October 24, 2017

Capsule Technologie, SAS
% Dave Yungvirt
CEO
Third Party Review Group, LLC
The Old Station House
24 Lackawanna Place
Millburn, New Jersey 07041

Re: K171751
Trade/Device Name: SmartLinx Vitals Plus Patient Monitoring System
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer And Rate Alarm)
Regulatory Class: Class II
Product Code: MWI, DXN, DQA, FLL
Dated: October 3, 2017
Received: October 5, 2017

Dear Dave Yungvirt:

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 (DICE) 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 (DICE) 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K171751

Device Name
SmartLinx Vitals Plus Patient Monitoring System

Indications for Use *(Describe)*
The SmartLinx Vitals Plus Patient Monitoring System is intended for monitoring and alarming of physiologic parameters, including non-invasive blood pressure (systolic, diastolic, and mean arterial pressure), pulse rate, functional arterial oxygen saturation (SpO2), and temperature, on adult, pediatric, and neonatal patients in hospital environments when used by clinical physicians or appropriate medical staff under the direction of physicians.

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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Applicant / Manufacturer's Name	Capsule Technologie, SAS 76-78 avenue de France CS21416 75644 Paris Cedex 13
Official Correspondent	James Hodge Director QA/RA Capsule Tech, Inc. 300 Brickstone Square, Suite 203 Andover, MA 01810 Phone: 978-482-2362 Email: jhodge@qualcommlife.com
Date Prepared	October 3, 2017
Device Trade Name	SmartLinx Vitals Plus Patient Monitoring System
Common Name	Physiological or Vital Signs Monitor, Patient Monitor
Classification Name	21 CFR 870.2300 Cardiac monitor (including cardiotachometer and rate alarm)
Regulatory Class	II
Product Code	MWI, monitor, physiological, patient (without arrhythmia detection or alarms)
Primary Predicate Device	CASMED 740 Select K130411 This device was selected as the primary predicate since its monitoring functionality closely matches the modifications to the SmartLinx Vitals Plus device of this submission. Likewise, the Covidien FILAC 3000 thermometer integrated with this device is the same component added to SmartLinx Vitals Plus. This predicate has not been subject to a design-related recall.
Other Predicate Device	SmartLinx Vitals Plus Patient Monitoring System K151071 This device was selected as a predicate since the Vitals Plus of this submission is a modification of it. The modified Vitals Plus shares a common design based on the Vitals Plus Application, externally-integrated vital signs modules (same NIBP module, same SpO2 pulse oximeter, and same Exergen TAT-5000S thermometer), and the Neuron 2. This predicate has not been subject to a design-related recall.

Device Description

The SmartLinx Vitals Plus Patient Monitoring System operates on top of the SmartLinx Medical Device Information System (MDIS) to present patient information to the clinical user for active monitoring purposes at the point of care. SmartLinx Vitals Plus consists of the following components:

SmartLinx Vitals Plus Application

The SmartLinx Vitals Plus Application is a mobile medical application operating on the SmartLinx Neuron 2 Mobile Platform. The Vitals Plus Application controls the externally integrated vital signs modules and the Alarm Hub through interfaces on the SmartLinx Neuron 2 Mobile Platform, and presents patient information to the user for active monitoring purposes at the point of care. The supported physiological parameters are: NIBP (systolic, diastolic, mean arterial pressure (MAP), Pulse Rate, SpO2, and Temperature.

New functionality added to the Vitals Plus Application since the initial clearance of Vitals Plus in K151071 includes:

1. Intervals Mode for NIBP (Automatic repetition of NIBP measurements)
2. Physiological alarms for NIBP (Sys, Dia, MAP), Pulse Rate, SpO2, and Temperature, which are visibly annunciated on the Neuron 2 and audibly annunciated on the SmartLinx Vitals Plus Alarm Hub
3. Continuous SpO2 monitoring with pulse tone pitches that vary according to oxygen saturation, SpO2 alarm delay, and SpO2 sensor off alarm
4. Temperature measurements with the Covidien FILAC 3000 Thermometer

SmartLinx Vitals Plus NIBP Module

The SmartLinx Vitals Plus NIBP Module is the same hardware component previously cleared in K151071. Incorporating the SunTech Medical Advantage A+ OEM NIBP module and associated blood pressure cuffs and hoses, it measures systolic, diastolic and mean arterial blood pressures (MAP), and pulse rates for adult, pediatric and neonatal patients. The module is controlled by the SmartLinx Vitals Plus Application to manage the inflation and deflation of blood pressure cuffs, and to measure blood pressures and pulse rates.

