DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 30, 2017

Welch Allyn, Inc.
Mark Alsberge
Lead Engineer, Regulatory Affairs
4341 State Street Road
Skaneateles Falls, New York 13153

Re: K171621
Trade/Device Name: Welch Allyn Connex Vital Signs Monitor 6000 Series, Welch Allyn Connex Integrated Wall System 80000 Series, 901060 Vital Signs Monitor
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer And Rate Alarm)
Regulatory Class: Class II
Product Code: MHX, MWI
Dated: May 31, 2017
Received: June 2, 2017

Dear Mark Alsberge:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K171621

Device Name
Welch Allyn Connex® Vital Signs Monitor 6000 Series
Welch Allyn Connex® Integrated Wall System 80000 Series
901060 Vital Signs Monitor

Indications for Use *(Describe)*
The VSM 6000 series of monitors is intended to be used by clinicians and medically qualified personnel for monitoring of neonatal, pediatric, and adult patients for:

– noninvasive blood pressure,
– pulse rate,
– noninvasive functional oxygen saturation of arteriolar hemoglobin (SpO2), and
– body temperature in normal and axillary modes.

The most likely locations for patients to be monitored are general medical and surgical floors, general hospital, and alternate care environments.

The optional Masimo Rainbow SET® Pulse CO-Oximeter and accessories are indicated for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate, total hemoglobin concentration (SpHb), and/or respiration rate (RRa). The Masimo Rainbow SET® Radical 7R Pulse CO-Oximeter and accessories are 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.

The optional Oridion module and accessories are intended for the continuous non invasive measurement and monitoring of carbon dioxide concentration of the expired and inspired breath and respiration rate. It is intended for use with neonatal, pediatric and adult patients in hospitals and hospital type facilities.

The optional Oridion module also provides the clinician with an integrated pulmonary index (IPI). The IPI is based on four parameters provided by the monitor: end tidal carbon dioxide, respiration rate, oxygen saturation and pulse rate. The IPI is a single index of an adult or pediatric patient's ventilatory status displayed on a scale of 1 - 10, where 10 indicates optimal pulmonary status. IPI monitoring displays a single value that represents the patient's pulmonary parameters and alerts clinicians to changes in the patient's pulmonary status.

The IPI is an adjunct to, and is not intended to replace, vital sign monitoring.

Optional compatible weight scales (e.g., Health o meter®) can be used for height, weight, and BMI input.

The Welch Allyn Connex® Vital Signs Monitor (CVSM) 6000 Series also contains the Welch Allyn Applications Framework ("Framework"). The Framework is general purpose software that allows medical device and non-medical device software applications to be run on the CVSM independently of, and isolated from, the CVSM's vital signs monitoring functionality. All such applications are intended to be used on the CVSM by trained professionals in a health care setting.

The EarlySense (Everon) module is intended for continuous measurement of respiration rate, heart rate and movement. in an automatic contact-less manner, in a hospital or clinic setting. The system is indicated for use in children, adolescents and adults. The operation of the EarlySense has been studied in children (weight $\geq$ 10 Kg) and adults (weight <111 Kg) during sleep and resting condition.

The Welch Allyn ECG/Impedance Respiration module and associated software acquires and analyzes ECG signals from

patients. Patients are people with coronary problems, suspected coronary problems, or recent medical procedures that require cardiac monitoring.
This ECG module can be used on adult and pediatric patients.
The ECG module is indicated for use by healthcare professionals whenever there is aneed to monitor a patient's physiological parameters for the following:
• ECG
• ECG with alarms for ventricular tachycardia, ventricular fibrillation, and asystole
• Impedance respiration

Handle module assembly (Connex Integrated Wall System 8000 series only - Handle Module) - Handles supply power to Welch Allyn 3.5V instruments.

This product is available for sale only upon the order of a physician or licensed health care professional.

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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510(k) Summary

[As described in 21 CFR 807.92]

Submitted by: Welch Allyn Inc.
4341 State Street Road
Skaneateles Falls, NY 13153-0220

Contact Person: Mark Alsberge
Lead Regulatory Affairs Engineer
Phone: (315) 685-4471
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Date Prepared: May 19, 2017

Trade Name: Connex® Vital Signs Monitor 6000 Series
Connex® Integrated Wall System 80000 Series
901060 Vital Signs Monitor

Common Name: monitor, physiological, patient(with arrhythmia detection or alarms)

Classification Reference: Class II, monitor, physiological, patient(with arrhythmia detection or alarms)
(21 CFR 870.1025, Product Code MHX)

Predicate Device: Connex® Vital Signs Monitor 6000 Series
510(k) Number: K132808
monitor,physiological,patient(without arrhythmia detection or alarms), 21 CFR 870.2300
Class II, MWI

Matrix Mini ECG Monitor
510(k) Number: K152701
Arrhythmia Detector and Alarm (Including ST-Segment Measurement and Alarm), 21 CFR 870.1025
Class II, DSI, DRT, BZQ

Description of the Device:

The Welch Allyn Connex® Vital Signs Monitor 6000 Series (CVSM) is designed to provide a scalable, modular system of components which can be configured to address the needs for vital signs spot checking and continuous monitoring.

