Masimo Corporation
Kertana Shankar
Senior Regulatory Affairs
52 Discovery
Irvine, California 92618

September 7, 2023

Re: K232389
Trade/Device Name: Carescape SpO2 - Masimo; Masimo rainbow SET IntelliVue
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: August 8, 2023
Received: August 9, 2023

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,

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

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)*
K232389

Device Name
Carescape SpO2 - Masimo

Indications for Use *(Describe)*
The CARESCAPE SpO2 - Masimo is intended to be used with multiparameter physiological patient monitors (e.g., GE CARESCAPE ONE) for use in multiple areas and intrahospital transport within a professional healthcare facility.

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

The CARESCAPE SpO2 – Masimo with Radius PPG is indicated for the continuous monitoring of functional arterial oxygen saturation of hemoglobin (SpO2) and pulse rate (PR) for use with adult, pediatric, and neonatal patients during both no motion and motion conditions and for patients who are well or poorly perfused.

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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The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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Office of Chief Information Officer
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PRAStaff@fda.hhs.gov

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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)*
K232389

Device Name
Masimo rainbow SET IntelliVue

Indications for Use *(Describe)*
The Masimo rainbow SET® IntelliVue Module Pulse CO-Oximeter® is intended to be used with compatible Philips Intellivue Patient Monitors.

The Masimo rainbow SET® IntelliVue Module Pulse CO-Oximeter® is intended for the noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate, carboxyhemoglobin saturation (SpCO), methemoglobin saturation (SpMet), total hemoglobin concentration (SpHb), and/or respiratory rate (RRa).

The Masimo rainbow SET® IntelliVue Module Pulse CO-Oximeter® is indicated for the non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR) of adult, pediatric, infant, and neonatal patients during both no motion and motion conditions, and for patients who are well or poorly perfused.

The Masimo rainbow SET® IntelliVue Module Pulse CO-Oximeter® is indicated for the non-invasive monitoring of carboxyhemoglobin saturation (SpCO) of adult, pediatric, and infant patients during no motion conditions.

The Masimo rainbow SET® IntelliVue Module Pulse CO-Oximeter® is indicated for the non-invasive monitoring of methemoglobin saturation (SpMet) of adult, pediatric, infant, and neonatal patients during no motion conditions.

The Masimo rainbow SET® IntelliVue Module Pulse CO-Oximeter® is indicated for the non-invasive monitoring of total hemoglobin concentration (SpHb) of adult and pediatric patients during no motion conditions.

The Masimo rainbow SET® IntelliVue Module Pulse CO-Oximeter® is indicated for the non-invasive monitoring of respiratory rate (RRa) for adult and pediatric patients during no motion conditions.

The Masimo rainbow SET® IntelliVue Module Pulse CO-Oximeter® with Radius PPG is indicated for the continuous monitoring of functional arterial oxygen saturation of hemoglobin (SpO2) and pulse rate (PR) for use with adult, pediatric, and neonatal patients during both no motion and motion conditions and for patients who are well or poorly perfused.

The Masimo rainbow SET® IntelliVue Module Pulse CO-Oximeter® is not intended to be used as the sole basis for making diagnosis or treatment decisions related to suspected carbon monoxide poisoning; it is intended to be used in conjunction with additional methods of assessing clinical signs and symptoms.

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)

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MASIMO CORPORATION
52 Discovery
Irvine, CA 92618

K232389
510(k) Summary

CARESCAPE SpO2 – Masimo:

Submitter and Address of Manufacturing Facility:	Masimo Corporation 52 Discovery Irvine, CA 92618 Phone: (949) 297-7000
Date:	September 1, 2023
Contact:	Kertana Shankar Senior Regulatory Specialist Masimo Corporation Phone: (949) 390-0140
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:	Addition of Radius PPG as accessory
Predicate Device:	K221953 - Masimo Carescape SpO2 - Masimo with SpHb
Reference Device:	K183697 – Rad-97 with Centroid O2
Performance Standards	There are no performance standards pursuant to Section 514 of the Food, Drug and Cosmetic Act for the above device.

