October 29, 2019

Philips Medizin Systeme Boeblingen GmbH
Greg Li
Regulatory Affairs Specialist
Hewlett-Packard Strasse 2
Boeblingen, 71034 DE

Re: K190624
Trade/Device Name: EarlyVue VS30
Regulation Number: 21 CFR 870.1100
Regulation Name: Blood pressure alarm
Regulatory Class: Class II
Product Code: DSJ, DSK, DXN, DQA, DSA, FLL
Dated: September 23, 2019
Received: September 24, 2019

Dear Greg Li:

This letter corrects our substantially equivalent letter of October 27, 2019.

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,

Stephen C. Browning -S5

Stephen Browning
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190624

Device Name
EarlyVue VS30

Indications for Use *(Describe)*
The EarlyVue VS30 is intended to measure, display, alarm and, record physiological information of adult, pediatric and neonatal patients in hospitals and in out-of-hospital patient care settings in which care is administered by a healthcare professional (such as clinics, outpatient surgery facilities, long-term care facilities, and physician offices). It is not intended for use in mobile settings such as ambulances and aircraft. Clinical users may use the monitor during patient transport within a healthcare facility.

The intended use of measurement parameters for each patient type is shown in table below (Parameter (patient types)):
Non-invasive BP--NBP (Adult, Pediatric, Neonatal);
SpO2 --Masimo rainbow SET or Philips FAST (Adult, Pediatric, Neonatal);
Pulse Rate --PR--derived from SpO2 or NBP (Adult, Pediatric, Neonatal);
Temperature-Predictive, Temporal (Adult, Pediatric, Neonatal);
end tidal CO2--etCO2 (Adult, Pediatric, Neonatal);
Respiration Rate: airway respiration--awRR (Adult, Pediatric, Neonatal);
Respiration Rate: acoustic respiration--RRa (Adult, Pediatric);
Non-invasive Total Hemoglobin--SpHb (Adult, Pediatric)

Contra-indications: Not for transport outside the healthcare facility. Not for use in home setting.

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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PHILIPS
Philips Healthcare

510K Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 CFR 807-92(c).

1. The submitter and contact person of this pre-market notification is:

   The submitter/manufacturer:

   Philips Medizin Systeme Böblingen GmbH
   Hewlett-Packard Strasse 2
   71034 Böblingen
   Germany

   Contact person:

   Greg Li
   Philips Healthcare
   3000 Minuteman Road
   Andover, MA 01810
   United States

   Tel: 978-659-4227
   Fax: 978-659-7323
   Email: Greg.li@philips.com

2. Date this summary is prepared:
   This summary is prepared on October 24, 2019.

3. Subject device

   Name of Device: EarlyVue VS30 Vital Signs Monitor
   Trade Name: EarlyVue VS30
   Common or Usual name: multi-parameter patient monitor
   Regulatory Class: II
   Classification names and Product Code:

Device Panel	Classification	Product Code	Description
Cardiovascular	870.1100, II	DSJ	Alarm, Blood Pressure
	870.1110, II	DSK	Computer, Blood Pressure
	870.1130, II	DXN	System, Measurement, Blood Pressure, Non-Invasive

Device Panel	Classification	Product Code	Description
	870.2700, II	DQA	Oximeter
	870.2900, II	DSA	Cable, transducer and electrode, patient connector
General Hospital and Personal Use	880.2910, II	FLL	Thermometer, Electronic, Clinical
Anesthesiology & Respiratory Therapy	868.1400, II	CCK	Analyzer, Gas

4. Predicate Device:
   Philips SureSigns VS4 Vital Signs Monitor cleared under K163649, K151761, K133961.

   Reference Device:
   Philips Efficia CM patient monitors with 510(k) K151812

5. Product Description

   The subject device EarlyVue VS30 is a platform redesigned from the predicate device Suresign VS4 to provide the measurement of the same physiological parameters. It is a multi-parameter compact, portable monitor, offering several configurations and optional features that are intended to meet the customer's needs. The VS30 is designed with a simple, intuitive user interface for ease of operation. It is used to measure or monitor NBP, SpO2, SpHb, RRa, CO2 and optional temperature primarily in non-acute settings.

   The subject VS30 also provides the wireless option. The wireless functions for VS30 are for the monitors to communicate with the hospital EMR system or to communicate with Philips IGS software over the hospital's wireless infrastructure.