The Welch Allyn Connex® Vital Signs Monitor 6000 Series monitor is intended to be used by clinicians and medically qualified personnel for measuring or monitoring patient vital signs. The particular vital sign measurements available are determined by the sensor/processing modules installed into the base unit including;

- NIBP Module provides measurements of noninvasive blood pressure and pulse rate,
- SpO_2 Modules from Nellcor and Masimo provide pulse rate, noninvasive functional oxygen saturation of arteriolar hemoglobin,
- The Masimo SpO_2 Module can also provide hemoglobin measurements (SpHb, SpHbv) and acoustic respiration rate (RRa),
- The SureTemp Temperature Module measures body temperature in normal and axillary modes of neonatal, pediatric, and adult patients. Temperature can also be measured IR ear thermometer.
- The Oridion Capnography Module equipped systems are also capable of carbon dioxide (CO_2), respiration rate (RR) and calculation of Integrated Pulmonary Index (IPI) measurements,
- The EarlySense Module provide users the option of continuous and contact-less monitoring of respiration rate, heart rate and patient movement.
- The Global Instruments module provides 3 -5 lead ECG/Impedance Respiration. The ECG modules is for continuous measurement of respiration rate, heart rate and detection of cardiac standstill (asystole), ventricular tachycardia and ventricular fibrillation The addition of this Global Instruments Module is the subject of this 510(k)

The CVSM can also display and transmit patient data that is electronically or manually entered from external and accessory devices, e.g., weight and height data, barcode scanner, IR temperature, and other patient or facility information. Data can be transmitted electronically via USB, wired Ethernet, or wireless communications, including, for example, to electronic record systems and for remote display and alarming (e.g., central station).

Indications for Use:

The Connex® Vital Signs Monitor 6000 series of monitors is intended to be used by clinicians and medically qualified personnel for monitoring of neonatal, pediatric, and adult patients for:

- noninvasive blood pressure,
- pulse rate,
- noninvasive functional oxygen saturation of arteriolar hemoglobin (SpO2), and
- body temperature in normal and axillary modes.

The most likely locations for patients to be monitored are general medical and surgical floors, general hospital, and alternate care environments.

The optional Masimo Rainbow SET® Pulse CO-Oximeter and accessories are indicated for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate, total hemoglobin concentration (SpHb), and/or respiration rate (RRa). The Masimo Rainbow SET® Radical 7R Pulse CO-Oximeter and accessories are 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.

The optional Oridion module and accessories are intended for the continuous non invasive measurement and monitoring of carbon dioxide concentration of the expired and inspired breath and respiration rate. It is intended for use with neonatal, pediatric and adult patients in hospitals and hospital type facilities.

The optional Oridion module also provides the clinician with an integrated pulmonary index (IPI). The IPI is based on four parameters provided by the monitor: end tidal carbon dioxide, respiration rate, oxygen saturation and pulse rate. The IPI is a single index of an adult or pediatric patient's ventilatory status displayed on a scale of 1 - 10, where 10 indicates optimal pulmonary status. IPI monitoring displays a single value that represents the patient's pulmonary parameters and alerts clinicians to changes in the patient's pulmonary status.

The IPI is an adjunct to, and is not intended to replace, vital sign monitoring.

Optional compatible weight scales (e.g., Health o meter®) can be used for height, weight, and BMI input.

The Welch Allyn Connex® Vital Signs Monitor (CVSM) 6000 Series also contains the Welch Allyn Applications Framework ("Framework"). The Framework is general purpose software that allows medical device and non-medical device software applications to be run on the CVSM independently of, and isolated from, the CVSM's vital signs monitoring functionality. All such applications are intended to be used on the CVSM by trained professionals in a health care setting.

The EarlySense (Everon) module is intended for continuous measurement of respiration rate, heart rate and movement. in an automatic contact-less manner, in a hospital or clinic setting. The system is indicated for use in children, adolescents and adults. The operation of the EarlySense has been studied in children (weight ≥ 10 Kg) and adults (weight <111 Kg) during sleep and resting condition.

The optional ECG/Impedance Respiration System is intended for continuous measurement of respiration rate, heart rate and detection of cardiac standstill (asystole), ventricular tachycardia and ventricular fibrillation in general medical and surgical floors, general hospital and professional healthcare facilities. The system is indicated for use in pediatric and adult patients.

This product is available for sale only upon the order of a physician or licensed health care professional.