Masimo rainbow SET IntelliVue Module:

Submitter and Address of Manufacturing Facility:	Masimo Corporation 52 Discovery Irvine, CA 92618 Phone: (949) 297-7000
Date:	September 1, 2023
Contact:	Kertana Shankar Senior Regulatory Specialist Masimo Corporation Phone: (949) 390-0140
Trade Name:	Masimo rainbow SET IntelliVue Module
Common Name:	Oximeter

MASIMO CORPORATION
52 Discovery
Irvine, CA 92618

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Classification Regulation/ Product Code:	21 CFR 870.2700, Class II/ DQA
Establishment Registration Number:	3011353843
Reason for Premarket Notification:	Addition of Radius PPG as accessory
Predicate Device:	K162675 - Masimo Rainbow SET Intellivue Module Pulse CO-Oximeter
Reference Device:	K183697 – Rad-97 with Centroid O2
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 purpose of this submission is to add Radius PPG as a compatible accessory to the Carescape SpO2 – Masimo (K221953) and Masimo rainbow SET IntelliVue (K162675). The description of the subject devices is provided below:

Carescape SpO2 – Masimo

The Carescape SpO2 – Masimo is a module intended to be connected to a compatible patient monitor (e.g., GE CARESCAPE ONE, K213234) 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.

Masimo rainbow SET IntelliVue

The Masimo rainbow SET IntelliVue is a module intended to be connected to compatible patient monitors (e.g., Philips IntelliVue, K221348) to provide continuous, noninvasive measurements of functional oxygen arterial hemoglobin (SpO2), pulse rate, carboxyhemoglobin (SpCO), methemoglobin (SpMet), oxygen content (SpOC) and respiration rate (RRa). 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.

2 System Specifications

The specifications for the Carescape SpO2 – Masimo (K221953) and the Masimo rainbow SET IntelliVue (K162675) are the same as the previous clearances.

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Irvine, CA 92618

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510(k) Summary

See Tables 2-1 and Table 2-2 below for the subject device specifications:

Table 2-1 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
Mode of Operation per IEC 60601-1	
Mode of Operation	Continuous

Table 2-2 Masimo rainbow SET IntelliVue Specifications	
Feature	**Specification**
Performance Specification (Arms)	
SpO_2, No Motion (60-80%)	3% (Adults, Pediatrics, Infants)
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)
SpCO (1-40%)	3% (Adults, Pediatrics, and Infants)
SpMet (1-15%)	1% (Adults, Pediatrics, Infants, and Neonates)
SpHb (8-17 g/dL)	1 g/dL (Adults and Pediatrics)
RRa (4-70 bpm)	1 bpm (Adults and Pediatrics)
Environmental	
Operating Temperature	0°C to +55°C
Storage Temperature	-40°C to +70°C
Operating Humidity	95% RH max at 40°C

Table 2-2 Masimo rainbow SET IntelliVue Specifications	
Feature	**Specification**
Storage Humidity	95% RH max at 65°C
Mode of Operation per IEC 60601-1	
Mode of Operation	Continuous

3 Intended Use/ Indications For Use

The intended use statements for the subject devices are provided below:

CARESCAPE SpO2 – Masimo

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

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

The CARESCAPE SpO2 – Masimo with Radius PPG is indicated for the continuous monitoring of functional arterial oxygen saturation of hemoglobin (SpO2) and pulse rate (PR) for use with adult, pediatric, and neonatal patients during both no motion and motion conditions and for patients who are well or poorly perfused.

Masimo rainbow SET IntelliVue

The Masimo Rainbow SET IntelliVue Module Pulse CO-Oximeter is intended to be used with compatible Philips IntelliVue Patient Monitors. The indications for use as specified for the IntelliVue Patient Monitors applies.

The Masimo Rainbow SET IntelliVue Module Pulse CO-Oximeter is intended for the noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate, carboxyhemoglobin saturation (SpCO), methemoglobin saturation (SpMet), total hemoglobin concentration (SpHb), and/or respiratory rate (RRa).

The Masimo Rainbow SET IntelliVue Module Pulse CO-Oximeter is indicated for the non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR) of adult, pediatric, infant, and neonatal patients during both no motion and motion conditions, and for patients who are well or poorly perfused.

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The Masimo rainbow SET® IntelliVue Module Pulse CO-Oximeter® is indicated for the non-invasive monitoring of carboxyhemoglobin saturation (SpCO) of adult, pediatric, and infant patients during no motion conditions.