   The differences in the technological characteristics are as follows:

   a) The subject VS30 does not provide Tympanic temperature measure whilst the predicate VS4 does have this option

   b) The outside appearance of the VS30 monitor looks different. User interface is changed comparing to the predicate VS4.

   c) The VS30 has different hardware comparing to VS4, including new Central Processing Unit (CPU), Printed Circuit Board Assemblies (PCAs).

d) The VS30 software operating system is Linux while VS4 uses Win CE. The software is recoded.

e) The wireless module used on VS30 is different from VS4. They are both from the same supplier. The VS30 wireless module has FCC certificate and FCC identification.

f) The subject VS30 has a new feature called monitor-to-monitor communication.

g) VS30 added RFID scanner for entry of patient ID and user ID.

6. The subject device EarlyVue VS30 has the same Intended Use as the legally marketed predicate device, SureSigns VS4 (the predicate VS4 has Tympanic temperature measurement but the subject VS30 does not have this measurement).

The indications for use for the subject EarlyVue VS30 is as following:

The EarlyVue VS30 is intended to measure, display, alarm and, record physiological information of adult, pediatric and neonatal patients in hospitals and in out-of-hospital patient care settings in which care is administered by a healthcare professional (such as clinics, outpatient surgery facilities, long-term care facilities, and physician offices). It is not intended for use in mobile settings such as ambulances and aircraft. Clinical users may use the monitor during patient transport within a healthcare facility.

The intended use of measurement parameters for each patient type is shown in table below:

	Patient Types		
Parameter	**Adult**	**Pediatric**	**Neonatal**
Non-invasive BP (NBP)	√	√	√
SpO2 (Masimo rainbow SET or Philips FAST)	√	√	√
Pulse Rate (PR) derived from SpO2 or NBP	√	√	√
Temperature (Predictive, Temporal)	√	√	√
end tidal CO2 (etCO2)	√	√	√
Respiration Rate: airway respiration (awRR)	√	√	√
Respiration Rate: acoustic respiration (RRa)	√	√	
Non-invasive Total Hemoglobin (SpHb)	√	√	

Contra-indications: Not for transport outside the healthcare facility. Not for use in home setting.

7. The subject device EarlyVue VS30 has the same fundamental technological characteristics as the legally marketed predicate device SureSigns VS4. Through the pre-defined verification and validation, the performance data demonstrates the subject device EarlyVue VS30 is as safe and effective as the predicate device for all the measurements.

Comparative Characteristic	**Predicate Device** **SureSigns VS4 Vital Signs Monitor** **SW A.07** **Latest 510(k): K163649**	**Subject Device** **EarlyVue VS30 Vital Signs Monitor** **SW A.00.00**	**Comparison**
Model/model number/ Reference numbers	SureSigns VS4/863283	EarlyVue VS30/863380	New Model is assigned to VS30

<table>
<tr><th>Comparative Characteristic</th><th>Predicate Device
SureSigns VS4 Vital Signs Monitor
SW A.07
Latest 510(k): K163649</th><th>Subject Device
EarlyVue VS30 Vital Signs Monitor
SW A.00.00</th><th>Comparison</th></tr>
<tr><td>Indications for use</td><td>The SureSigns VS4 vital signs monitor is for use by health care professionals whenever there is a need for monitoring the physiological parameters of patients. The SureSigns VS4 is for monitoring, recording and alarming of multiple physiological parameters in healthcare environments for patient types listed below. Additionally, the monitor may be used in transport situations within a healthcare facility.
<table>
<tr><th rowspan="2">Parameter</th><th colspan="3">Patient Types</th></tr>
<tr><th>Adult</th><th>Pediatric</th><th>Neonatal</th></tr>
<tr><td>NBP</td><td>√</td><td>√</td><td>√</td></tr>
<tr><td>SpO2</td><td>√</td><td>√</td><td>√</td></tr>
<tr><td>Temperature</td><td>√</td><td>√</td><td>√</td></tr>
<tr><td>CO2</td><td>√</td><td>√</td><td>√</td></tr>
<tr><td>RRa</td><td>√</td><td>√</td><td></td></tr>
<tr><td>SpHb</td><td>√</td><td>√</td><td></td></tr>
</table>
Contraindications: Not for transport outside the healthcare facility</td><td>The EarlyVue VS30 is intended to measure, display, alarm and, record physiological information of adult, pediatric and neonatal patients in hospitals and in out-of-hospital patient care settings in which care is administered by a healthcare professional (such as clinics, outpatient surgery facilities, long-term care facilities, and physician offices). It is not intended for use in mobile settings such as ambulances and aircraft. Clinical users may use the monitor during patient transport within a healthcare facility.
The intended use of measurement parameters for each patient type is shown in table below:
<table>
<tr><th rowspan="2">Parameter</th><th colspan="3">Patient Types</th></tr>
<tr><th>Adult</th><th>Pediatric</th><th>Neonatal</th></tr>
<tr><td>Non-invasive BP (NBP)</td><td>√</td><td>√</td><td>√</td></tr>
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<tr><td>Pulse Rate (PR) derived from SpO2 or NBP</td><td>√</td><td>√</td><td>√</td></tr>
<tr><td>Temperature (Predictive, Temporal)</td><td>√</td><td>√</td><td>√</td></tr>
<tr><td>end tidal CO2 (etCO2)</td><td>√</td><td>√</td><td>√</td></tr>
<tr><td>Respiration Rate: airway respiration (awRR)</td><td>√</td><td>√</td><td>√</td></tr>
<tr><td>Respiration Rate: acoustic respiration (RRa)</td><td>√</td><td>√</td><td></td></tr>
<tr><td>Non-invasive Total Hemoglobin (SpHb)</td><td>√</td><td>√</td><td></td></tr>
</table>
Contra-indications: Not for transport outside the healthcare facility. Not for use in home setting.</td><td>--both predicate VS4 and subject VS30 are intended to measure/ monitor/alar/ record patient physiological information;