Contraindications:

This system (all configurations) is not intended to be used:

- on patients connected to heart/lung machines
- on patients being transported outside a healthcare facility
- within the controlled access area of MRI equipment
- in a hyperbaric chamber
- in the presence of flammable anesthetics
- in the presence of electrocauterization devices

Systems configured with EarlySense are not intended to be used:

- on patients for whom proper positioning cannot be achieved or maintained
- on patients who do not meet the weight limits tested or specified

Systems configured with a GI ECG module are not intended to be used:

- The Welch Allyn ECG/Impedance Respiration module is not intended for infants weighing less than 10 Kg (22 lbs) or neonatal patients.

- This module is not designed for direct cardiac application.
- This module is not suitable for transport.
- Computer-assisted ECG data acquisition and interpretation is a valuable tool when used properly. However, no automated interpretation is completely reliable. Interpretations should be reviewed by a qualified physician before treatment, or non-treatment, of any patient.

Technological Characteristics:

The fundamental hardware and mechanical aspects of the CVSM itself remain the same as the predicate CVSM device cleared under K132808 and Global Instruments ECG module cleared under K152701. As noted above, this special 510(k) is for minor software modifications to integrate and display signals from the cleared Global Instruments ECG module on the CVSM system. No changes were made to the Global Instruments ECG technology as cleared; the only changes that are the subject of this submission are the modifications to the CVSM to accommodate integration of the Global Instruments ECG module.

Non-Clinical Tests:

The Welch Allyn Connex® Vital Signs Monitor 6000 Series was tested to evaluate its safety and effectiveness based on the following standards:

Standard	Version	Title
IEC 60601-1	2012	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN/IEC 60601-1-2	2007	Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests
IEC 60601-1-6	2010 (3.1 Edition) + A1:2013	Medical electrical equipment Part 1-6 General requirements for safety - Collateral Standard: Usability
IEC 62366	2007 (First Edition) + A1: 2014	Medical devices – Application of usability engineering to medical devices

IEC 60601-2-49	2011 (2nd Edition)	Medical electrical equipment Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment
IEC 60601-1- 8	2006 (Second Edition) + Am.1: 2012	Medical electrical equipment 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
IEC 62304	2006 (First Edition) + A1:2015	Medical Device Software - Software Life Cycle Processes
IEC 60601-2-27	2011 (Third Edition)	Medical electrical equipment Part 2-27: Particular Requirements for the Safety, Including Essential Performance of Electrocardiographic Monitoring Equipment
IEC 80601-2-30	2009/AMD1: 2013	Medical Electrical Equipment - Part 2-30: Particular Requirements For The Basic Safety And Essential Performance Of Automated Non-Invasive Sphygmomanometers
ISO 80601-2-55	2011 (First Edition)	Medical Electrical Equipment - Part 2-55: Particular Requirements For The Basic Safety And Essential Performance Of Respiratory Gas Monitors
ISO 80601-2-56	2009 (First Edition)	Medical Electrical Equipment - Part 2-56: Particular Requirements For Basic Safety And Essential Performance Of Clinical Thermometers For Body Temperature Measurement.
ISO 80601-2-61	2011 (First Edition)	Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
EN/ISO 14971	2007 / (R) 2010	Medical Devices – Application of Risk Management to Medical Devices

Additional performance Bench Testing:

Report --- Description	Objective of the Test	Conclusions
60077449 Safety Test – CVSM/CIWS Connex Vital Signs Monitor / Connex Integrated Wall System	Test the device per requirements of 60601-1 General Standard, along with associated Collateral and Particular Standards to ensure that the device meets the requirements for Electrical Medical Device Safety	**Pass**
60082806 Electromagnetic Compatibility test CVSM Connex Vital Signs Monitor	Test the device per 60601-1-2 to ensure that the device meets the requirements for Electromagnetic Compatibility	**Pass**
600829806 Electromagnetic Compatibility test CIWS Connex Integrated Wall System	Test the device per 60601-1-2 to ensure that the device meets the requirements for Electromagnetic Compatibility	**Pass**
60072154 CVSM-CIWS ECG Interface Test.	To verify the ECG module functions when integrated into the platform device. This test is also user to verify ECG Module functions after the system is exposed to the various test conditions below and appears in the criteria column when repeated	**PASS**
60054591 Mobile Stand Threshold	The purpose of this test is to verify that the product is capable of withstanding the stresses caused by rough handling as defined by IEC 60601-1)	**Pass**
60056145 Mobile Stand Tilt	The purpose of this test is to verify that the product is stable on a stand as defined by IEC 60601-1	**Pass**
60056145 Shock and Vibration Test	To verify product safety and performance after exposure to shock and vibration.	**Pass**
60056405 Thermal Shock Test	To verify product performance after the thermal shock conditions specified in Applied standards.	**Pass**

