August 4, 2022

Masimo Corporation
Unji Lee
Regulatory Affairs Specialist I
52 Discovery
Irvine, California 92618

Re: K221953
Trade/Device Name: Masimo CARESCAPE SpO2 - Masimo with SpHb
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: June 30, 2022
Received: July 5, 2022

Dear Unji Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Todd Courtney
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

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.

510(k) Number *(if known)*

K221953

Device Name
Masimo CARESCAPE SpO2 - Masimo with SpHb

Indications for Use *(Describe)*

The CARESCAPE SpO2 - Masimo is intended to be used with multi-parameter physiological patient monitors (e.g., GE CARESCAPE ONE) for use in multiple areas and intra-hospital transport within a professional healthcare facility.

The CARESCAPE SpO2 – Masimo is indicated for the continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR) of adult, pediatric, and neonatal patients and on one patient at a time.

The CARESCAPE SpO2 – Masimo is indicated for the continuous non-invasive monitoring of total hemoglobin concentration (SpHb) for use on adult and pediatric patients and on one patient at a time.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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MASIMO CORPORATION
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Irvine, CA 92618

510(k) Summary
K221953

Submitter and Address of Manufacturing Facility:	Masimo Corporation 52 Discovery Irvine, CA 92618 Phone: (949) 297-7260 FAX: (949) 297-7592
Date:	August 3, 2022
Contact:	Unji Lee Regulatory Affairs Specialist II Masimo Corporation Phone: (949) 563-7426
Trade Name:	Masimo CARESCAPE SpO2 – Masimo with SpHb
Common Name:	Oximeter
Classification Regulation/ Product Code:	21 CFR 870.2700, Class II/ DQA
Establishment Registration Number:	3011353843
Reason for Premarket Notification:	Labeling update
Primary Predicate:	Masimo CARESCAPE SpO2 – Masimo (K212876)
Secondary Predicate:	CARESCAPE ONE (K213234)
Performance Standards:	There are no performance standards pursuant to Section 514 of the Food, Drug and Cosmetic Act for the above device.

1. Device Description

The Masimo CARESCAPE SpO2 – Masimo with SpHb ("CARESCAPE SpO2 – Masimo") is a module intended to be connected to a compatible patient monitor (e.g., GE CARESCAPE ONE) to provide the ability to continuously monitor Masimo pulse oximetry parameters (SpO2, PR, and SpHb). One end of the module interfaces with the patient monitor to communicate parameter data and alarm status information and the other end of the module connects to Masimo patient cable and sensor accessories.

The CARESCAPE SpO2 – Masimo is the same module cleared as the GE CARESCAPE SpO2 – Masimo as part of the secondary predicate device (K213234), which provides the Masimo SET and rainbow SET Technology for the measurement and monitoring of pulse oximetry data. The only difference between the two modules is that the subject device is labeled for distribution by Masimo, and the secondary predicate is labeled for distribution by GE Healthcare. The difference between the subject device and primary predicate

is the activation of the SpHb feature, the same as what was cleared as part of the secondary predicate (K213234).

As part of the development of the CARESCAPE SpO2 – Masimo, the module was also referenced as the following: "USB rainbow SET module", "CARESCAPE SpO2", and GE CARESCAPE SpO2 – Masimo".

As the CARESCAPE SpO2 – Masimo and GE CARESCAPE SpO2 – Masimo are the same, the performance specifications for the subject device and the secondary predicate device are also the same.

Figure 1 – CARESCAPE SpO2 – Masimo

Refer to Table 1 for product specifications:

Table 1 CARESCAPE SpO2 – Masimo Specifications

Feature	Specification
Performance Specification (Arms)	
SpO_2, No Motion (70-100%)	2% (Adults, Pediatrics, and Infants) 3% (Neonates)
SpO_2, Motion (70-100%)	3% (Adults, Pediatrics, Infants and Neonates)
SpO_2, Low Perfusion (70-100%)	2% (Adults, Pediatrics, and Infants) 3% (Neonates)
Pulse Rate, No Motion (25-240 bpm)	3 bpm (Adults, Pediatrics, and Neonates)
Pulse Rate, Motion (25-240 bpm)	5 bpm (Adults, Pediatrics, and Neonates)
Pulse Rate, Low Perfusion (25-240 bpm)	3 bpm (Adults, Pediatrics, and Neonates)
SpHb (8-17 g/dL)	1 g/dL (Adults and Pediatrics)
Environmental	
Operating Temperature	0°C to +35°C
Storage Temperature	-30°C to +70°C
Operating Humidity	5% to 95% RH, non-condensing
Storage Humidity	5% to 95% RH, non-condensing
Operating Altitude	-500 m to 4000 m
Storage Altitude	-500 m to 5573 m
Ingress Protection from Solids/ Liquids	IP47 (per IEC 60529)
Mode of Operation per IEC 60601-1	
Mode of Operation	Continuous

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2. Intended Use/Indications For Use

The CARESCAPE SpO2 - Masimo is intended to be used with multi-parameter physiological patient monitors (e.g., GE CARESCAPE ONE) for use in multiple areas and intra-hospital transport within a professional healthcare facility.