--VS4 identified clinical setting as healthcare environments, VS30 clarifies this with details hospitals and in out-of-hospital patient care settings in which care is administered by a healthcare professional (such as clinics, outpatient surgery facilities, long-term care facilities, and physician offices). Technically the clinical setting is not changed.

--patient types for VS4 and VS30 are identical

--parameters are clarified in VS30 comparing to VS4. VS30 will not provide Tympanic temperature but VS4 has. Respiration Rate: airway RR (awRR) and Pulse Rate (PR) derived from SpO2 or NBP are not new. VS4 had these but not listed in the indications table.
So the parameters are identical except the VS30 will not provide Tympanic temperature.

Summary Indications for use and intended use of VS30 and VS4 are the same.</td></tr>
</table>

Comparative Characteristic	Predicate Device SureSigns VS4 Vital Signs Monitor SW A.07 Latest 510(k): K163649	Subject Device EarlyVue VS30 Vital Signs Monitor SW A.00.00	Comparison
Physical specifications: Height Length Depth Weight	Width: 26.0 cm (10.2 in) Height: 22.0 cm (8.6 in) Depth: 14.5 cm (5.7 in) Weight: 3.6 Kg (8 lbs) including battery, excluding temperature, excluding optional recorder, optional connectivity package or mounting hardware. Screen type: 8.4" 5-Wire resistive touch screen display with LED backlight	Width: 33 cm Height: 25 cm Depth: 18 cm Weight: <8 kg when fully optioned and with battery installed 10.1" (25.7 cm) LCD touch screen with LED backlight	Similar dimensions Similar. The weight in VS30 is for fully optioned and the number for VS4 does not include options. VS30 has bigger screen but still similar to VS4
Device keys	The following fixed key switches are located on the front panel with the associated labels • Alarm silence "Silence" • NBP start/stop "NBP" • NBP interval "Interval" • Main "Main" • Print "Print	The control keys are soft keys.	VS30 changes fixed keys to soft keys. The new user interface has been verified and validated. The VS30 passed the verification and validation.
Number of waveforms	Two: one for etCO2 and the other one for SpO2 or RRa, or SpO2 with RRa overlapped	Two: one for etCO2 and the other one for SpO2 or RRa, or SpO2 with RRa overlapped	Identical
Physiological Measurements: varies by configuration or option	Temperature (has Tympanic temperature option), Non-invasive Blood Pressure, SpO2, Pulse Rate, SpHb, RRa, CO2	Temperature (no Tympanic temperature option), Non-invasive Blood Pressure, SpO2, Pulse Rate, SpHb, RRa, CO2	Same except that the subject VS30 does not have Tympanic temperature but the predicate VS4 has.