60056431 Operating Environmental Test (Temperature and Humidity)	To verify product safety and performance within the specified temperature and humidity environment.	**Pass**
60056898 Ambient Characterization Test	The purpose of this test is ensure that the module level components do not exceed each of their operating temperatures when integrated into the Platform Device and exposed to the operating temperature limits of that device.	**Pass**
60056476 Functional Drop	To verify product safety and performance after exposure to free fall.	**Pass**
60056426 VVP Device Weight Test	To verify the configured Platform device weight.	**Pass**
60056945 Device Ship Test	Ensure device, enclosed in the selected shipping container, meets specifications.	**Pass**
60042214 Battery Use Cycles Per Charge– Continuous Monitoring	Verify that the battery shall operate for a minimum of 2 hours under the continuous monitoring use case conditions specified in PMP PAS 60028508 Section 4.4.	**Pass**
60072092 2 ECG Module Connected to CVSM - Misuse	The purpose of the test is to investigate the behavior of the device after two ECG modules are connected to it. **Misuse Testing –** reasonably foreseeable misuse use by the operator in a way not intended by the manufacturer but which can result from readily predictable human behavior.	**Pass**
60082302 CVSM-CIWS ECG Patient Cable shorting	The purpose of the test is to investigate the behavior of the device, connected to an ECG module via USB, when the patient cables are all shorted together. This is a common trouble shooting technique with other ECG products to ensure that the patient cable leads are intact. **Abuse Testing –** reasonably foreseeable abusive use by the operator in a way not intended by the manufacturer but which can result from readily predictable human behavior.	**Pass**
60042215 PMP BOM Verification	The objective of this test is to verify that the released CVSM-ECG BOM includes the specified components identified within the requirements being tested section of this test. This is not a functional test, it is intended as a device inventory to ensure models can be built that will support the features indicated.	**Pass**
60047144 Thermal Shock – 25 cycle	To identify design flaws or behaviors that may occur as a result of the device being exposed to stimulus beyond what is specified within the device thermal shock requirements.	**Pass**

60082307 CIWS ECG Patient Cable Abuse	The purpose of the test is to investigate the behavior of the device, connected to an ECG module via USB, when cables connected to the ECG module are pulled with a force. Abuse Testing – reasonably foreseeable abusive use by the operator in a way not intended by the manufacturer but which can result from readily predictable human behavior.	
VVR 60082325 For 60072367 CVSM ECG USB and Patient Cable Abus	The purpose of the test is to investigate the behavior of the device, connected to an ECG module via USB, when cables connected to the ECG module are pulled with a force. **Abuse Testing –** reasonably foreseeable abusive use by the operator in a way not intended by the manufacturer but which can result from readily predictable human behavior.	
60082350 for 60072546 ECG Device List	This protocol verifies that WAST (WelchAllyn Service Tool) lists the ECG device with CVSM connected via USB, and updates when any device is added or removed	
VVR 60082506 For 60082431 CVSM ECG ACM Mount Reliability Test.	Test the Reliability of ECG module mounting to repeated use	

Clinical Performance Data:

No clinical studies were utilized for the purpose of obtaining safety and effectiveness data.

Device Comparison Table:

The Welch Allyn Connex® Vital Signs Monitor 6000 Series is substantially equivalent in operation and performance to the Welch Allyn Vital Signs Monitor 6000 Series monitor (K121013).

Subject Device and Predicate Device Comparison			
Characteristic	***Predicate Devices***	***Subject Device***	***Differences***
Device Name	Connex® VSM 6000 Series and Matrix Mini ECG Monitor	Connex® VSM 6000 Series	Same Added ECG Module
Manufacturer	**Welch Allyn, Inc., and Global Instrumentation , LLC**	**Welch Allyn, Inc.,**	Same – Welch Allyn will be distributor of ECG Module
510(k) Number	K132808 K152701	N/A	N/A
Product Code	**MWI** DSI, DRT, BZQ	**MHX**	Update with addition of ECG module
Regulation Name	870.2300 – Cardiac monitor (including cardiotachometer and rate alarm) 870.1025 - Arrhythmia Detector and Alarm (Including ST-Segment Measurement and Alarm)	870.1025 – monitor, physiological, patient(with arrhythmia detection or alarms)	Update with addition of ECG module
Indications For Use	Welch Allyn Connex ® VSM 6000 Series The VSM 6000 series of monitors is intended to be used by clinicians and medically qualified personnel for monitoring of neonatal, pediatric, and adult patients	Welch Allyn Connex ® VSM 6000 Series The VSM 6000 series of monitors is intended to be used by clinicians and medically qualified personnel for monitoring of neonatal, pediatric, and adult patients	