The Masimo rainbow SET® IntelliVue Module Pulse CO-Oximeter® is indicated for the non-invasive monitoring of methemoglobin saturation (SpMet) of adult, pediatric, infant, and neonatal patients during no motion conditions.

The Masimo rainbow SET® IntelliVue Module Pulse CO-Oximeter® is indicated for the non-invasive monitoring of total hemoglobin concentration (SpHb) of adult and pediatric patients during no motion conditions.

The Masimo rainbow SET® IntelliVue Module Pulse CO-Oximeter® is indicated for the non-invasive monitoring of respiratory rate (RRa) for adult and pediatric patients during no motion conditions.

The Masimo rainbow SET® IntelliVue Module Pulse CO-Oximeter® with Radius PPG is indicated for the continuous monitoring of functional arterial oxygen saturation of hemoglobin (SpO2) and pulse rate (PR) for use with adult, pediatric, and neonatal patients during both no motion and motion conditions and for patients who are well or poorly perfused.

The Masimo Rainbow SET IntelliVue Module Pulse CO-Oximeter is not intended to be used as the sole basis for making diagnosis or treatment decisions related to suspected carbon monoxide poisoning; it is intended to be used in conjunction with additional methods of assessing clinical signs and symptoms.

4 Technological Characteristics

4.1 Principles of Operation

There have been no changes to the principles of operation of the subject devices from their previous clearances under K221953 and K162675.

See below for the principles of operation of the subject devices:

Carescape SpO2 – Masimo

The Carescape SpO2 – Masimo uses the same Masimo SET and rainbow SET Pulse Oximetry technology as the predicate device (K221953) to noninvasively monitor SpO2, pulse rate, and SpHb.

Carescape SpO2 – Masimo relies on the following principles:

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

Based upon the above principles, the periodic variations in the absorption of light are used to determine the pulse rate.

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Masimo rainbow SET IntelliVue

The Masimo rainbow SET IntelliVue uses the same Masimo rainbow SET Pulse Oximetry technology as the predicate device (K162675) to provide the noninvasive optical measurements of SpO2, pulse rate, SpCO, SpMet and SpHb.

The Masimo rainbow SET IntelliVue relies on the following principles:

- Oxyhemoglobin (oxygenated blood) and deoxyhemoglobin (non-oxygenated blood), carboxyhemoglobin (blood with carbon monoxide content), methemoglobin (blood with oxidized hemoglobin) and blood plasma constituents differ in their absorption of visible and infrared light (using spectrophotometry).

- The amount of arterial blood in tissue changes with pulse (photoplethysmography).

The Masimo Rainbow Acoustic Monitoring (RAM) technology uses acoustic signals for respiration rate (RRa) measurements. RRa measures a patient's respiration rate based on airflow sounds generated in the upper airway.

4.2 Mechanism of Action for Achieving the Intended Effect

The subject devices still achieve their intended purpose through the application of an optical sensor to the patient's measurement site to detect physiological signal data, same as the predicate devices (K221953 and K162675).

This signal data is then sent to the subject devices, either through a wired sensor and cable connection, or through the Radius PPG. When used with the Radius PPG, the Radius PPG reusable module is paired with the wireless receiver connected to the subject devices through the subject device's sensor cable port similar to a wired sensor connection. Once paired, the Radius PPG reusable module is connected to the Radius PPG sensor part to begin monitoring and communication of the measured data to the subject devices.

The subject devices have Masimo technology boards installed that process the data to provide physiological parameter data, which is then communicated to the patient monitor (e.g., GE CARESCAPE ONE, Philips IntelliVue) 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.

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

Similarities and Differences between Predicate and Subject Devices

The subject devices (i.e., CARESCAPE SpO2 – Masimo, Masimo rainbow SET IntelliVue) and the respective predicate devices have the following key similarities:

- Both devices have the same intended use and technological characteristics.

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- Both devices have the same principle of operation and mechanism of action.
- Both devices are indicated for the same patient population.
- Both devices support the continuous monitoring of physiological parameters.

Differences between the subject and predicate device:

- Updated list of compatible accessories to include Radius PPG.