Comparative Characteristic	Predicate Device SureSigns VS4 Vital Signs Monitor SW A.07 Latest 510(k): K163649	Subject Device EarlyVue VS30 Vital Signs Monitor SW A.00.00	Comparison
NBP Specifications	Philips picoNBP – K051366 Technique: Oscillometric using stepwise deflation pressure In Adult Mode, the NBP measurement range is: • Systolic 30-270mmHg • Diastolic 10-240mmHg • Mean 20-250mmHg In Pediatric Mode, the NBP measurement range is: • Systolic 30-180mmHg • Diastolic 10-150mmHg • Mean 20-160mmHg In Neonate Mode, the NIBP measurement has the following ranges for its values: • Systolic 30-130mmHg • Diastolic 10-100mmHg • Mean 20-120mmHg accuracy over the listed ranges: Maximum Standard Deviation: 8 mmHg Maximum Mean Error: +/- 5 mmHg A Pulse Rate is derived from the NBP measurement with accuracy: 40 – 100 bpm: +/- 5 bpm	Philips picoNBP – K051366 Technique: Oscillometric using stepwise deflation pressure In Adult Mode, the NBP measurement range is: • Systolic 30-270mmHg • Diastolic 10-240mmHg • Mean 20-250mmHg In Pediatric Mode, the NBP measurement range is: • Systolic 30-180mmHg • Diastolic 10-150mmHg • Mean 20-160mmHg In Neonate Mode, the NIBP measurement has the following ranges for its values: • Systolic 30-130mmHg • Diastolic 10-100mmHg • Mean 20-120mmHg accuracy over the listed ranges: Maximum Standard Deviation: 8 mmHg Maximum Mean Error: +/- 5 mmHg A Pulse Rate is derived from the NBP measurement with accuracy: 40 – 100 bpm: +/- 5 bpm	Identical

Comparative Characteristic	Predicate Device SureSigns VS4 Vital Signs Monitor SW A.07 Latest 510(k): K163649	Subject Device EarlyVue VS30 Vital Signs Monitor SW A.00.00	Comparison
	101 - 200 bpm: +/- 5% of reading 201 – 300 bpm: +/- 10% of reading (average over NIBP measurement cycle) Initial cuff inflation - Adult: 160 mmHg - Pediatric: 140 mmHg - Neonatal: 100 mmHg Subsequent cuff inflation: 30 mmHg above the last measured Systolic value -one programmable interval with up to five periods. Each period can be composed of a duration and interval. The options for each are: Duration: Off, 2, 5, 15, 30, 60, 90, 120, 150, 180, 210, 240, 270, 300 Minutes Interval: Off, 1, 2, 3, 5, 10, 15, 30, 60, 90, 120 Minutes	101 - 200 bpm: +/- 5% of reading 201 – 300 bpm: +/- 10% of reading (average over NIBP measurement cycle)Initial cuff inflation - Adult: 160 mmHg - Pediatric: 140 mmHg - Neonatal: 100 mmHg Subsequent cuff inflation: 30 mmHg above the last measured Systolic value -one programmable interval with up to five periods. Each period can be composed of a duration and interval. The options for each are: Duration: Off, 2, 5, 15, 30, 60, 90, 120, 150, 180, 210, 240, 270, 300 Minutes Interval: Off, 1, 2, 3, 5, 10, 15, 30, 60, 90, 120 Minutes	

Comparative Characteristic	Predicate Device SureSigns VS4 Vital Signs Monitor SW A.07 Latest 510(k): K163649	Subject Device EarlyVue VS30 Vital Signs Monitor SW A.00.00	Comparison
SpO_2: Philips SpO2	Measurement range - SpO2: 0 - 100% - Pulse rate: 30 - 300 bpm Pulse rate accuracy: Greater of + 2% or + 1 bmp Resolution of SpO2 measurement: 1% Wavelength range: 500 – 1000 nm for all specified sensors Maximum optical output power: ⩽ 15mW for all specified sensors Variable pitch tone for SpO2 Pleth wave displayed configurable alarm delay times: High/ Low SpO2 Alarm delay time, seconds: 0-30 Increments of change: 1 Desat Alarm: delay time, seconds: 0-30 Increments of change: 1 Default setting is : 0 seconds	Measurement range - SpO2: 0 - 100% - Pulse rate: 30 - 300 bpm Pulse rate accuracy: Greater of + 2% or + 1 bmp Resolution of SpO2 measurement: 1% Wavelength range: 500 – 1000 nm for all specified sensors Maximum optical output power: ⩽15mW for all specified sensors Variable pitch tone for SpO2 Pleth wave displayed configurable alarm delay times: High/ Low SpO2 Alarm delay time, seconds: 0-30 Increments of change: 1 Desat Alarm: delay time, seconds: 0-30 Increments of change: 1 Default setting is : 0 seconds	Identical