Subject Device and Predicate Device Comparison			
Characteristic	***Predicate Devices***	***Subject Device***	***Differences***
	for: - noninvasive blood pressure, - pulse rate, - noninvasive functional oxygen saturation of arteriolar hemoglobin (SpO_2), and - body temperature in normal and axillary modes. The most likely locations for patients to be monitored are general medical and surgical floors, general hospital, and alternate care environments. The optional Masimo Rainbow SET® Pulse CO-Oximeter and accessories are indicated for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2), pulse rate, total hemoglobin concentration (SpHb), and/or respiration rate (RRa). The Masimo Rainbow SET® Radical 7R Pulse CO-Oximeter and accessories are 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. The optional Oridion module and accessories are intended for the continuous non invasive measurement and monitoring of carbon dioxide concentration of the expired and inspired breath and respiration rate. It is intended for use with neonatal, pediatric and adult patients in hospitals	for: - noninvasive blood pressure, - pulse rate, - noninvasive functional oxygen saturation of arteriolar hemoglobin (SpO_2), and - body temperature in normal and axillary modes. The most likely locations for patients to be monitored are general medical and surgical floors, general hospital, and alternate care environments. The optional Masimo Rainbow SET® Pulse CO-Oximeter and accessories are indicated for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2), pulse rate, total hemoglobin concentration (SpHb), and/or respiration rate (RRa). The Masimo Rainbow SET® Radical 7R Pulse CO-Oximeter and accessories are 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. The optional Oridion module and accessories are intended for the continuous non invasive measurement and monitoring of carbon dioxide concentration of the expired and inspired breath and respiration rate. It is intended for use with neonatal, pediatric and adult patients in	Same

Subject Device and Predicate Device Comparison			
Characteristic	***Predicate Devices***	***Subject Device***	***Differences***
	and hospital type facilities. concentration of the expired and inspired breath and respiration rate. It is intended for use with neonatal, pediatric, and adult patients in hospitals and hospital type facilities. The optional Oridion module also provides the clinician with an integrated pulmonary index (IPI). The IPI is based on four parameters provided by the monitor: end tidal carbon dioxide, respiration rate, oxygen saturation and pulse rate. The IPI is a single index of an adult or pediatric patient's ventilatory status displayed on a scale of 1 - 10, where 10 indicates optimal pulmonary status. IPI monitoring displays a single value that represents the patient's pulmonary parameters and alerts clinicians to changes in the patient's pulmonary status. The IPI is an adjunct to, and is not intended to replace, vital sign monitoring. Optional compatible weight scales (e.g.,Health o meter®) can be used for height, weight, and BMI input. The Welch Allyn Connex® Vital Signs Monitor (CVSM) 6000 Series also contains the Welch Allyn Applications Framework ("Framework"). The Framework is general purpose software that allows medical device and non-medical device software applications to be run on the	hospitals and hospital type facilities. concentration of the expired and inspired breath and respiration rate. It is intended for use with neonatal, pediatric, and adult patients in hospitals and hospital type facilities. The optional Oridion module also provides the clinician with an integrated pulmonary index (IPI). The IPI is based on four parameters provided by the monitor: end tidal carbon dioxide, respiration rate, oxygen saturation and pulse rate. The IPI is a single index of an adult or pediatric patient's ventilatory status displayed on a scale of 1 - 10, where 10 indicates optimal pulmonary status. IPI monitoring displays a single value that represents the patient's pulmonary parameters and alerts clinicians to changes in the patient's pulmonary status. The IPI is an adjunct to, and is not intended to replace, vital sign monitoring. Optional compatible weight scales (e.g.,Health o meter®) can be used for height, weight, and BMI input. The Welch Allyn Connex® Vital Signs Monitor (CVSM) 6000 Series also contains the Welch Allyn Applications Framework ("Framework"). The Framework is general purpose software that allows medical device and non-medical device software applications to be run on the	Same (The base intended use remains the monitoring of patient vital signs. As with previous submissions, the Global Instruments Module's cleared indications for use statement is appended unchanged into the

Subject Device and Predicate Device Comparison			
Characteristic	***Predicate Devices***	***Subject Device***	***Differences***
	CVSM independently of, and isolated from, the CVSM's vital signs monitoring functionality. All such applications are intended to be used on the CVSM by trained professionals in a health care setting. The optional EarlySense® (Everon) System is intended for continuous measurement of respiration rate, heart rate, and movement in an automatic contact-less manner, in a hospital or clinic setting. The system is indicated for use in children, adolescents, and adults. The operation of the EarlySense has been studied in children (weight ≥ 10 Kg) and adults (weight <111 Kg) during sleep and resting condition. This product is available for sale only upon the order of a physician or licensed health care professional.	CVSM independently of, and isolated from, the CVSM's vital signs monitoring functionality. All such applications are intended to be used on the CVSM by trained professionals in a health care setting. The optional EarlySense® (Everon) System is intended for continuous measurement of respiration rate, heart rate, and movement in an automatic contact-less manner, in a hospital or clinic setting. The system is indicated for use in children, adolescents, and adults. The operation of the EarlySense has been studied in children (weight ≥ 10 Kg) and adults (weight <111 Kg) during sleep and resting condition. **The optional ECG/Impedance Respiration System is intended for continuous measurement of respiration rate, heart rate and detection of cardiac standstill (asystole), ventricular tachycardia and ventricular fibrillation in general medical and surgical floors, general hospital and professional healthcare facilities. The system is indicated for use in pediatric and adult patients.** This product is available for sale only upon the order of a	CVSM's cleared indications for use statement, as shown by the bold text in the column to the left. The Global Instruments module was previously cleared in Global Instruments module 510(k) K152701).