The CARESCAPE SpO2 – Masimo is indicated for the continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR) of adult, pediatric, and neonatal patients and on one patient at a time.

The CARESCAPE SpO2 – Masimo is indicated for the continuous non-invasive monitoring of total hemoglobin concentration (SpHb) for use on adult and pediatric patients and on one patient at a time.

3. Technological Characteristics

Principle of Operation

The subject device uses the same Masimo SET and rainbow SET Pulse Oximetry technology as the primary predicate device (K212876) and secondary predicate device (K213234) to noninvasively monitor SpO2, pulse rate, and SpHb.

CARESCAPE SpO2 – Masimo relies on the following principles:

1. Oxyhemoglobin (oxygenated blood), deoxyhemoglobin (non-oxygenated blood), and blood plasma constituents differ in their absorption of visible and infrared light.
2. The amount of light absorbed by arterial blood changes with your pulse (photoplethysmography).

Based upon the above principles, Masimo rainbow SET technology uses multiple wavelengths of light (red to infrared) to identify the differences in absorption at the different wavelengths to determine SpO2 and SpHb. The periodic variations in the absorption of light are used to determine the pulse rate.

Mechanism of Action for Achieving the Intended Effect

The subject device and predicate devices have the same mechanism of action.

The CARESCAPE SpO2 – Masimo still achieves its intended use through the connection of an optical sensor applied to the patient's measurement site to detect physiological signal data. This signal data is then sent to the module (subject device), which processes the data and provides physiological parameter data, which is then communicated to the patient monitor (e.g. GE CARESCAPE ONE) through the power and communication connector interface. The communicated parameter data is in turn displayed on the connected patient monitor, along with any visual and audible alarms that are triggered by the parameter data.

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4. Summary of Technological Characteristics of the Subject Device Compared to the Predicate Device

The subject and primary predicate device (K212876) have the following similarities:

- Both devices have the same intended use.
- Both devices have the same principle of operation and mechanism of action.
- Both devices have the same performance specifications for oxygen saturation (SpO2) and pulse rate (PR).
- Both devices are indicated for the same patient populations for oxygen saturation (SpO2) and pulse rate (PR).

The subject and primary predicate device (K212876) have the following difference:

- The subject device supports the continuous non-invasive monitoring of total hemoglobin concentration (SpHb) as it was cleared as part of the secondary predicate (K213234).

The subject and predicate devices were found to be substantially equivalent, as both have the same intended use. The technological difference between the subject and primary predicate device is that total hemoglobin concentration (SpHb) monitoring is enabled on the subject device, the same as it was cleared on the secondary predicate (K213234).

To support that the technological difference between the subject device and the predicate device does not raise different questions of safety and effectiveness, the secondary predicate device (K213234) is included in this submission. The secondary predicate is the same device as the subject device, with exception to the labeling that is specific to the distribution under Masimo. The subject device and secondary predicate have the same intended use and same technological characteristics, as they are the same device.

Accordingly, the subject device was determined to be substantially equivalent.

Refer to Table 4-1 below for the comparison between the subject and predicate devices.

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Table 4-1				
Feature	**CARESCAPE SpO2 – Masimo with SpHb**	**CARESCAPE SpO2 – Masimo**	**CARESCAPE ONE – GE CARESCAPE SpO2 - Masimo**	**Comparison to Predicate Device**
510(k) Number	**Subject Device**	**Primary Predicate (K212876)**	**Secondary Predicate (K213234)**	
General Information				
Intended Use	The CARESCAPE SpO2 - Masimo is intended to be used with multi-parameter physiological patient monitors (e.g., GE CARESCAPE ONE) for use in multiple areas and intra-hospital transport within a professional healthcare facility. The CARESCAPE SpO2 – Masimo is indicated for the continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR) of adult, pediatric, and neonatal patients and on one patient at a time. The CARESCAPE SpO2 – Masimo is indicated for the continuous non-invasive monitoring of total hemoglobin concentration (SpHb) for use on adult and pediatric patients and on one patient at a time.	The CARESCAPE SpO2 - Masimo is intended to be used with multi-parameter physiological patient monitors (e.g., GE CARESCAPE ONE) for use in multiple areas and intra-hospital transport within a professional healthcare facility. The CARESCAPE SpO2 – Masimo is indicated for the monitoring of Functional Oxygen Saturation (SpO2) and Pulse Rate (PR). The CARESCAPE SpO2 – Masimo is indicated for use on adult, pediatric, and neonatal patients and on one patient at a time.	CARESCAPE ONE is both a multi-parameter physiological patient monitor and an accessory to a multi-parameter patient monitor intended for use in multiple areas and intra-hospital transport within a professional healthcare facility. CARESCAPE ONE is indicated for the monitoring of hemodynamic and respiratory physiological parameters. When the CARESCAPE ONE is operated as a standalone multi-parameter physiological patient monitor, it provides the following physiological parameters: • ECG (heart rate, ST segment, and arrhythmia detection) • Pulse oximetry (pulse rate, functional oxygen saturation [SpO2]) • Non-invasive blood pressure (systolic, diastolic, and mean arterial pressures) • Invasive pressure (pulse rate and systolic, diastolic, and mean pressures) • Temperature • Respiratory carbon dioxide (EtCO2, FiCO2, and respiration rate)	Same. Subject device and predicates have the same intended use. The subject device includes the SpHb feature, the same as the secondary predicate.

