August 8, 2018

Capsule Technologie
Maylin Truesdell
Senior Manager, Regulatory Affairs
300 Brickstone Square, Suite 203
Andover, Massachusetts 01810

Re: K180734
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: April 25, 2018
Received: April 25, 2018

Dear Maylin Truesdell:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for 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)*
K180734

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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510(k) Summary

1. Administrative Information

Applicant / Manufacturer's Name	Capsule Technologie, SAS 76-78 avenue de France CS21416 75644 Paris Cedex 13
Official Correspondent	Maylin Truesdell Sr. Regulatory Affairs Manager Capsule Tech, Inc. 300 Brickstone Square, Suite 203 Andover, MA 01810 Phone: 978-482-2365 Email: mtruesde@qualcommlife.com
Date Prepared	August 7, 2018
Device Trade Name	SmartLinx Vitals Plus Patient Monitoring System
Common Name	Physiological or Vital Signs Monitor, Patient Monitor
Classification Name	Cardiac monitor (including cardiotachometer and rate alarm)
Regulatory Class	II
Product Code	MWI, monitor, physiological, patient (without arrhythmia detection or alarms)
Predicate Device	SmartLinx Vitals Plus Patient Monitoring System, K171751 This device was selected as the predicate since this submission seeks marketing clearance for design changes implemented in this device, SmartLinx Vitals Plus Patient Monitoring System, cleared under K171751. The intended use and fundamental operating principle for the ***proposed*** SmartLinx Vitals Plus are **identical** to the cleared ***predicate*** SmartLinx Vitals Plus The ***predicate*** SmartLinx has not been subject to a design-related recall.

Reference Devices	Zoe Medical's 740 Select, K130411 This device was selected as a reference device since it served as the primary predicate device for K171751, and it supports the functionality of the Nellcor and Masimo SpO2 Modules This reference device has not been subject to a design-related recall. Nellcor K141518 and K012891

2. Device Description

The legally marketed, ***predicate device,*** SmartLinx Vitals Plus Patient Monitoring System, was cleared in K171751. 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 Application*

  The SmartLinx Vitals Plus Application is a mobile medical application operating on the SmartLinx Neuron 2 Mobile Platform. The SmartLinx 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:

  > Supported physiological parameters: NIBP (systolic, diastolic, mean arterial pressure (MAP), Pulse Rate, SpO2, and Temperature

  > Intervals mode for Intervals Mode for NIBP (Automatic repetition of NIBP measurements)

  > Physiological alarms for NIBP (Sys, Dia, MAP), Pulse Rate, SpO2, and Temperature; visibly annunciated on the Neuron 2; and audibly annunciated on the SmartLinx Vitals Plus Alarm Hub

  > Continuous SpO2 monitoring with pulse tone pitches that vary according to oxygen saturation, SpO2 alarm delay, and SpO2 sensor off alarm

  > Temperature measurements via the Exergen TAT-5000S or Covidien FILAC 3000 thermometer

- *SmartLinx Vitals Plus NIBP Module*

  The SmartLinx Vitals Plus NIBP Module incorporates 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, including Intervals Mode for NIBP (Automatic repetition of NIBP measurements). 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. 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 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 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 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. The Vitals Plus App running on the Neuron 2 alone evaluates current vital signs values versus upper and lower limits in order to evaluate alarm conditions. When an alarm condition is found to be true, a visual alarm signal is annunciated within the app user interface and on the Neuron LED, and the app sends a command to the directly attached Alarm Hub to make an audible annunciation so long as the condition is true or until the clinical user acknowledges the alarm by touching the screen.

- *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. 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

The ***proposed*** SmartLinx Vitals Plus Patient Monitoring System is identical to the ***predicate*** SmartLinx Vitals Plus Patient Monitoring System, cleared in K171751, with the exception of:

- *Changes to add the option of Nellcor SpO2 Pulse Oximetry solution, Rev. 1.0*
- *Changes to upgrade SmartLinx Vitals Plus Patient Monitoring System from version 2.2.1 to version 2.3*
- *Changes to upgrade SmartLinx Vitals Plus Application from version 9.0.3 to version 9.2*
- *Software modifications to the SmartLinx Vital Plus Patient Monitoring System cleared in K171751, documented to file*

The function of the ***proposed*** device is the same as the ***predicate*** SmartLinx Vitals Plus Patient Monitoring System in that the SmartLinx Vitals Plus Application enables collection of vital signs data. To do so, various sensors are connected to the SmartLinx Neuron 2 Mobile Platform, a mobile computer utilizing industry standard PC architecture and the Microsoft (MS) Windows operating system. The SmartLinx Neuron 2 collects the vital signs data from sensors and serves as the user interface for the medical staff and supports connectivity with the electronic medical record (eMR).