Subject Device and Predicate Device Comparison			
Characteristic	***Predicate Devices***	***Subject Device***	***Differences***
		physician or licensed health care professional.	
Basic Description	The Welch Allyn Connex® Vital Signs Monitor 6000 Series is designed to provide a scalable, modular system of components that could be configured to address the needs for vitals signs spot check and monitoring. The CVSM 6000 Series of monitors are intended to be used by clinicians and medically qualified personnel for monitoring of noninvasive blood pressure, pulse rate, noninvasive functional oxygen saturation of arteriolar hemoglobin (SpO_2), and body temperature in normal and axillary modes of neonatal, pediatric, and adult patients. Electronic transmission of date from external accessory devices is supported including temperature, Weight, Height, and BMI. When equipped with Masimo Rainbow SET® Pulse Co-oximeter and accessories may be used for continuous noninvasive monitoring of total hemoglobin concentration and acoustic respiration rate (RRa). Patient monitors equipped with Oridion capnography are also capable of carbon dioxide (CO_2), respiration rate (RR) and calculation of Integrated Pulmonary Index (IPI). **Patient monitors equipped with the EarlySense Module can measure respiration rate, heart rate, and movement in an automatic**	The Welch Allyn Connex® Vital Signs Monitor 6000 Series is designed to provide a scalable, modular system of components that could be configured to address the needs for vitals signs spot check and monitoring. The CVSM 6000 Series of monitors are intended to be used by clinicians and medically qualified personnel for monitoring of noninvasive blood pressure, pulse rate, noninvasive functional oxygen saturation of arteriolar hemoglobin (SpO_2), and body temperature in normal and axillary modes of neonatal, pediatric, and adult patients. Electronic transmission of date from external accessory devices is supported including temperature, Weight, Height, and BMI. When equipped with Masimo Rainbow SET® Pulse Co-oximeter and accessories may be used for continuous noninvasive monitoring of total hemoglobin concentration and acoustic respiration rate (RRa). Patient monitors equipped with Oridion capnography are also capable of carbon dioxide (CO_2), respiration rate (RR) and calculation of Integrated Pulmonary Index (IPI). Patient monitors equipped with the EarlySense Module can measure respiration rate, heart rate, and movement in an automatic contact-less	ECG Module added

Subject Device and Predicate Device Comparison			
Characteristic	***Predicate Devices***	***Subject Device***	***Differences***
	contact-less manner using EarlySense sensors.	manner using EarlySense sensors. **The optional ECG/Impedance Respiration System is intended for continuous measurement of respiration rate, heart rate and detection of cardiac standstill (asystole), ventricular tachycardia and ventricular fibrillation.**	
Target Population	**Neonatal, Pediatric, and Adult Patients of any gender.**	Neonatal, Pediatric, and Adult Patients of any gender.	Same
Where Used	**The product is intended for use in a clinical environment general medical and surgical floors, general hospital, and alternate care environments.**	The product is intended for use in a clinical environment general medical and surgical floors, general hospital, and alternate care environments.	Same
Design/Technology	**Modular**	Modular	Same
Alarms	• **Can configure, observe, and respond to an alarm condition.**	• **Can configure, observe, and respond to an alarm condition.**	Same
Nurse Call (wired)	• **Can connect to customer nurse call system. Provides NO/NC relay.**	• **Can connect to customer nurse call system. Provides NO/NC relay.**	Same
Patient data management	• **Change patient type (adult, pediatric, neonate)** • **View and enter manual parameters (height, weight, pain, respiration)** • **Manage patient vitals record** • **Assign patient and clinician ID to readings** • **Automated data input of weight, height, and BMI** • **Connectivity to Electronic Records Management systems for transfer of patient data.** • **Connectivity to Central Station for continuous**	• **Change patient type (adult, pediatric, neonate)** • **View and enter manual parameters (height, weight, pain, respiration)** • **Manage patient vitals record** • **Assign patient and clinician ID to readings** • **Automated data input of weight, height, and BMI** • **Connectivity to Electronic Records Management systems for transfer of patient data.** • **Connectivity to Central Station for continuous**	**Same**