Between the subject and predicate device, there are no differences in the intended use and technological characteristics. The subject devices have been previously cleared under K221953 and K162675, respectively, for use with Masimo sensor cable and sensor accessories.

The purpose of this submission is to include the Radius PPG (cleared as "Centroid O2" under K183697) as a compatible accessory for the subject devices. Bench testing was conducted to support the addition of the Radius PPG accessory did not raise different questions of safety and effectiveness.

The subject and predicate devices are the same and are therefore substantially equivalent. See Tables 5-1 and 5-2 for the comparison between the subject and predicate devices.

MASIMO CORPORATION
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Irvine, CA 92618

510(k) Summary

Table 5-1 Comparison between Subject Device (CARESCAPE SpO2 – Masimo) and Predicate Device			
Feature	**CARESCAPE SpO2 – Masimo Subject Device**	**CARESCAPE SpO2 – Masimo with SpHb, Predicate Device K221953**	**Comparison to Predicate**
Primary Classification Regulation/ Product Code	21 CFR 870.2700, Class II/ DQA	21 CFR 870.2700, Class II/ DQA	Same.
Intended Use/ Indications for Use	The CARESCAPE SpO2 - Masimo is intended to be used with multiparameter physiological patient monitors (e.g., GE CARESCAPE ONE) for use in multiple areas and intrahospital transport within a professional healthcare facility. The CARESCAPE SpO2 – Masimo is indicated for the continuous noninvasive 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 noninvasive 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 multiparameter physiological patient monitors (e.g., GE CARESCAPE ONE) for use in multiple areas and intrahospital transport within a professional healthcare facility. The CARESCAPE SpO2 – Masimo is indicated for the continuous noninvasive 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 noninvasive monitoring of total hemoglobin concentration (SpHb) for use on adult and pediatric patients and on one patient at a time.	Same.
Principle of Operation	CARESCAPE SpO2 – Masimo relies on the following principles: 1. Oxyhemoglobin (oxygenated blood), deoxyhemoglobin (non-oxygenated blood),	CARESCAPE SpO2 – Masimo relies on the following principles: 1. Oxyhemoglobin (oxygenated blood), deoxyhemoglobin (non-oxygenated blood),	Same.

Table 5-1 Comparison between Subject Device (CARESCAPE SpO2 – Masimo) and Predicate Device			
Feature	**CARESCAPE SpO2 – Masimo Subject Device**	**CARESCAPE SpO2 – Masimo with SpHb, Predicate Device K221953**	**Comparison to Predicate**
	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.	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.	
Performance Specifications (Arms)			
SpO2, No Motion (70-100%)	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)	Same.
SpO2, Low perfusion (70-100%)	2% (Adults, Pediatrics, and Infants) 3% (Neonates)	2% (Adults, Pediatrics, and Infants) 3% (Neonates)	Same.
Pulse Rate, No motion (25-240 bpm)	3 bpm (Adults, Pediatrics, Neonates)	3 bpm (Adults, Pediatrics, Neonates)	Same.
Pulse Rate, Motion (25-240 bpm)	5 bpm (Adults, Pediatrics, and Neonates)	5 bpm (Adults, Pediatrics, and Neonates)	Same.
Pulse Rate, Low Perfusion	3 bpm (Adults, Pediatrics, and Neonates)	3 bpm (Adults, Pediatrics, and Neonates)	Same.

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Table 5-1 Comparison between Subject Device (CARESCAPE SpO2 – Masimo) and Predicate Device			
Feature	**CARESCAPE SpO2 – Masimo Subject Device**	**CARESCAPE SpO2 – Masimo with SpHb, Predicate Device K221953**	**Comparison to Predicate**
(25-240 bpm)			
Accessories			
Compatible Accessories	Masimo wired sensors and cables, Radius PPG	Masimo wired sensors and cables.	Different. Radius PPG is included as a compatible accessory to the subject device. Bench testing was performed to support the substantial equivalence.
Mechanical			
Overall Dimensions	5.40” by 2.68’’ by 1.00’’	5.40” by 2.68’’ by 1.00’’	Same.
Environmental Specifications			
Operating Conditions			
Temperature	0°C to 35°C	0°C to 35°C	Same.
Electrical			
Power Source	Host device	Host device	Same.
Electrical Safety	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	Same.
Classification per IEC 60601-1			
Mode of operation per IEC 60601-1	Continuous	Continuous	Same.

