery Irvine, CA 92618 Phone: (949) 297-7000 FAX: (949) 297-7592
Date:	December 15, 2023
Contact:	Kertana Shankar Regulatory Specialist II Masimo Corporation Phone: (949) 297-7260
Trade Name:	MightySat – OTC
Common Name:	Oximeter
Classification Regulation/ Product Code:	21 CFR 870.2700, Class II/OLK
Establishment Registration Number:	3011353843
Reason for Premarket Notification:	Over-the-counter use
Primary Predicate:	K181956 – Masimo MightySat Fingertip Pulse Oximeter
Performance Standards	No performance standards for the above device have been promulgated pursuant to Section 514.

### 1.0 Device Description

The subject device, MightySat-OTC, is a fingertip pulse oximeter that includes Masimo SET technology for the measurement of functional oxygen saturation of arterial hemoglobin (SpO<sub>2</sub>) and pulse rate (PR) in individuals 18 years and older. The predicate MightySat that was previously cleared under K181956, has the same intended use as the subject device except it is cleared for prescription use only.

The subject device is identical to the predicate with the exception that the RRp and PVi parameters have been disabled in the subject device and the labeling has been modified to provide additional information on the role of pulse oximeters for OTC users. There were no hardware changes made to the MightySat Rx (predicate device, K181956) that resulted in the MightySat-OTC. Like the predicate device, the subject device, has the combined function of a pulse oximeter monitor and a reusable sensor. It includes a color display, enclosed by plastic housing, and powered by two alkaline “AAA” batteries. It also includes optional Bluetooth wireless technology for the wireless transfer of patient data to mobile device application.



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As part of this submission, the MightySat-OTC is being submitted to be marketed for Over-The-Counter (OTC) use.

The following are specifications for MightySat-OTC:

FEATURE	SPECIFICATION
<b>Display</b>	
Display Type	OLED color display
Display Range	Oxygen Saturation (SpO <sub>2</sub> ): 0-100%
	Pulse Rate (PR): 25-240 beats per minute (BPM)
	Perfusion Index (Pi): 0.02-20%
Display Resolution	SpO <sub>2</sub> : 1%
	PR: 1 BPM
<b>Measurement Accuracy in Accordance with ISO 80601-2-61</b>	
SpO <sub>2</sub> , No Motion	70 – 100%, 1.5%, A <sub>RMS</sub> , 18 years and older
SpO <sub>2</sub> , Low Perfusion	70 – 100%, 2%, A <sub>RMS</sub> , 18 years and older
Pulse Rate, No Motion	25 – 240 BPM, 3 BPM A <sub>RMS</sub> , 18 years and older
Pulse Rate, Low Perfusion	25 – 240 BPM, 3 BPM A <sub>RMS</sub> , 18 years and older
<b>Power</b>	
Internal battery	Two Alkaline “AAA” batteries
<b>Interface</b>	
Wireless	Bluetooth LE
<b>Mechanical</b>	
Dimensions	2.9” x 1.6” x 1.2” (7.4 cm x 4.1 cm x 3.0 cm)
Weight	0.16 lbs (73 g)
<b>Environmental</b>	
Operating Temperature	5°C to +40°C, ambient humidity
Storage Temperature	-40°C to +70°C, ambient humidity
Operating/ Storage Humidity	10% to 95%, non-condensing
Atmospheric Pressure	540 mBar to 1060 mBar
<b>Mode of Operation per IEC 60601-1</b>	
Mode of Operation	Continuous

### 2.0 Intended Use/ Indications For Use

The Masimo MightySat-OTC is intended for the spot-checking of functional oxygen saturation of arterial hemoglobin (SpO<sub>2</sub>) and pulse rate (PR).

The Masimo MightySat-OTC is indicated for use with individuals 18 years and older who are well or poorly perfused under no motion conditions.

The Masimo MightySat-OTC is not intended for diagnosis or screening of lung disease and treatment decisions using the device should only be under the advice of a healthcare provider.



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### 3.0 Technological Characteristics

#### *Principle of Operation*

There has been no change to the principle of operation as part of this submission. The subject device, MightySat-OTC, utilizes the same principle of operation as the predicate device cleared under (K181956). The MightySat-OTC still relies on the principle that light is absorbed differently for oxygenated hemoglobin and deoxygenated hemoglobin and the ratio of the absorptions can be used to monitoring the changes in oxygen saturation and pulse rate. However, as part of the MightySat-OTC, the calibration curve has been adjusted to allow for improved accuracy performance, including across different skin pigments and genders.

#### *Mechanism of Action for Achieving the Intended Effect*

There has been no change to the mechanism of action as part of this submission. The subject device MightySat-OTC utilizes the same mechanism of action as the predicate device cleared under (K181956). MightySat automatically turns on when the device is opened. The device is then positioned on the patient's finger. Once the device is applied to the finger, it collects and processes physiological signals, and then displays the measurements on the device's display screen. The MightySat automatically turns off after removing the device from the finger.