Subject Device and Predicate Device Comparison			
Characteristic	***Predicate Devices***	***Subject Device***	***Differences***
	patient monitoring and distributed alarms	**patient monitoring and distributed alarms**	
Memory	• **Save patient data to device memory - (300) readings**	• **Save patient data to device memory - (300) readings**	Same
Printer	Yes - 57mm Internal Thermal	Yes - 57mm Internal Thermal	Same
Non-Invasive Blood Pressure (NIBP)	• Display systolic, diastolic, and MAP measurements • Manual and automatic NIBP measurements • Can measure blood pressure as the cuff is inflating • Can measure blood pressure as the cuff is deflating	• Display systolic, diastolic, and MAP measurements • Manual and automatic NIBP measurements • Can measure blood pressure as the cuff is inflating • Can measure blood pressure as the cuff is deflating	Same – the NIBP module has not been modified
Algorithm	• Oscillatory BP Algorithm • Fast BP Algorithm	• Oscillatory BP Algorithm • Fast BP Algorithm	Same
Systolic range	• Adult: 30 to 260 mmHg • Pediatric: 30 to 260 mmHg • Neonate: 20 to 120 mmHg	• Adult: 30 to 260 mmHg • Pediatric: 30 to 260 mmHg • Neonate: 20 to 120 mmHg	Same
Diastolic range	• Adult: 20 to 220 mmHg • Pediatric: 20 to 220 mmHg • Neonate: 10 to 110 mmHg	• Adult: 20 to 220 mmHg • Pediatric: 20 to 220 mmHg • Neonate: 10 to 110 mmHg	Same
Pulse rate range using BP	• Adult: 30 to 200 bpm • Pediatric: 30 to 200 bpm • Neonate: 35 to 220 bpm	• Adult: 30 to 200 bpm • Pediatric: 30 to 200 bpm • Neonate: 35 to 220 bpm	Same
Pulse rate accuracy	• ±3 bpm	• ±3 bpm	Same
Thermometer (Thermister probe)	• Welch Allyn SureTemp Plus technology • Temperature range: 80 – 110ºF • Either the Predictive (Normal) or Direct (Monitor) Mode • °C or °F • Oral, axillary, rectal	• Welch Allyn SureTemp Plus technology • Temperature range: 80 – 110ºF • Either the Predictive (Normal) or Direct (Monitor) Mode • °C or °F • Oral, axillary, rectal	Same – the Thermometer module has not been modified
SpO_2	• Masimo Sensor • Nellcor Sensor • SpO_2 saturation percentage and the pulse amplitude display • Perfusion index • Sat Seconds	• Masimo Sensor • Nellcor Sensor • SpO_2 saturation percentage and the pulse amplitude display • Perfusion index • Sat Seconds	Same – the SpO_2 modules have not been modified
Pulse rate Range and accuracy using	• 20 - 250 +/- 3bpm, based with Nellcor SpO_2 parameter	• 20 - 250 +/- 3bpm, based with Nellcor SpO_2 parameter	Same

Subject Device and Predicate Device Comparison			
Characteristic	***Predicate Devices***	***Subject Device***	***Differences***
SpO_2 determination	• 25 - 240 +/- 3bpm, based on Masimo SpO_2 parameter	• 25 - 240 +/- 3bpm, based on Masimo SpO_2 parameter	
O_2 Saturation Range and accuracy	• Nellcor O_2 sat (%) values shall be +/- 3 digits between the range of 70 - 100% • Masimo O_2 sat (%) values shall be +/- 2.0% of the values set between the range of 70 – 100%	• Nellcor O_2 sat (%) values shall be +/- 3 digits between the range of 70 - 100% • Masimo O_2 sat (%) values shall be +/- 2.0% of the values set between the range of 70 – 100%	Same
Total Hemoglobin range and accuracy (SpHb g/dL)	• Masimo Sensor only – Range 0 – 25 g/dL Adults/Infants/Pediatrics 8-17 g/dL + 1 g/dL	• Masimo Sensor only – Range 0 – 25 g/dL Adults/Infants/Pediatrics 8-17 g/dL + 1 g/dL	Same
Acoustic Respiration Rate (RRa)	Masimo hardware provided and software enabled • 4 – 70 +/- 1 breath per minute, adults (>30kg)	Masimo hardware provided and software enabled • 4 – 70 +/- 1 breath per minute, adults (>30kg)	Same
Capnography for carbon dioxide (CO_2), respiration rate (RR) measurements and calculation of Integrated Pulmonary Index (IPI).	CO_2 accuracy: 0 to 38 mmHg: ±2 mmHg 39 to 150 mmHg: ±2 (5% of reading + 0.08% for every 1 mmHg above 38 mmHg) Flow rate: 50 (42.5 ≤ flow ≤ 65) ml/min, flow measured by volume Initialization time: 40 seconds (typical, includes power-up and initialization time) System response time: 2.9 seconds Compensation: BTPS (standard correction used by Microstream capnography during all measurement procedures for	CO_2 accuracy: 0 to 38 mmHg: ±2 mmHg 39 to 150 mmHg: ±2 (5% of reading + 0.08% for every 1 mmHg above 38 mmHg) Flow rate: 50 (42.5 ≤ flow ≤ 65) ml/min, flow measured by volume Initialization time: 40 seconds (typical, includes power-up and initialization time) System response time: 2.9 seconds Compensation: BTPS (standard correction used by Microstream capnography during all measurement procedures for	Same – the CO_2 module has not been modified

