October 8, 2021

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

Re: K212876
Trade/Device Name: CARESCAPE SpO_2 - Masimo
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: September 7, 2021
Received: September 9, 2021

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 (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

Jennifer Shih 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K212867

Device Name
Carescape SpO2 - Masimo

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 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.

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
52 Discovery
Irvine, CA 92618

510(k) Summary – K212876

Submitter and Address of Manufacturing Facility:	Masimo Corporation 52 Discovery Irvine, CA 92618 FAX: (949) 297-7592
Date:	September 7, 2021
Contact:	Kertana Shankar Regulatory Specialist II Masimo Corporation Phone: (949) 297-7260
Trade Name:	CARESCAPE SpO2 - Masimo
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:	K200494 – CARESCAPE ONE
Secondary Predicate:	Masimo SET IntelliVue Pulse Oximeter Module (K040259)
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 CARESCAPE SpO_2 –Masimo (module) is a module intended to be connected to a compatible patient monitor (e.g., GE CARESCAPE ONE) to provide the ability to monitor Masimo pulse oximetry parameters (SpO2 and PR). 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 equipped with the same Masimo Technology Board as the predicate device (K200494), which provides the Masimo SET Technology for the measurement and monitoring of pulse oximetry data.

The module is labeled CARESCAPE SpO_2 – Masimo or GE CARESCAPE SpO_2 –Masimo. Both versions are identical except for the labeling to distinguish the version distributed by Masimo. The purpose of this submission is to receive clearance to market CARESCAPE SpO2 – Masimo under its own 510(k).

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The performance specifications for CARESCAPE SpO2 - Masimo remains the same as that previously 510(k) cleared for the predicate device, GE CARESCAPE SpO2 – Masimo (K200494).

See **Table 1** below 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 and 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)
Environmental	
Operating Temperature	0°C to +35°C, ambient humidity
Storage Temperature	-40°C to +70°C, ambient humidity
Operating Humidity	5% to 95%, non-condensing
Storage Humidity	5% to 95%, non-condensing
Operating Altitude	-500 m to 4000 m
Storage Altitude	-500 m to 5572 m
Ingress Protection from Solids/ Liquids	IP47 (per IEC 60529) IPX2 (per IEC 60529 when used with sensor and sensor interface)
Mode of Operation per IEC 60601-1	
Mode of Operation	Continuous

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 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.

3 Technological Characteristics

Principle of Operation

There is no change in the principle of operation as part of this submission from the previous clearance under K200494. The module still utilizes the same principles of operation for pulse oximetry governed by 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.

Mechanism of Action for Achieving the Intended Effect

There is no change to the Mechanism of Action of the CARESCAPE SpO2 – Masimo from the previous clearance K200494.

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) monitor through the power and communication connector interface. The communicated parameter data is in turn displayed on the connected patient monitor (e.g., GE CARESCAPE ONE) along with any visual and audible alarms that are triggered by the parameter data.

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

The subject device, CARESCAPE SpO2 – Masimo, and the primary predicate device, GE CARESCAPE SpO2 – Masimo cleared as part of CARESCAPE ONE (K200494), have the following key similarities:

- Both devices have the same intended use
- Both devices are indicated for the same patient population
- Both devices have the same principle of operation and mechanism of action

The subject device and the primary predicate device have the following differences:

- The labeling for the CARESCAPE SpO2 - Masimo was modified to include the revised indications for use description specific to the subject device's cleared indications as part of the primary predicate clearance (K200494).

To support the addition of the Carescape SpO2 – Masimo module's indications for use statement as substantially equivalent, a secondary predicate, Masimo SET IntelliVue Pulse Oximeter Module (K040259), which has the same intended use and technological characteristics as the subject device and primary predicate was referenced to align the indications for use description. There is no change in the intended use or technological characteristics from the primary predicate.

The subject and primary predicate are the same and therefore substantially equivalent. The subject device labeling changes do not modify the intended use from the primary predicate device.

See Table 2 - below for the comparison between the subject device and the predicate devices.

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Table 2 – Comparison Table				
Feature	**CARESCAPE SpO2 - Masimo**	**CARESCAPE ONE (K200494) – GE CARESCAPE SpO2 - Masimo**	**Masimo SET IntelliVue Module (K040259)**	**Comparison to Predicate Device**
510(k) Number	**Subject Device**	**Primary Predicate**	**Secondary Predicate**	
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 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.	The 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. The CARESCAPE ONE is indicated for the monitoring of hemodynamic (including ECG, ST segment, arrhythmia detection, invasive pressure, non-invasive blood pressure, SpO2, pulse rate, and temperature), and respiratory (impedance respiration and CO2 airway gas) physiological parameters. The CARESCAPE ONE can be used as a standalone monitor. In this mode of operation, the CARESCAPE ONE provides ECG, ST segment, arrhythmia detection, invasive pressure, noninvasive blood pressure, SpO2, pulse rate, temperature, impedance respiration, and CO2 airway gas parameter acquisition and monitoring.	The Masimo SET® IntelliVue Pulse Oximeter Module is intended for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (measured by an SpO2 sensor) for adult, pediatric, and neonatal patients in hospitals and hospital-type facilities. The IntelliVue Pulse Oximeter Module is indicated for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin and pulse rate. The IntelliVue Pulse Oximeter Module is indicated for use with adult, pediatric and neonatal patients during both motion and no motion conditions, and for patients who are well or poorly perfused in hospitals and hospital-type facilities.	Same Intended use of the subject device is the same as the predicates in providing SpO2 and Pulse Rate. However, as this submission is specific to the clearance of CARESCAPE SpO2 – Masimo, the description of the indications for use is revised to be specific to the subject device's cleared indications for use as part of predicate (K200494). The description of the indications for use for the subject device is revised to align with the secondary predicate which has the same intended use and same technology as the subject device and primary predicate but specific language around the indications that is