Masimo uSpO2 Pulse Oximetry Cable

The Masimo uSpO2 Pulse Oximetry Cable is a patient cable with an integrated MS-2000 series circuit board contained in an enclosure that connects to Masimo pulse oximetry sensors and provides functional oxygen saturation (SpO2) and pulse rate and other information via a serial digital interface. This is the same component as

was previously cleared with the SmartLinx Vitals Plus Patient Monitoring System in K151071. The SmartLinx Vitals Plus Application controls the operation of the uSpO2 to measure SpO2 and pulse rate in adult, pediatric, and neonatal patients.

Exergen TAT-5000S Thermometer

The Exergen TAT-5000S thermometer is the same component previously cleared in K151071. The TAT-5000S is designed for accurate, noninvasive temperature assessment by scanning the temporal artery. The thermometer operates independently, but communicates its results to the SmartLinx Vitals Plus Application for display and monitoring.

Covidien FILAC 3000 Thermometer

The Covidien FILAC 3000 Thermometer is a new component of Vitals Plus. The FILAC 3000 acquires temperature measurements through the application of a probe at Oral, Axillary, and Rectal sites. The typical measurement mode of the thermometer is a Predictive Mode that returns a measurement in 6-10, 8-12, and 10-14 seconds respectively for Oral, Axillary, and Rectal sites. The thermometer also has a Direct Mode (simulating a standard thermometer) and a Cold Mode (a predictive mode for patients at a lower temperature).

SmartLinx Vitals Plus Alarm Hub

The Alarm Hub is a new component of SmartLinx Vitals Plus that is used with the optional Advanced Monitoring license for the Vitals Plus Application. The Alarm Hub offers a primary speaker for alarm annunciations (with failover to a backup speaker), watchdog functionality, and a USB hub for expansion.

SmartLinx Neuron 2 Mobile Platform

The SmartLinx Neuron 2 Mobile Platform is a mobile computer utilizing industry standard PC architecture and the Microsoft Windows operating system, that is used within the SmartLinx Medical Device Information System and IEC 60601-1 Medical Electrical Systems for collection, transmission, conversion, storage and display of medical device data. The Neuron 2 runs different SmartLinx applications depending upon the care area and desired functionality, including SmartLinx Vitals Stream, SmartLinx Chart Xpress, and SmartLinx Vitals Plus. The Neuron 2 is utilized as part of an active monitoring system when running the SmartLinx Vitals Plus Application.

SmartLinx Early Warning Scoring System

The SmartLinx Early Warning Scoring System (EWSS) is an optional software component that integrates with the SmartLinx Vitals Plus Application and runs on the

SmartLinx Neuron 2 Mobile Platform. The EWSS component is unchanged from that described in the cleared K151071 Vitals Plus submission.

SmartLinx EWSS performs a medical calculation that aids clinical users in patient assessment and condition trending. This calculation, which would otherwise be completed manually, produces an aggregate patient score from a set of sub-scores determined from the values of measured vital signs and manually entered nursing observations. The resulting aggregate score is displayed on the Vitals Plus Application, and may be communicated to other healthcare information systems. EWSS requires the clinical user to attend the patient in order to function. There is no automatic or continuous scoring. The specific scoring method used within SmartLinx EWSS to calculate a patient's score is determined by the customer.

Intended Use

The SmartLinx Vitals Plus Patient Monitoring System is intended for monitoring and alarming of physiologic parameters, including non-invasive blood pressure (systolic, diastolic, and mean arterial pressure), pulse rate, functional arterial oxygen saturation (SpO2), and temperature, on adult, pediatric, and neonatal patients in hospital environments when used by clinical physicians or appropriate medical staff under the direction of physicians.

Comparison of Technical Characteristics with the Predicate Device

The SmartLinx Vitals Plus Patient Monitoring System features design characteristics and technologies that are substantially equivalent to those of the predicate devices. As discussed in Table 1 and Table 2, the differences in technological characteristics do not raise different questions of safety or effectiveness.

Do the devices have the same technological characteristics?

No. The proposed modifications to SmartLinx Vitals Plus have similar technological characteristics compared to its predicate devices with some differences as shown in Table 1 and Table 2.