### 4.0 Summary of Technological Characteristics of the subject device compared to the predicate device

#### *Similarities and Differences between Predicate and Subject Device*

The subject device, MightySat-OTC, and the predicate device, MightySat (K181956), are identical in design and have the following key similarities:

- Both devices have the same intended use;
- Both devices have the same technological characteristics;
- Both devices use the same principle of operation and mechanism of action;
- Both devices include wireless Bluetooth feature for transferring patient information from the device to a mobile device, such as a smartphone;

The subject device, MightySat-OTC, and the predicate device, MightySat (K181956), have the following key differences:

- The subject device is to be marketed for Over-The-Counter (OTC) use;
- The subject device is indicated for a subset of populations;
- The subject device is provided with an updated calibration curve for improved performance, including across different skin pigments and genders;
- The subject device does not provide the RRp and PVi features.



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Between the subject device and the predicate device, there was no change in the intended use. To address the difference in the OTC marketing, the indication for use has been modified to be more appropriate for lay users who would most benefit from the OTC availability of a medical pulse oximeter. To mitigate concerns around the OTC availability as compared to the predicate, the indications for use statement excludes the use for self-diagnosis or self-screening of medical conditions.

To support the OTC availability does not affect the safety and effectiveness, consideration was made to the factors that may be necessary for a pulse oximeter to be used as an OTC device. These factors included the usability and the demonstrated effectiveness during low blood circulation, different genders, and dark to light skin. Additionally, the labeling was made appropriate for lay users to mitigate any remaining residual risks.

There are no changes to the principle of operation or the mechanism of action from the predicate device. However, there is an update to calibration curve to allow for improved performance, including across different skin pigments and genders. The subject device also provides a reduced number of parameters from the predicate. Otherwise, there are no technological differences for the parameters provided on both devices.

The differences did not change the intended use of the subject device from the predicate. Provided the same intended use and same technological characteristics, the subject device was found to be substantially equivalent to the predicate.

See Table 4.0-1 for the comparison between the subject and predicate devices.



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Table 4.0-1 Comparison between Subject and Predicate Device			
Feature	MightySat – OTC, Subject Device	MightySat Fingertip Pulse Oximeter, Predicate	
510(k) Number	Pending	K181956	Comparison
General Information			
Indications for Use	<p>The Masimo MightySat-OTC is intended for the spot-checking of functional oxygen saturation of arterial hemoglobin (SpO<sub>2</sub>) and pulse rate (PR).</p> <p>The Masimo MightySat-OTC is indicated for use with individuals 18 years and older who are well or poorly perfused under no motion conditions.</p> <p>The Masimo MightySat-OTC is not intended for diagnosis or screening of lung disease and treatment decisions using the device should only be under the advice of a healthcare provider.</p>	<p>The Masimo MightySat Fingertip Pulse Oximeter is intended for hospitals, hospital-type facilities, home environments, and transport.</p> <p>The Masimo MightySat Fingertip Pulse Oximeter is indicated for the noninvasive spot-checking of functional oxygen saturation of arterial hemoglobin (SpO<sub>2</sub>) and pulse rate (PR) for adult and pediatric patients during both no motion and motion conditions, and for patients who are well or poorly perfused.</p> <p>The Masimo MightySat Fingertip Pulse Oximeter is indicated for the non-invasive spot checking of respiration rate (RRp) for adult.</p>	<p>Same. The devices have the same intended use, but the subject device’s indications for use has been modified to be appropriate for OTC lay users. There is no change in the intended use from the predicate device.</p> <p>The subject device also provides a subset of the parameters supported by the predicate device. The subject device does not provide PV<sub>i</sub> and RR<sub>p</sub> features. These features are supplemental to the SpO<sub>2</sub> and Pulse Rate monitoring and therefore does not change the intended use from the predicate.</p>
Classification Regulation/Product Code	21 CFR 870.2700, Class II/OLK	21 CFR 870.2700, Class II/DQA 21 CFR 868.2375, Class II/BZQ	Same as predicate, except the subject device is for OTC use and does not provide respiration rate monitoring.
Rx/ OTC	OTC	Rx	Different. Subject device is indicated for OTC use.