Comparative Characteristic	Predicate Device SureSigns VS4 Vital Signs Monitor SW A.07 Latest 510(k): K163649	Subject Device EarlyVue VS30 Vital Signs Monitor SW A.00.00	Comparison
SpO_2 Sensors	SpO2 accuracy: With SpO2 values between 70 – 100% range oxygenation Philips reusable sensors • ±2%: M1191B, M1191BL, M1191A, M1191AL, M1192A • ±3%: M1191T, M1192T, M1193T with adult use, M1193A, M1194A, M1195A, M1196A, M1196T, M1196S • ±4% - M1193T with Neonatal use Philips disposable sensors • ±2% - M1132A, M1133A, M1134A • ±3% - M1131A	SpO2 accuracy: With SpO2 values between 70 – 100% range oxygenation Philips reusable sensors • ±2%: M1191B, M1191BL, M1191A, M1191AL, M1192A • ±3%: M1191T, M1192T, M1193T with adult use, M1193A, M1194A, M1195A, M1196A, M1196T, M1196S • ±4% - M1193T with Neonatal use Philips disposable sensors • ±2% - M1132A, M1133A, M1134A ±3% - M1131A	Identical

Comparative Characteristic	Predicate Device SureSigns VS4 Vital Signs Monitor SW A.07 Latest 510(k): K163649	Subject Device EarlyVue VS30 Vital Signs Monitor SW A.00.00	Comparison
Predicative Temp Measurement range: (optional)	Measurement Range: 26.7 – 43.3°C (80 – 110°F) Accuracy in monitoring mode: ± 0.1 °C (± 0.2°F) Measurement Time • Oral: 4-6 seconds • Adult axillary: 12-15 sec • Pediatric axillary: 10-13 sec. (17 year and younger) • Rectal: 10-13 seconds Resolution: 0.1 °C Measurement sites: Oral, rectal and axillary	Measurement Range: 26.7 – 43.3°C (80 – 110°F) Accuracy in monitoring mode: ± 0.1 °C (± 0.2°F) Measurement Time • Oral: 4-6 seconds • Adult axillary: 12-15 sec • Pediatric axillary: 10-13 sec. (17 year and younger) • Rectal: 10-13 seconds Resolution: 0.1 °C (± 0.1 °F) Measurement sites: Oral, rectal and axillary	Identical

Comparative Characteristic	Predicate Device SureSigns VS4 Vital Signs Monitor SW A.07 Latest 510(k): K163649	Subject Device EarlyVue VS30 Vital Signs Monitor SW A.00.00	Comparison
Tympanic Temp measurement (optional)	The ear measurement algorithm has these correction factors for these mode built in depending on setting: Ear = None Core = Ear mode + 1.04 °C Oral = Ear mode + 0.60 °C Rectal = Ear mode + 1.16 °C The overall range of the temperature measurement is 33.0 °C to 42.0 °C (91.4 °F to 107.6 °F) Accuracy at overall temperature range is + 0.2 °C (+ 0.4 °F) The displayed resolution of the tympanic temperature measurement is 0.1 °C or 0.1 °F Approximate measurement time is equal to or better than 2 seconds. Pulse timer beeps once at each of these intervals: 15, 30, 45 and 60 seconds.	The VS30 will not provide this option	This option is not provided by the subject VS30
Masimo SpO2, SpHb, RRa measurement	yes	yes	Identical
Range of Masimo SpO2 measurement	0-100%	0-100%	Identical

Comparative Characteristic	**Predicate Device** **SureSigns VS4 Vital Signs Monitor** **SW A.07** **Latest 510(k): K163649**	**Subject Device** **EarlyVue VS30 Vital Signs Monitor** **SW A.00.00**	**Comparison**
Resolution of SpO2 measurement	1%	1%	Identical
Accuracy of Masimo SpO2	No motion: • 60-80 +/- 3%, for adults/pediatrics/infants • 70-100 +/-2%, for adults/pediatrics/infants, • 70-100 +/-3%, for neonates Motion: • 70-100 +/-3%, for adults/pediatrics/infants/ neonates Low perfusion: • 70-100 +/-2%, for adults/pediatrics/infants/ neonates	No motion: • 60-80 +/- 3%, for adults/pediatrics/infants • 70-100 +/-2%, for adults/pediatrics/infants, • 70-100 +/-3%, for neonates Motion: • 70-100 +/-3%, for adults/pediatrics/infants/ neonates Low perfusion: 70-100 +/-2%, for adults/pediatrics/infants/ neonates	Identical
Pleth waveform	A pleth waveform is derived from measurement	A pleth waveform is derived from measurement	Identical
Pulse rate derived from the Masimo SpO2 measurement	Yes	Yes	Identical
Pulse rate range	25-240 bpm	25-240 bpm	Identical
Pulse rate resolution	1 bpm	1 bpm	Identical