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Table 4-1				
Feature	**CARESCAPE SpO2 – Masimo with SpHb**	**CARESCAPE SpO2 – Masimo**	**CARESCAPE ONE – GE CARESCAPE SpO2 - Masimo**	**Comparison to Predicate Device**
510(k) Number	**Subject Device**	**Primary Predicate (K212876)**	**Secondary Predicate (K213234)**	
			• Impedance respiration When The CARESCAPE ONE is connected as an accessory to a compatible host monitor, it provides the following physiological parameters to the host monitor: • ECG (heart rate, ST segment, and arrhythmia detection) • Pulse oximetry (pulse rate, functional oxygen saturation [SpO2], and total hemoglobin concentration [SpHb]) • Non-invasive blood pressure (systolic, diastolic, and mean arterial pressures) • Invasive pressure (pulse rate and systolic, diastolic, and mean pressures) • Regional oxygen saturation (rSO2) • Temperature • Respiratory carbon dioxide (EtCO2, FiCO2, and respiration rate) • Impedance respiration When the CARESCAPE ONE is connected as an accessory to a compatible host monitor, visual and audible alarms, user controls, and user interface are	

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Table 4-1				
Feature	**CARESCAPE SpO2 – Masimo with SpHb**	**CARESCAPE SpO2 – Masimo**	**CARESCAPE ONE – GE CARESCAPE SpO2 - Masimo**	**Comparison to Predicate Device**
510(k) Number	**Subject Device**	**Primary Predicate (K212876)**	**Secondary Predicate (K213234)**	
			provided on the compatible host monitor and not on CARESCAPE ONE. CARESCAPE ONE is intended for use on adult, pediatric, and neonatal patients and on one patient at a time. Regional oxygen saturation (rSO2) is an adjunct parameter for noninvasive monitoring of cerebral/somatic regional oximetry of blood in the brain or other tissue beneath the sensor. It is intended to be used on patients greater than 40 kg (88 lbs) at risk for reduced-flow or no-flow ischemic states. CARESCAPE ONE is intended for use under the direct supervision of a licensed healthcare practitioner, or by personnel trained in the proper use of the equipment in a professional healthcare facility. Contraindications for using CARESCAPE ONE: The CARESCAPE ONE is not intended for use within a controlled MR environment.	
Classification Regulation/ Product Code	21 CFR 870.2700/ DQA	21 CFR 870.2700/ DQA	21 CFR 870.1025/ MHX	Same.