Table 1 Comparison With SmartLinx Vitals Plus (K151071)

	SmartLinx Vitals Plus	SmartLinx Vitals Plus	Discussion of Differences
510(k) Number	K171751	K151071	
Intended Use	The SmartLinx Vitals Plus Patient Monitoring System is intended for monitoring and alarming of physiologic parameters, including non-invasive blood pressure (systolic, diastolic, and mean arterial pressure), pulse rate, functional arterial oxygen saturation (SpO2), and temperature, on adult, pediatric, and neonatal patients in hospital environments when used by clinical physicians or appropriate medical staff under the direction of physicians.	The SmartLinx Vitals Plus Patient Monitoring System is intended for monitoring physiologic parameters, including non-invasive blood pressure (systolic, diastolic, and mean arterial pressure), pulse rate, functional arterial oxygen saturation (SpO2), and temperature, on adult, pediatric, and neonatal patients in healthcare facilities when used by clinical physicians or appropriate medical staff under the direction of physicians.	Same.
NIBP Measurement	SmartLinx Vitals Plus NIBP module using the SunTech Advantage A+ module of oscillometric design for Spot Check and Intervals Mode measurements.	SmartLinx Vitals Plus NIBP module using SunTech Advantage A+ module of oscillometric design for Spot Check Mode.	Same except for addition of NIBP Intervals Mode to Vitals Plus, which is compared to the CASMED primary predicate device (K130411).

SpO2 Monitoring	Masimo uSpO2 Oximetry Cable using Masimo SET technology integrated externally to the Neuron via a USB connection for Spot Check measurements and Continuous Monitoring.	Masimo uSpO2 Oximetry Cable using Masimo SET technology integrated externally to the Neuron via a USB connection for Spot Check measurements.	Same except for addition of Continuous Monitoring with associated features, which is compared to the CASMED primary predicate device (K130411).
Temperature Measurement	Two different thermometry options: 1) Covidien FILAC 3000 probe. 2) Exergen TAT-5000S infrared scanner.	Exergen TAT-5000S infrared scanner.	Same except for addition of Covidien FILAC 3000 probe thermometer, which compared to the CASMED primary predicate device (K130411).
Alarms	Configuration, annunciation, and acknowledgement of physiological and technical alarms for (Sys, Dia, MAP, Pulse Rate, SpO2, and Temp). Alarms are visibly annunciated and acknowledged on the screen. Alarms are audibly annunciated via two possible speaker configurations: 1) One speaker for non-Advanced Monitoring configurations, using the single speaker inside the Neuron 2.	Configuration, annunciation, and acknowledgement of technical alarms for (Sys, Dia, MAP, Pulse Rate, SpO2, and Temp). Alarms are visibly annunciated and acknowledged on the screen. Alarms are audibly annunciated via a single speaker inside the Neuron 2.	Vitals Plus supports the same single speaker configuration of K151071 for non-Advanced Monitoring Mode. It also adds the Alarm Hub with its primary speaker and watchdog processor for Advanced Monitoring Mode. The two speaker configuration for Advanced Monitoring Mode is compared to the CASMED primary predicate device (K130411).

	2) Two speakers for Advanced Monitoring configurations, using the speaker inside the Alarm Hub as the primary, and the speaker inside the Neuron 2 as a backup.		
Applied Parts	SunTech Durable One-Piece, Disposable, and Vinyl blood pressure NIBP cuffs, and GE CRITIKON SOFT-CUF cuffs in neonate through adult thigh sizes. Masimo LNCS family of reusable and disposable SpO2 sensors. Covidien FILAC 3000 Probe Covers. Exergen disposable probe covers and sheaths.	SunTech Durable One-Piece, Disposable, and Vinyl blood pressure NIBP cuffs in neonate through adult thigh sizes. Masimo LNCS family of reusable and disposable SpO2 sensors. Exergen disposable probe covers and sheaths.	NIBP cuffs are the same except for the addition of two new sizes in the SunTech Disposable cuffs and the addition of the GE CRITIKON SOFT-CUFs. FILAC probe covers are new to Vitals Plus and are compared to the CASMED primary predicate device (K130411).
Energy Source	Main Battery Neuron 2: Lithium-Ion 3S1P 2600 mAh or 3050 mAh. Extended Battery Neuron 2: Lithium-Ion 3S2P 5200 mAh or 6100 mAh (1 or 2 depending on use of Dual Battery Dock).	Main Battery Neuron 2: Lithium-Ion 3S1P 2600 mAh. Extended Battery Neuron 2: Lithium-Ion 3S2P 5200 mAh (1 or 2 depending on use of Dual Battery Dock).	Vitals Plus supports new larger battery capacities and uses a Class I power supply as the expressed preference of most hospitals for this category of device.

	Exergen: 9V alkaline. Power Supply: 100-240 VAC, 2.0-1.0 A, 50-60 Hz, Class I.	Exergen: 9V alkaline. Power Supply: 100-240 VAC, 2.0-1.0 A, 50-60 Hz, Class II.	