Comparative Characteristic	Predicate Device SureSigns VS4 Vital Signs Monitor SW A.07 Latest 510(k): K163649	Subject Device EarlyVue VS30 Vital Signs Monitor SW A.00.00	Comparison
Pulse rate accuracy	+/-5 bpm motion or low perfusion worst case	+/-5 bpm motion or low perfusion worst case	Identical
Range of SpHb measurement	0-25 g/dL	0-25 g/dL	Identical
SpHb accuracy	8-17 g/dL (arterial or venous) adults/pediatrics: +/- 1g/dL	8-17 g/dL (arterial or venous) adults/pediatrics: +/- 1g/dL	Identical
SpHb resolution	0.1 g/dL	0.1 g/dL	Identical
Range of respiratory rate (RRa)	0-70 breaths per minute (bpm)	0-70 breaths per minute (bpm)	Identical
RRa accuracy	In the range of 4-70 bpm: +/-1 bpm, adults (>30kg)	In the range of 4-70 bpm: +/-1 bpm, adults (>30kg)	Identical
Technology used for RRa measurement and calculation	Rainbow SET technology (K110028)	Rainbow SET technology (K110028)	Identical Please refer to section 7.2 for respiration rate comparison between the VS30 and Masimo Rainbow SET RRa
RRa resolution	1 breath per minute (bpm)	1 breath per minute (bpm)	Identical
Firmware	Rainbow SET Technology, MX board/circuitry from Masimo	Rainbow SET Technology, MX board/circuitry from Masimo	Identical
Wavelength range	653 to 905 nm for all specified sensors	500 nm to 1400 for all specified sensors	Identical
Maximum optical output power	<=25mW for all specified sensors	<=25mW for all specified sensors	Identical

Comparative Characteristic	**Predicate Device** **SureSigns VS4 Vital Signs Monitor** **SW A.07** **Latest 510(k): K163649**	**Subject Device** **EarlyVue VS30 Vital Signs Monitor** **SW A.00.00**	**Comparison**
Temporal Temperature measurement	yes	yes	Identical
Can display both °C and oF	yes	yes	Identical
Range of temperature measurement	16 °C - 43 °C	16 °C - 43 °C	Identical
Clinical accuracy	+/- 0.2 oF or 0.1 °C per ASTM E1112	+/- 0.2 oF or 0.1 °C per ASTM E1112	Identical
Arterial heat balance range for body temperature	34.5 °C -43 °C Normal range is defined as 35.9°C to 37.5°C, with mean of 37°C.	34.5 °C -43 °C Normal range is defined as 35.9°C to 37.5°C, with mean of 37°C.	Identical
Resolution	Both on probe and on monitor 0.1 °C or 0.1 oF	Both on probe and on monitor 0.1 °C or 0.1 oF	Identical
Response time	<=1 second	<=1 second	Identical
CO2 Measurement	yes	yes	Identical
Measurement range	0 – 150 mmHg	Same	Identical
Sampling rate	Waveform sampling, 20 samples per second	Same	Identical
Flow rate	50 ml/min, + 15 ml/min, - 7.5 ml/min	Same	Identical