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<b>Table 4.0-1 Comparison between Subject and Predicate Device</b>			
<b>Feature</b>	<b>MightySat – OTC, Subject Device</b>	<b>MightySat Fingertip Pulse Oximeter, Predicate</b>	
<b>510(k) Number</b>	<b>Pending</b>	<b>K181956</b>	<b>Comparison</b>
Principle of operation	<p>Pulse oximetry is governed by the following principles:</p> <p>Oxyhemoglobin (oxygenated blood) and deoxyhemoglobin (non-oxygenated blood) differ in their absorption of red and infrared light (spectrophotometry).</p> <p>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.</p>	<p>Pulse oximetry is governed by the following principles:</p> <p>Oxyhemoglobin (oxygenated blood) and deoxyhemoglobin (non-oxygenated blood) differ in their absorption of red and infrared light (spectrophotometry).</p> <p>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.</p> <p>Respiration rate (RRp) is governed by the following principle:</p> <p>Measures the respiration rate by analyzing cyclic variations in the photoplethysmogram</p>	Same as predicate, except the subject device does not provide RRp and PVi features.
Indicated Population	18 years and older	Adult, Pediatric	Similar. Subject device is indicated for a subset of populations supported by the predicate.
<b>Display</b>			
Type	Color display	Color display	Same as predicate



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<b>Table 4.0-1 Comparison between Subject and Predicate Device</b>			
<b>Feature</b>	<b>MightySat – OTC, Subject Device</b>	<b>MightySat Fingertip Pulse Oximeter, Predicate</b>	
<b>510(k) Number</b>	<b>Pending</b>	<b>K181956</b>	<b>Comparison</b>
<b>Measurement Ranges</b>			
Oxygen Saturation (SpO <sub>2</sub> )	0-100%	0-100%	Same as predicate
Pulse Rate (PR)	25-240 beats per minute (BPM)	25-240 beats per minute (BPM)	Same as predicate
Perfusion Index (Pi)	0.02-20%	0.02-20%	Same as predicate
<b>Accuracy</b>			
SpO <sub>2</sub> , No Motion	70 – 100%, 1.5% A <sub>RMS</sub> , 18 years and older	70 – 100%, 2% A <sub>RMS</sub> , adults/pediatrics	Different. Subject device provides improved performance.  Testing is provided to support substantial equivalence.
SpO <sub>2</sub> , Low Perfusion	70 – 100%, 2%, A <sub>RMS</sub> , 18 years and older	70 – 100%, 2%, A <sub>RMS</sub> , adults/pediatrics	Same as predicate
Pulse Rate, No Motion	25 – 240 BPM, 3 BPM A <sub>RMS</sub> , 18 years and older	25 – 240 BPM, 3 BPM A <sub>RMS</sub> , adults/pediatrics	Same as predicate
Pulse Rate, Low Perfusion	25 – 240 BPM, 3 BPM A <sub>RMS</sub> , 18 years and older	25 – 240 BPM, 3 BPM A <sub>RMS</sub> , adults/pediatrics	Same as predicate
<b>Display Resolution</b>			
SpO <sub>2</sub>	1%	1%	Same as predicate
Pulse Rate	1 BPM	1 BPM	Same as predicate
<b>Biocompatibility</b>			
Materials	Patient contacting materials are biocompatible per ISO 10993-1	Patient contacting materials are biocompatible per ISO 10993-1	Same as predicate
<b>Environmental</b>			
Operating Temperature	41°F to 104 °F (5°C to +40°C)	41°F to 104 °F (5°C to +40°C)	Same as predicate



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<b>Table 4.0-1 Comparison between Subject and Predicate Device</b>			
<b>Feature</b>	<b>MightySat – OTC, Subject Device</b>	<b>MightySat Fingertip Pulse Oximeter, Predicate</b>	
<b>510(k) Number</b>	<b>Pending</b>	<b>K181956</b>	<b>Comparison</b>
Storage Temperature	-40°F to 158°F (-40°C to 70°C)	-40°F to 158°F (-40°C to 70°C)	Same as predicate
Operational/Storage Humidity	10 to 95%, non-condensing	10 to 95%, non-condensing	Same as predicate
Atmospheric Pressure	540 to 1060 mBar	540 to 1060 mBar	Same as predicate
<b>Mechanical</b>			
General Overall Dimension	2.9” x 1.6” x 1.2” (7.4 cm x 4.1 cm x 3.0 cm)	2.9” x 1.6” x 1.2” (7.4 cm x 4.1 cm x 3.0 cm)	Same as predicate
Weight	0.16 lbs (73g)	0.16 lbs (73g)	Same as predicate
<b>Electrical</b>			
Type of power	Internal batteries, two standard “AAA” batteries	Internal batteries, two standard “AAA” batteries	Same as predicate
Electrical Safety/EMC	IEC 60601-1/ IEC 60601-1-2	IEC 60601-1/ IEC 60601-1-2	Same as predicate
<b>Interface</b>			
Wireless	Bluetooth	Bluetooth	Same as predicate
<b>Mode of Operation per IEC 60601-1</b>			
Mode of Operation	Continuous	Continuous	Same as predicate



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### **5.0 Performance Data**

#### **Performance Bench Testing**

Performance bench testing is included as part of this submission to support the device performance and to support the substantial equivalence to the predicate device (K181956).