Subject Device and Predicate Device Comparison			
Characteristic	***Predicate Devices***	***Subject Device***	***Differences***
	body temperature, pressure, and saturation)	body temperature, pressure, and saturation)	
EarlySense Module	Yes	Yes	Same
Respiration rate	Also provided by Early Sense, Masimo and Oridion Modules	6 to 45 breaths per minute (±4% or ±1.5 breaths per minute, whichever is greater)	Same as cleared by Global Instruments Impedance Respiration in K152701.
Heart Rate	Also provided by Early Sense, Masimo and Oridion Modules	30 to 170 beats per minute (±4% or ±5 beats per minute, whichever is greater)	Same as cleared by Global Instruments Impedance Respiration in K152701.
Display of ECG	N/A	3 – 5 Lead ECG added by Global Instruments Module	Same as cleared by Global Instruments in K152701.
Detect abnormal ECG's	N/A	**detection of cardiac standstill (asystole), ventricular tachycardia and ventricular fibrillation.**	Same as cleared by Global Instruments in K152701
Patient Movement	Movement during defined period (percent of time moving in1.5 minutes) 0 = 0% L = Up to 40% M = 40% to 60% H = 60% to 80% EH = 80% to 100% (Adult: 0 = 100%, L = 100%, M = 81%, H = 100%, EH = 96%	Movement during defined period (percent of time moving in1.5 minutes) 0 = 0% L = Up to 40% M = 40% to 60% H = 60% to 80% EH = 80% to 100% (Adult: 0 = 100%, L = 100%, M = 81%, H = 100%, EH = 96%	Same.

Subject Device and Predicate Device Comparison			
Characteristic	***Predicate Devices***	***Subject Device***	***Differences***
	Pediatric: 0 = 100%, L = 100%, M = 81%, H = 86%, EH = 94%).	Pediatric: 0 = 100%, L = 100%, M = 81%, H = 86%, EH = 94%)	
External Device Communication Protocol	WACP	WACP	Same
Communication with electronic record systems for alarming and remote monitoring (e.g., central station)	Patient date uploaded episodically to electronic record systems. SpO_2 and Pulse Rate continuous monitoring and interval measurements of NIBP and Temperature	Patient date uploaded episodically to electronic record systems. SpO_2 and Pulse Rate continuous monitoring and interval measurements of NIBP and Temperature. Interface also allows clinician to manually enter Patient notes.	Same.
Display type	LCD Touch Screen	LCD Touch Screen	Same
Barcode scanner	Yes The monitor enables the scanning of patients' and/or clinicians' barcodes to enter identification information. The barcode scanner supports linear and 2D barcodes.	Yes The monitor enables the scanning of patients' and/or clinicians' barcodes to enter identification information. The barcode scanner supports linear and 2D barcodes.	Same
Sterility	Device not supplied Sterile	Device not supplied Sterile	Same
Power source	100 -240 V ac 50/60 Hz	100 -240 V ac 50/60 Hz	Same
Battery Power	• Yes • Level of Charge indicator • Lithium ion	• Yes • Level of Charge indicator • Lithium ion	Same

Conclusion

Based on the information presented in this 510(k) premarket notification the Connex® Vital Signs Monitor 6000 Series(CVSM) is considered substantially equivalent (as safe, as effective and performs as well as) the currently marketed devices (K132808 and K152701) citied in this submission. The differences noted between the CVSM and the predicate devices do not impact safety or effectiveness based on the successfully conducted testing of the

modified device. The hardware, software, and mechanical aspects of the CVSM itself remain the same as the cleared device (Vital Signs Monitor – VSM 6000 Series, K132808, S.E. date November 30, 2012) except as described below. The modification is to make the Global Instruments ECG module (K152701) available on the CVSM to provide ECG monitoring. The software of the CVSM has been modified to enable display of the Global Instruments ECG measurements, which are received by CVSM via the same USB communications used to receive data from the currently available modules. It follows the same software communication format as our currently available modules. The fidelity of these data transfers were tested in our design control process. Like the predicate CVSM device, this version of the CVSM can transfer acquired data electronically via USB, wired Ethernet, or wireless communications to other locations. Like the CVSM cleared in K132808, this version of the CVSM can transmit data continuously for secondary remote viewing and alarming (e.g., central station, NCE).