Table 5-2 Comparison between Subject Device (Masimo rainbow SET IntelliVue) and Predicate Device			
Feature	**Masimo rainbow SET IntelliVue Subject Device**	**Masimo rainbow SET IntelliVue Predicate Device K162675**	**Comparison to Predicate**
Primary Classification Regulation/ Product Code	21 CFR 870.2700, Class II/ DQA	21 CFR 870.2700, Class II/ DQA	Same.
Intended Use/ Indications for Use	The Masimo Rainbow SET IntelliVue Module Pulse CO-Oximeter is intended to be used with compatible Philips IntelliVue Patient Monitors. The indications for use as specified for the IntelliVue Patient Monitors applies. The Masimo Rainbow SET IntelliVue Module Pulse CO-Oximeter is indicated for the noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate, carboxyhemoglobin saturation (SpCO), methemoglobin saturation (SpMet), total hemoglobin concentration (SpHb), and/or respiratory rate (RRa). The Masimo Rainbow SET IntelliVue Module Pulse CO-Oximeter is indicated for use during both no motion and motion conditions, and for patients who are well or poorly perfused. The Masimo Rainbow SET IntelliVue Module Pulse CO-Oximeter is not intended	The Masimo Rainbow SET IntelliVue Module Pulse CO-Oximeter is intended to be used with compatible Philips IntelliVue Patient Monitors. The indications for use as specified for the IntelliVue Patient Monitors applies. The Masimo Rainbow SET IntelliVue Module Pulse CO-Oximeter is indicated for the noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate, carboxyhemoglobin saturation (SpCO), methemoglobin saturation (SpMet), total hemoglobin concentration (SpHb), and/or respiratory rate (RRa). The Masimo Rainbow SET IntelliVue Module Pulse CO-Oximeter is indicated for use during both no motion and motion conditions, and for patients who are well or poorly perfused. The Masimo Rainbow SET IntelliVue Module Pulse CO-Oximeter is not intended	Same.

Table 5-2 Comparison between Subject Device (Masimo rainbow SET IntelliVue) and Predicate Device			
Feature	**Masimo rainbow SET IntelliVue Subject Device**	**Masimo rainbow SET IntelliVue Predicate Device K162675**	**Comparison to Predicate**
	to be used as the sole basis for making diagnosis or treatment decisions related to suspected carbon monoxide poisoning; it is intended to be used in conjunction with additional methods of assessing clinical signs and symptoms.	to be used as the sole basis for making diagnosis or treatment decisions related to suspected carbon monoxide poisoning; it is intended to be used in conjunction with additional methods of assessing clinical signs and symptoms.	
Principle of Operation	Masimo rainbow SET IntelliVue 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, SpCO, SpMet, and SpHb. The periodic variations in the absorption of light are used to determine the pulse rate.	Masimo rainbow SET IntelliVue 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, SpCO, SpMet, and SpHb. The periodic variations in the absorption of light are used to determine the pulse rate.	Same.

Table 5-2 Comparison between Subject Device (Masimo rainbow SET IntelliVue) and Predicate Device			
Feature	**Masimo rainbow SET IntelliVue Subject Device**	**Masimo rainbow SET IntelliVue Predicate Device K162675**	**Comparison to Predicate**
	The Masimo Rainbow Acoustic Monitoring (RAM) technology uses acoustic signals for respiration rate (RRa) measurements. RRa measures a patient's respiration rate based on airflow sounds generated in the upper airway.	The Masimo Rainbow Acoustic Monitoring (RAM) technology uses acoustic signals for respiration rate (RRa) measurements. RRa measures a patient's respiration rate based on airflow sounds generated in the upper airway.	
Performance Specifications (Arms)			
SpO2, No Motion (60-80%)	3% (Adults, Pediatrics, and Infants)	3% (Adults, Pediatrics, and Infants)	Same.
SpO2, No Motion (70-100%)	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)	Same.
SpO2, Low perfusion (70-100%)	2% (Adults, Pediatrics, Infants, and Neonates)	2% (Adults, Pediatrics, Infants, and Neonates)	Same.
Pulse Rate, No motion (25-240 bpm)	3 bpm (Adults, Pediatrics, Infants, and Neonates)	3 bpm (Adults, Pediatrics, Infants, and Neonates)	Same.
Pulse Rate, Motion (25-240 bpm)	5 bpm (Adults, Pediatrics, Infants, and Neonates)	5 bpm (Adults, Pediatrics, Infants, and Neonates)	Same.
Pulse Rate, Low Perfusion (25-240 bpm)	3 bpm (Adults, Pediatrics, Infants, and Neonates)	3 bpm (Adults, Pediatrics, Infants, and Neonates)	Same.
SpCO (1-40%)	3% (Adults, Pediatrics, Infants)	3% (Adults, Pediatrics, Infants)	Same.
SpMet (1-15%)	1% (Adults, Pediatrics, Infants, and Neonates)	1% (Adults, Pediatrics, Infants, and Neonates)	Same.
SpHb (8-17 g/dL)	1 g/dL (Adults, and Pediatrics)	1 g/dL (Adults, and Pediatrics)	Same.