Comparative Characteristic	Predicate Device SureSigns VS4 Vital Signs Monitor SW A.07 Latest 510(k): K163649	Subject Device EarlyVue VS30 Vital Signs Monitor SW A.00.00	Comparison
Warm-up time for CO2 measurement	30 seconds (typical)	30 seconds (typical)	Identical
Calibration interval	Initial Calibration after 1,200 hours or after one year whichever comes first, then once per year or every 4000 hours, whichever comes first	Initial Calibration after 1,200 hours or after one year whichever comes first, then once per year or every 4000 hours, whichever comes first	Identical
Accuracy of etCO2 measurement	0 – 38 mmHg: ±2 mmHg 39 – 150 mmHg: ±(5% of reading + 0.08% for every 1 mmHg above 38 mmHg)	0 – 38 mmHg: ±2 mmHg 39 – 150 mmHg: ±(5% of reading + 0.08% for every 1 mmHg above 38 mmHg)	Identical
Range of Respiration rate	Respiration rate can be displayed with a range of 0-150 respirations/ minute	Respiration rate can be displayed with a range of 0-150 respirations/ minute	Identical
accuracy of Respiration Rate	±1 rpm in the range of 0– 70 rpm ±2 rpm in the range of 71 – 120 rpm ±3 rpm in the range of 121 – 150 rpm	±1 rpm in the range of 0– 70 rpm ±2 rpm in the range of 71 – 120 rpm ±3 rpm in the range of 121 – 150 rpm	Identical
Technology used for respiration rate calculation	Oridion MicroMediCO2 module (K123690)	Oridion MicroMediCO2 module (K123690)	Identical Please refer to section 7.1 for respiration rate comparison between the VS30 and the Oridion MicroMediCO2.
CO2 response time	CO2 Response Time (Delay time + Rise time + System time) is approximately 3.9 seconds. Long lines add an additional 3 seconds to the overall response time.	CO2 Response Time (Delay time + Rise time + System time) is approximately 3.9 seconds. Long lines add an additional 3 seconds to the overall response time.	Identical
Battery power operation	3 hour	6 hour	Battery can operate with longer time

Comparative Characteristic	Predicate Device SureSigns VS4 Vital Signs Monitor SW A.07 Latest 510(k): K163649	Subject Device EarlyVue VS30 Vital Signs Monitor SW A.00.00	Comparison
Bar Code scanner	Yes – the bar code reader allows for entry of patient identification information and user ID	Yes – the bar code reader allows for entry of patient identification information and user ID	Identical
RFID scanner	No	Yes-- allows for entry of patient identification information and user ID	This application is a non-medical application. The subject VS30 has an option of RFID scanner for entry of patient identification information and user ID. This is fully verified and verification passed all tests.
Quick Capture	Yes	Yes	Identical
Quick Check	Yes	Yes	Identical
Quick Alerts	Yes	Yes	Identical
Connection with Philips IGS software	Yes	Yes	Identical
Get EWS from IGS	Yes	Yes	Identical
On-device EWS	Yes	Yes	Identical
Device operating temperature	10°C to 40°C monitor 16°C to 33°C monitor with tympanic 10°C to 40°C for WelchAllyn 0°C to 50°C for Masimo 16°C to 40°C for Exergen	10°C to 40°C monitor 10°C to 40°C for WelchAllyn 16°C to 40°C for Exergen	Same

Comparative Characteristic	Predicate Device SureSigns VS4 Vital Signs Monitor SW A.07 Latest 510(k): K163649	Subject Device EarlyVue VS30 Vital Signs Monitor SW A.00.00	Comparison
Storage temperature	-20°C to 50°C for the monitor -20°C to 40°C for the monitor plus accessories -20°C to 50°C for WelchAllyn -40°C to 70°C for Masimo -20°C to 50°C for Exergen	20°C to 50°C for the monitor -20°C to 40°C for the monitor plus accessories	Same
Operation and storage Humidity	Up to 90% Relative Humidity non-condensing Up to 80% Relative Humidity non-condensing with recorder and paper 15-90% for Welch Allyn predictive temperature (non-condensing) 10-90% Masimo SpO2	Composite test range 10% to 90% RH (non-condensing) for monitor Composite test range 10% to 80% RH for monitor with print recorder and paper	Same
Monitor to monitor sharing	No	Yes ---view saved patient records remotely on up to 15 monitors ---view the last saved record for up to 100 patients ---view patient data trends in graphical or tabular format, up to 35 records.	This is a non-medical application. This is a new feature . The view is only to view records. The user can not use one monitor to monitor/measure patient who is connected to other monitors. This is a hospital work flow improvement feature but not a medical application. This feature is fully verified and the verification passed the tests.