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Table 2 – Comparison Table				
Feature	**CARESCAPE SpO2 - Masimo**	**CARESCAPE ONE (K200494) – GE CARESCAPE SpO2 - Masimo**	**Masimo SET IntelliVue Module (K040259)**	**Comparison to Predicate Device**
510(k) Number	**Subject Device**	**Primary Predicate**	**Secondary Predicate**	
		The CARESCAPE ONE can be connected as an accessory to a compatible CARESCAPE monitor. In this mode of operation, the CARESCAPE ONE provides ECG, ST segment, arrhythmia detection, invasive pressure, non-invasive blood pressure, SpO2, pulse rate, temperature, impedance respiration, and CO2 airway gas parameter acquisition. Visual and audible alarms, user controls, and user interface on the CARESCAPE ONE are not active in this mode. The CARESCAPE ONE is indicated for use on adult, pediatric, and neonatal patients and on one patient at a time. The CARESCAPE ONE is indicated 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.		applicable to both the subject device and primary predicate.

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Table 2 – Comparison Table

Feature	CARESCAPE SpO2 - Masimo	CARESCAPE ONE (K200494) – GE CARESCAPE SpO2 - Masimo	Masimo SET IntelliVue Module (K040259)	Comparison to Predicate Device
510(k) Number	**Subject Device**	**Primary Predicate**	**Secondary Predicate**	
Classification Regulation/ Product Code	21 CFR 870.2700/ DQA	21 CFR 870.2700/ DQA	21 CFR 870.2700/ DQA	Same
Principle of Operation	Pulse oximetry is governed by 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.	Pulse oximetry is governed by 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.	Pulse oximetry is governed by 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.	Same
Performance Specifications				
SpO2, No Motion (70-100%)	2% (Adults, Pediatrics, Infants) 3% (Neonates)	2% (Adults, Pediatric, Infant) 3% (Neonates)	2% (Adults, Pediatric, Infant) 3% (Neonates)	Same.
SpO2, Motion (70-100%)	3% (All population)	3% (All population)	3% (All population)	Same
SpO2, Low Perfusion (70-100%)	2% (Adults, Pediatrics, Infants) 3% (Neonates)	2% (Adults, Pediatric, Infant) 3% (Neonates)	2% (Adults, Pediatric, Infant) 3% (Neonates)	Same
Pulse Rate, No Motion (25 – 240 bpm)	3 bpm (Adults, Pediatrics, and Neonates)	3 bpm (Adults, Pediatrics, and Neonates)	3 bpm (Adults, Pediatrics, and Neonates)	Same
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

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Table 2 – Comparison Table				
Feature	**CARESCAPE SpO2 - Masimo**	**CARESCAPE ONE (K200494) – GE CARESCAPE SpO2 - Masimo**	**Masimo SET IntelliVue Module (K040259)**	**Comparison to Predicate Device**
510(k) Number	**Subject Device**	**Primary Predicate**	**Secondary Predicate**	
Mechanical				
Overall Dimension	5.40” by 2.68’’ by 1.00’’	5.40” by 2.68’’ by 1.00’’	3.9” by 3.8” by 1.4”	Same as primary predicate
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 55°C	Same as primary predicate
Mode of Operation per IEC 60601-1				
Mode of Operation	Continuous	Continuous	Continuous	Same

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5 Performance Data

Performance Bench Testing

As there are no hardware or software changes as part of this submission from the previous clearance, no performance bench testing was included as part of this submission.

Biocompatibility Testing

As there are no changes to the patient contacting materials as part of this submission from the previous clearance, no biocompatibility testing was included as part of this submission.

Electromagnetic Compatibility, Electrical Safety, Environmental, Mechanical and Cleaning

As there were no changes to the hardware or software as part of this submission from the previous clearance, no Electromagnetic Compatibility, Electrical Safety, Environmental, Mechanical and Cleaning testing was included with this submission.

Software Verification and Validation Testing

As there are no software changes as part of this submission from the previous clearance, no software testing was included as part of this submission.

Wireless and Cybersecurity Testing

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

Human Factors and Usability Testing

As there are no changes made to user interfaces as part of this submission from the previous clearance, no human factors and usability testing was included as part of this submission.

Non-clinical Testing

As there were no hardware, software or performance changes made to the subject device when compared to the primary predicate device, no additional non-clinical testing was considered necessary to support the substantial equivalence.

Clinical Testing

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

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6 Conclusion

The subject device, CARESCAPE SpO2 - Masimo, and the primary predicate device, GE CARESCAPE SpO2 – Masimo (K200494) were found to be substantially equivalent as both have the same intended use and same technological characteristics.