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Table 4-1				
Feature	**CARESCAPE SpO2 – Masimo with SpHb**	**CARESCAPE SpO2 – Masimo**	**CARESCAPE ONE – GE CARESCAPE SpO2 - Masimo**	**Comparison to Predicate Device**
510(k) Number	**Subject Device**	**Primary Predicate (K212876)**	**Secondary Predicate (K213234)**	
Principle of Operation	CARESCAPE SpO2 – Masimo relies on the following principles: 1. Oxyhemoglobin (oxygenated blood), deoxyhemoglobin (non-oxygenated blood), and blood plasma constituents differ in their absorption of visible and infrared light. 2. The amount of light absorbed by arterial blood changes with your pulse (photoplethysmography). Based upon the above principles, Masimo rainbow SET technology uses multiple wavelengths light (red to infrared) to identify the differences in absorption at the different wavelengths to determine SpO2 and SpHb. The periodic variations in the absorption of light are used to determine the pulse rate.	CARESCAPE SpO2 – Masimo relies on the following principles: 1. Oxyhemoglobin (oxygenated blood) and deoxyhemoglobin (non-oxygenated blood) differ in their absorption of red and infrared light (spectrophotometry). 2. 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.	CARESCAPE SpO2 – Masimo relies on the following principles: 1. Oxyhemoglobin (oxygenated blood), deoxyhemoglobin (non-oxygenated blood), and blood plasma constituents differ in their absorption of visible and infrared light. 2. The amount of light absorbed by arterial blood changes with your pulse (photoplethysmography). Based upon the above principles, Masimo rainbow SET technology uses multiple wavelengths light (red to infrared) to identify the differences in absorption at the different wavelengths to determine SpO2 and SpHb. The periodic variations in the absorption of light are used to determine the pulse rate.	Same.
Performance Specifications (Arms)				
SpO2, No Motion (70-100%)	2% (Adults, Pediatrics, and Infants) 3% (Neonates)	2% (Adults, Pediatrics, and Infants) 3% (Neonates)	2% (Adults, Pediatrics, and Infants) 3% (Neonates)	Same.
SpO2, Motion (70-100%)	3% (Adults, Pediatrics, Infants, and Neonates)	3% (Adults, Pediatrics, Infants, and Neonates)	3% (Adults, Pediatrics, Infants, and Neonates)	Same.
SpO2, Low Perfusion (70-100%)	2% (Adults, Pediatrics, and Infants) 3% (Neonates)	2% (Adults, Pediatrics, and Infants) 3% (Neonates)	2% (Adults, Pediatrics, and Infants) 3% (Neonates)	Same.
Pulse Rate, No Motion	3 bpm (Adults, Pediatrics, Neonates)	3 bpm (Adults, Pediatrics, Neonates)	3 bpm (Adults, Pediatrics, Neonates)	Same.

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Table 4-1				
Feature	**CARESCAPE SpO2 – Masimo with SpHb**	**CARESCAPE SpO2 – Masimo**	**CARESCAPE ONE – GE CARESCAPE SpO2 - Masimo**	**Comparison to Predicate Device**
510(k) Number	**Subject Device**	**Primary Predicate (K212876)**	**Secondary Predicate (K213234)**	
(25 – 240 bpm)				
Pulse Rate, Motion (25 – 240 bpm)	5 bpm (Adults, Pediatrics, and Neonates)	5 bpm (Adults, Pediatrics, and Neonates)	5 bpm (Adults, Pediatrics, and Neonates)	Same.
Pulse Rate, Low Perfusion (25 – 240 bpm)	3 bpm (Adults, Pediatrics, and Neonates)	3 bpm (Adults, Pediatrics, and Neonates)	3 bpm (Adults, Pediatrics, and Neonates)	Same.
SpHb (8-17 g/dL)	1 g/dL (Adults and Pediatrics)	Not applicable.	1 g/dL (Adults and Pediatrics)	Same.
Mechanical				
Overall Dimension	5.40” by 2.68’’ by 1.00’’	5.40” by 2.68” by 1.00”	5.40” by 2.68’’ by 1.00’’	Same.
Electrical				
Power Source	Host device	Host device	Host device	Same.
Electrical Safety	Conformed to IEC 60601-1	Conformed to IEC 60601-1	Conformed to IEC 60601-1	Same.
Electromagnetic compatibility	Conformed to IEC 60601-1-2	Conformed to IEC 60601-1-2	Conformed to IEC 60601-1-2	Same.
Environmental				
Operating Temperature	0°C to 35°C	0°C to 35°C	0°C to 35°C	Same.
Mode of Operation per IEC 60601-1				
Mode of Operation	Continuous	Continuous	Continuous	Same.

5. Performance Data

Performance Bench Testing

As there were no performance changes made to the subject device from its latest clearance as part of the CARESCAPE ONE (K213234), no performance bench testing was included in this submission.

Biocompatibility Testing

As no changes were made to patient-contacting materials in the subject device, compared to the previously cleared CARESCAPE SpO2 – Masimo (K212876), no biocompatibility testing was included in this submission.

Electromagnetic Compatibility, Electrical Safety, Environmental, Mechanical and Cleaning

As there were no software or hardware changes made to the subject device, compared to the previously cleared CARESCAPE SpO2 – Masimo (K212876), no Electromagnetic Compatibility, Electrical Safety, Environmental, Mechanical and Cleaning testing was included in this submission.

Software Verification and Validation Testing

As there were no software changes made to the subject device from its latest clearance as part of the CARESCAPE ONE (K213234), no software testing was included in this submission.

Wireless and Cybersecurity Testing

As the CARESCAPE SpO2 – Masimo uses wired communication for the transfer of parameter data and alarms status and does not have wireless features at this time, no wireless testing was included in this submission.

Human Factors and Usability Testing

As there were no user interface changes made to the subject device compared to the previously cleared CARESCAPE SpO2 – Masimo (K212876), no human factors and usability testing was included in this submission.

Clinical Testing

As the subject device uses the same monitoring technology as the predicate device, additional testing was not considered necessary to support substantial equivalence.

6. Conclusion

The subject device was found to be substantially equivalent.