Table 2 Comparison With Primary Predicate CASMED 740 Select (K130411)

	SmartLinx Vitals Plus	CASMED 740 Select	Discussion of Differences
510(k) Number	K171751	K130411	
Intended Use	The SmartLinx Vitals Plus Patient Monitoring System is intended for monitoring and alarming of physiologic parameters, including non-invasive blood pressure (systolic, diastolic, and mean arterial pressure), pulse rate, functional arterial oxygen saturation (SpO2), and temperature, on adult, pediatric, and neonatal patients in hospital environments when used by clinical physicians or appropriate medical staff under the direction of physicians.	The 740 Select is indicated for use as a bedside, portable device for use by healthcare professionals, clinicians and medically qualified personnel for spot checking, continuous monitoring and recording of adult, pediatric of adult, pediatric and neonatal patients. The monitor features world class technology to facilitate the monitoring of non-invasive blood pressure, pulse rate, functional arterial oxygen saturation (SpO2) and body temperature in a variety of clinical environments.	None in terms of practical meaning.

NIBP Measurement	SmartLinx Vitals Plus NIBP module using the SunTech Advantage A+ module of oscillometric design for Spot Check and Intervals Mode measurements.	MAXNIBP module of oscillometric design for Spot Check and Intervals Mode measurements.	Different module suppliers.
SpO2 Monitoring	Masimo uSpO2 Oximetry Cable using Masimo SET technology integrated externally to the Neuron via a USB connection for Spot Check measurements and Continuous Monitoring with the following features: 1) Pulse tone pitch varying with oxygen saturation 2) SpO2 alarm delay 3) SpO2 sensor off alarm	Masimo Rainbow SET OEM board integrated inside the monitor for Continuous Monitoring with the following features: 1) Pulse tone pitch varying with oxygen saturation 2) SpO2 alarm delay 3) SpO2 sensor off alarm	Both devices use the same core Masimo SET technology for measuring SpO2, pulse rate, and perfusion index. Vitals Plus also offers the clinical user the convenience of a Spot Check mode.
Temperature Measurement	Two different thermometry options: 1) Covidien FILAC 3000 probe. 2) Exergen TAT-5000S infrared scanner.	Covidien FILAC 3000 probe.	Only Vitals Plus offers the Exergen TAT-5000S, but this is the same component used in the Vitals Plus predicate device (K151071).
Alarms	Configuration, annunciation, and acknowledgement of physiological and technical alarms for (Sys, Dia, MAP,	Configuration, annunciation, and acknowledgement of physiological and technical alarms for (Sys, Dia, MAP,	Same except for speaker configurations. Non-Advanced Monitoring configurations of Vitals Plus may be

	Pulse Rate, SpO2, and Temp). Alarms are visibly annunciated and acknowledged on the screen. Alarms are audibly annunciated via two possible speaker configurations: 1) One speaker for non-Advanced Monitoring configurations, using the single speaker inside the Neuron 2 for technical alarms. 2) Two speakers for Advanced Monitoring configurations, using the speaker inside the Alarm Hub as the primary, and the speaker inside the Neuron 2 as a backup.	Pulse Rate, SpO2, and Temp). Alarms are visibly annunciated and acknowledged on the screen. Alarms are audibly annunciated via two speakers inside the monitor. Alarms first annunciate on a primary speaker, and then with a different tone on a backup speaker.	safely used with only the single speaker. Advanced Monitoring configurations of Vitals Plus require the Alarm Hub.
Applied Parts	SunTech Durable One-Piece, Disposable, and Vinyl NIBP cuffs, and GE CRITIKON SOFT-CUF cuffs in neonate through adult thigh sizes. Masimo LNCS family of reusable and disposable SpO2 sensors.	Softcheck Disposable and Ultracheck Reusable NIBP cuffs in infant through adult thigh sizes. Masimo M-LNCS family of reusable and disposable SpO2 sensors Covidien FILAC 3000 Probe Covers	Each device uses its own set of NIBP cuffs that conform to IEC 80601-2-30 when used with the device. Masimo sensors are the same except for the connector used. Exergen covers and sheaths are unique to Vitals Plus, but are the same components used in

	Covidien FILAC 3000 Probe Covers. Exergen disposable probe covers and sheaths.		the Vitals Plus predicate device (K151071).
Energy Source	Main Battery Neuron 2: Lithium-Ion 3S1P 2600 mAh or 3050 mAh. Extended Battery Neuron 2: Lithium-Ion 3S2P 5200 mAh or 6100 mAh (1 or 2 depending on use of Dual Battery Dock). Exergen: 9V alkaline. Power Supply: 100-240 VAC, 2.0-1.0 A, 50-60 Hz, Class I.	Main Battery: Lithium-Ion 10.8 VDC 7800 mAh. Power Supply: 100-240 VAC, 1.2 A Max (1.2A to 0.50 A), 50-60 Hz, Class II.	Each device uses a battery appropriate to its design and desired autonomy. The Exergen 9V battery is unique to Vitals Plus, but is the same component used in the Vitals Plus predicate device (K151071). Vitals Plus uses a Class I power supply as the expressed preference of most hospitals for this category of device.