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Table 5-2 Comparison between Subject Device (Masimo rainbow SET IntelliVue) and Predicate Device			
Feature	**Masimo rainbow SET IntelliVue Subject Device**	**Masimo rainbow SET IntelliVue Predicate Device K162675**	**Comparison to Predicate**
RRa (4-70 bpm)	1 bpm (Adults, and Pediatrics)	1 bpm (Adults, and Pediatrics)	Same.
Accessories			
Compatible Accessories	Masimo wired sensors and cables, Radius PPG	Masimo wired sensors and cables.	Different. Radius PPG is included as a compatible accessory to the subject device. Bench testing was performed to support the substantial equivalence.
Mechanical			
Overall Dimensions	4.0” by 3.9” by 1.4”	4.0” by 3.9” by 1.4”	Same.
Environmental Specifications			
Operating Conditions			
Temperature	0°C to 55°C (32°F to 131°F)	0°C to 55°C (32°F to 131°F)	Same.
Humidity	95% RH max at 40°C	95% RH max at 40°C	Same.
Storage conditions			
Temperature	-40°C to 70°C (-40°F to 158°F)	-40°C to 70°C (-40°F to 158°F)	Same.
Humidity	95% RH max at 65°C	95% RH max at 65°C	Same.
Classification per IEC 60601-1			
Mode of operation per IEC 60601-1	Continuous	Continuous	Same.

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6 Performance Data

Bench Testing

There were no hardware or software changes made to the subject devices as part of this submission from the previous clearances under K221953 and K162675.

Bench Testing is included in this submission to support compatibility between the subject devices and Radius PPG.

Biocompatibility Testing

As there were no changes made to the patient contacting materials of the subject devices from their previous clearances, no 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 devices from the previous clearances, no electrical safety, environmental, mechanical, and cleaning testing was included as part of this submission.

Although there are no hardware changes that were made to subject devices, EMC emissions and immunity testing was conducted to support the acceptability of the electromagnetic compatibility of the subject devices with Radius PPG.

Software Verification and Validation Testing

As there are no software changes made to the subject devices from the previous clearances, no software testing was included as part of this submission.

Wireless Testing

Wireless testing is provided with this submission to support the compatibility between the subject devices with Radius PPG.

Cybersecurity Testing

As there were no changes made to the subject device that affects cybersecurity, no additional cybersecurity testing was considered required to support the substantial equivalence.

Human Factors and Usability Testing

As there are no user interface changes made to the subject device from the previous clearances, no human factors and usability testing is included as part of this submission.

Clinical Testing

As the subject devices use the same monitoring technology as the previous clearances (K221953 and

K162675), no additional clinical testing was required to support the substantial equivalence.

However, to support the equivalence of the clinical performance of the Radius PPG on patients of different skin pigmentations, additional clinical data was provided. The results are provided below:

Patient Population	Subjects	Samples	Bias	Precision	Arms
Overall	22	762	0.04	1.75	1.75
Light	13	449	0.05	1.79	1.79
Dark	9	313	0.03	1.74	1.75

7 Conclusion

Based on the data provided as part of this submission, the subject devices, Carescape SpO2 – Masimo and Masimo rainbow SET IntelliVue, were found to be substantially equivalent to the predicate devices.