Additionally, to support the performance of the subject device with the updated calibration curve under low perfusion conditions, bench testing using a low perfusion simulator was provided as part of this submission. To support the dynamic range of the signal detection under low perfusion, additional bench testing with opacity filters to simulate different skin pigments was performed.

#### **Biocompatibility Testing**

Additional biocompatibility testing was not included as part of this submission as there was no change to the patient contacting materials from the previously cleared predicate device (K181956).

#### **Electromagnetic Compatibility, Electrical Safety, Environmental, Mechanical and Cleaning**

Additional electromagnetic compatibility, electrical safety, environmental, mechanical, and cleaning testing was not included as part of this submission as there was no change to the mechanical, hardware or electrical components from the previous clearance of the predicate (K181956).

#### **Software Verification and Validation Testing**

Masimo has established, implemented, and maintains procedures for software design, development, review, verification, and validation of its products in accordance with FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 11, 2005).

Consistent with the previously cleared predicate device (K181956), the subject device software is considered “Moderate” level of concern. This is because a failure or latent flaw in the device software could indirectly result in minor injury to the patient or operator through incorrect or delayed information or through the action of a care provider.

Software verification and validation testing was included as part of this submission to support the substantial equivalence of the subject device.

#### **Wireless and Cybersecurity Testing**

There were no changes made to the wireless capabilities of the MightySat-OTC from the predicate device (K181956) and therefore no additional wireless or cybersecurity testing was included as part of this submission.

#### **Human Factors and Usability Testing**

There were no changes made to the usability of the MightySat-OTC as part of this submission from the



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previous clearance (K181956).

To support the OTC use of the subject device, additional human factors validation testing (self-selection and knowledge task) was performed to validate users can understand labeling materials and correctly interpret the device outputs. The validation testing included a self-selection process in accordance with the FDA Guidance, Self-Selection Studies for Nonprescription Drug Products, to identify the intended user to participate in the human factors and usability validation of the device.

### Clinical Testing

To support the improved use by lay-users, the calibration curve was updated to improve the overall performance of the MightySat-OTC including across different skin pigments and genders to 1.5 % Arms.

To support the performance of the MightySat-OTC, clinical data is provided as part of this submission. The clinical performance testing included data from 39 healthy volunteer subjects with varying skin pigmentation, which was measured using the color-based Massey-Martin scale. The results of the clinical study were also separated by skin pigment groups to support the performance of the MightySat-OTC across different skin pigment groups.

The clinical performance testing was conducted in accordance with ISO 80601-2-61 and the prospective study included 39 healthy volunteer subjects, including 22 dark and 17 light pigmented subjects with at least 7 subjects in each gender and skin pigment bin, 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.

The overall performance was found to be 1.26 % Arms across the 70%-100% SaO<sub>2</sub> range and 1.22 % Arms in the 85%-95% SaO<sub>2</sub> range. The summary of the performance in these saturation ranges are provided in the table below.

SaO <sub>2</sub> Range	Number Subjects	Bias	Precision	A <sub>ARMS</sub>	Limits of Agreement	Data Pairs
70%-100%	39	-0.02	1.26	1.26	[-2.50, 2.45]	2030
85%-95%	39	-0.35	1.17	1.22	[-2.63, 1.94]	738

Additional sub-analysis was performed based upon skin pigment and gender to support the performance of the subject device across different skin pigments and genders was within the 1.5 % Arms:

Sub-Group	Number Subjects	SaO <sub>2</sub> Range	Bias	Precision	A <sub>ARMS</sub> (%)	Limits of Agreement	Data Pairs
Light Male	10	70%-100%	-0.13	1.26	1.27	[-2.61, 2.35]	384
Dark Male	15	70%-100%	0.11	1.44	1.44	[-2.70, 2.93]	612
Light Female	7	70%-100%	-0.06	1.11	1.11	[-2.11, 2.23]	258
Dark Female	7	70%-100%	-0.18	1.30	1.32	[-2.73, 2.38]	216

The result of the clinical testing supports the performance of the subject device, MightySat-OTC, across



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different skin pigmentation and gender combinations. The subject device demonstrated equitable performance for the intended user population across all the pigment and gender sub-groups and the accuracy was within 1.5% ARMS, without any clinically significant bias compared to the blood reference SaO<sub>2</sub>, or between the groups.

To further support the equitable performance, the data was bootstrapped for 1001 iterations with replacements. The bootstrapping was conducted both using all the data and also taking account flattening of the data across the bins. The supported the subject device still met the 1.5 % Arms across the different subgroups.

The data was also analyzed using linear mixed effects (LME) models to support the performance was not impacted gender and skin pigment.

### **6.0 Conclusion**

The data supported the MightySat-OTC is substantially equivalent.