Do the different technological characteristics of the device raise different questions of safety and effectiveness?

No. The different technological characteristics of the proposed Vitals Plus device do not raise different questions of safety and effectiveness as discussed below.

Safety

1. Biocompatibility

   The applied parts in used in the proposed Vitals Plus and both predicate devices raise the same questions regarding biocompatibility of patient applied parts. All components conform to ISO 10993-1 series requirements.

2. Energy Transfer

   The proposed Vitals Plus and both predicate devices raise the same questions with respect to energy transfer to the patient. The NIBP functions use the same mechanism of action, oscillometry. The SpO2 functions use the same Masimo technology. The temperature functions both use the same FILAC and Exergen technology.

3. Energy Source

Both devices raise the same questions of safety related to lithium ion batteries including heat, fire, explosion and exposure to potentially noxious gases.

Effectiveness

Both the proposed Vitals Plus and the CASMED 740 Select primary predicate raise the same questions of effectiveness concerning the new functionality added to Vitals Plus since its initial clearance.

Are the proposed scientific methods for evaluating new/different characteristics' effects on safety and effectiveness acceptable?

Yes. The proposed scientific methods for evaluating new/different characteristics' effects on safety and effectiveness are acceptable.

Safety and Performance Testing

Safety testing assures that the device complies with applicable sections of recognized industry and safety standards. Extensive performance testing ensures that the SmartLinx Vitals Plus Patient Monitoring System performs as well as the indicated predicate devices and meets all of its functional requirements and performance specifications. The SmartLinx Vitals Plus Patient Monitoring System complies with the voluntary standards listed in the table below.

Performance Characteristic	FDA Recognized standard	Standard Title
General	ANSI AAMI ES 60601-1:2005/ (R):2012 & A1:2012 & C1:2009/(R):2012 & A2:2010/(R):2012	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD
EMC	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
Usability	IEC 60601-1-6:2013	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability

Alarms	IEC 60601-1-8:2012	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
Software	IEC 62304:2006	Medical device software—Software life cycle processes
Usability	IEC 62366:2014	Medical devices – Application of usability engineering to medical devices
NIBP	IEC 80601-2-30:2013	Medical electrical equipment – Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
NIBP	ISO 81060-2:2013	Non-invasive sphygmomanometers Part 2: Clinical investigation of automated measurement type
Temp	ISO 80601-2-56:2009	Medical electrical equipment Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement
SpO2	ISO 80601-2-61:2011	Medical electrical equipment Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
Battery	IEC 62133:2012	Secondary Cells And Batteries Containing Alkaline Or Other Non-Acid Electrolytes - Safety Requirements For Portable Sealed Secondary Cells, And For Batteries Made From Them, For Use In Portable Applications [Including: Corrigendum 1 (2013)]
Patient Monitoring	IEC 60601-2-49:2011	Medical electrical equipment

Part 2-49: Particular requirements for the basic safety and essential performance

Reference Devices

The Zoll R Series Monitor Defibrillator cleared in K120907 is used as a reference device, just as it was in the original K151071 clearance of SmartLinx Vitals Plus. The R Series incorporates the same SunTech Advantage A+ oscillometric OEM NIBP module and uses the same firmware built into the Advantage A+ to control automatic repetition of interval blood pressure measurements as the modified SmartLinx Vitals Plus Application of this submission.

The modified CASMED 740 Select device cleared in K150620 is also used as a reference device. The Exergen TAT-5000S thermometer was added to the 740 Select with this clearance, which removes the only significant difference from the modified Vitals Plus of this submission.

Clinical Studies

The subject of this premarket submission, the SmartLinx Vitals Plus Patient Monitoring System, did not require clinical studies to support substantial equivalence.

Conclusions

Substantial equivalence of the SmartLinx Vitals Plus Patient Monitoring System is demonstrated through conformance with recognized consensus standards. The modifications to the SmartLinx Vitals Plus Patient Monitoring System results in an equivalent design, features and functionality as the predicate devices with few exceptions, and these exceptions do not affect the safety or effectiveness of the system.

No new questions of safety or effectiveness are raised as a result of the differences when compared to the predicate devices, and the data provided in the submission show that the subject device can be considered substantially equivalent.