7.1 Respiration rate comparison between Early VS30 and Oridion MicroMediCO2

Parameter	Oridion MicroMediCO2	EarlyVue VS30	Comparison

	K123690	K190624	
CO2 Respiration rate range	0-150 bpm	0 breaths/min to 150 breaths/min	Identical
CO2 Respiration rate accuracy	0-70 bpm: +/-1 bpm 71-120 bpm: +/-2 bpm 121-150 bpm: +/-3 bpm	±1 rpm in the range of 0 rpm–70 rpm ±2 rpm in the range of 71 rpm–120 rpm ±3 rpm in the range of 121 rpm–150 rpm	Identical

7.2 RRa respiration rate comparison between the VS30 and the Masimo RRa

Parameter	Masimo RRa respiration rate K110028	EarlyVue VS30 K190624	Comparison
RRa Measurement Range	4 – 70 breaths per minute	4 – 70 breaths per minute	Identical
RRa Accuracy	± 1 breath per minute in the range 4 – 70 breaths per minute, Adults (> 30 kg) and Adults/Pediatrics (> 10 kg)	± 1 breath per minute in the range 4 – 70 breaths per minute, Adults (> 30 kg) and Adults/Pediatrics (> 10 kg)	Identical

8. Verification and testing activities establish the performance, functionality, and reliability characteristics of the subject device VS30. Testing involved software, hardware, environmental and reliability, safety and performance.

   The VS30 is tested against applicable FDA consensus IEC/ISO standards.
   The following standards were tested and the EarlyVue VS30 passed the tests of all these standards:

Standard and Year	Description	FDA recognition number
IEC 60601-1 ed 3.1:2012 Issue Date: 2012-08-30	Medical electrical equipment. Part 1: General requirements for basic safety and essential performance	19-4
IEC 60601-1-2 ed 4.0:2014 Issue Date: 2014-02-28	Medical electrical equipment. Part 1-2: General requirements for basic safety and essential performance. Collateral standard: Electromagnetic compatibility. Requirements and tests	19-8
IEC 60601-1-6 ed 3.1:2013 Issue Date: 2013-10-31	Medical electrical equipment. Part 1-6: General requirements for basic safety and essential performance. Collateral standard: Usability	5-89
IEC 62366-1 ed 1.0:2015 Issue Date: 2015-02-28	Medical devices. Part 1: Application of usability engineering to medical devices	5-114
IEC 62304 ed 1.1:2015 Issue Date: 2015-06-29	Medical device software. Software life cycle processes	13-79
IEC 60601-1-8 ed 2.1:2012 Issue Date: 2012-11-30	Medical electrical equipment. Part 1-8: General requirements for basic safety and essential performance. Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems	5-76
IEC 80601-2-30 ed 1.1:2013 Issue Date: 2013-07-30	Medical electrical equipment. Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers	3-152
IEC 60601-2-49 ed 2.0:2011 Issue Date: 2011-02-28	Medical electrical equipment. Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment	Not recognized
ISO 80601-2-55:2011 Issue Date: 2011-12-15	Medical electrical equipment, part 2-55 — Particular requirements for the basic safety and essential performance of respiratory gas monitor	1-96
ISO 80601-2-56:2017 Issue Date: 2017-03	Medical electrical equipment. Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement	6-403
ISO 80601-2-61:2011 Issue Date: 2011-03-31	Medical electrical equipment. Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment	1-85
ISO 15223-1:2017 Issue Date: 2016-11	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements	5-117

In summary, the subject device VS30 has the same intended use as the predicate device VS4. The VS30 does not add any new measurement comparing to the predicate device VS4 and the measurement technologies used are identical.

Any new or different features have been verified and validated, such as the monitor to monitor sharing, the new user interface including the function keys. The result supports a determination of substantial equivalence of VS30 to the predict device VS4.

The VS30 has been tested to all applicable IEC/ISO safety, EMC and performance standards and passed all the tests.

All the VS30 measurement functions were verified through verification test/integration test.

The VS30 with the wireless module was tested to and passed the ANSI C63.27-2017 standard and comply with the FDA guidance “Radio Frequency Wireless Technology in Medical Devices Guidance”.

The VS30 software has been verified according to the design control process which was designed according to the FDA quality management system regulation.

All the VS30 electric interfaces has been tested and verified and comply with the FDA guidance: Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices.

In conclusion, the subject VS30 successfully passed all verifications, testing and validations. The results demonstrate that the Philips EarlyVue VS30 Vital Signs Monitor meets all safety, effectiveness and performance requirements. The subject EarlyVue VS30 is as safe, as effective and performs as well as the predicate device SureSigns VS4. The EarlyVue VS30 is substantially equivalent to the predicate device VS4.