3. 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 intended use of the ***proposed*** SmartLinx Vitals Plus Patient Monitoring System is identical to the intended use for the ***predicate*** SmartLinx Vitals Plus Patient Monitoring System, which serves as the primary predicate device.

4. Comparison of Similarities and Differences

As previously stated, the modifications to the SmartLinx Vitals Plus Patient Monitoring System consist of:

- *Changes to add the option of Nellcor SpO2 Pulse Oximetry solution, Rev. 1.0*
- *Changes to upgrade SmartLinx Vitals Plus Patient Monitoring System from version 2.2.1 to version 2.3*
- *Changes to upgrade SmartLinx Vitals Plus Application from version 9.0.3 to version 9.2*
- *Software modifications to the SmartLinx Vital Plus Patient Monitoring System cleared in K171751, documented to file*

The ***proposed*** SmartLinx Vitals Plus Patient Monitoring System features design characteristics and technologies that are substantially equivalent to those of the ***predicate*** SmartLinx Vitals Plus Patient Monitoring System, as the predicate device, and 740 Select, the reference device.

The reference device, 740 Select cleared in K130411, is manufactured and marketed by Zoe Medical supports both the Nellcor cleared in K141518 and K012891 and Masimo SpO2 Modules.

According to the 740 Select 510(k) Summary, the reference device is a portable and-rugged noninvasive multi-parameter device used for spot checking, continuous monitoring, and recording-of blood pressure, pulse rate, functional oxygen saturation (%SpO2), and predictive body temperature in-a variety of clinical environments. The Monitor includes features that are optional or configurable.

Table 1 **s**hows the similarities and differences between the ***proposed*** and ***predicate*** SmartLinx Vitals Plus Patient Monitoring System (primary predicate device) and the 740 Select (reference device).

Table 1: Comparison of Similarities and Differences

	UNM DIFIED Device SmartLinx Vitals Plus Patient Monitoring System	**MODIFIED Device** SmartLinx Vitals Plus Patient Monitoring System	**Reference Device** 740 Select
Manufacturer	Capsule Tech	Capsule Tech	Zoe Medical
Regulation Name	Cardiac monitor (including cardiotachometer and rate alarm)	Same as ***predicate*** device	Cardiac monitor (including cardiotachometer and rate alarm)
Regulation Number	21 CFR 870.2300	Same as ***predicate*** device	21 CFR 870.2300
Product Code	MWI, DXN, DQA, FLL	Same as ***predicate*** device	MWI
510(k) #	K171751	Pending	K130411
Intended Use / Indication for 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.	Identical to ***predicate*** device	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.
Technological Characteristics			
Design	Intervals Mode for NIBP (Automatic repetition of NIBP measurements): SmartLinx Vitals Plus NIBP Module using SunTech Advantage A+ oscillometric OEM NIBP module with intervals at 1, 2, 3, 4, 5, 10, 15, 30, 60, 90, 120 and 240 minutes	Same as ***predicate*** device and similar to reference device	Intervals Mode for NIBP (Automatic repetition of NIBP Measurements): Proprietary oscillometric design with intervals at 1, 2, 3, 4, 5, 10, 15, 30, 60 and 90 minutes; similar to ***predicate*** and ***proposed***

	UNMODIFIED Device SmartLinx Vitals Plus Patient Monitoring System	**MODIFIED Device** SmartLinx Vitals Plus Patient Monitoring System	**Reference Device** 740 Select
Design, continued	SpO2 Measurement: Masimo uSpO2 Oximetry Cable with Masimo SET technology. Continuous SpO2 Monitoring: Pulse tone pitch varying with oxygen saturation, SpO2 alarm delay, and SpO2 sensor off alarm. Optional: Nellcor® SpO_2 algorithms	Different from ***predicate*** device with respect to optional Nellcor® SpO_2 algorithms; same as reference device for optional Nellcor® SpO_2 algorithms	Continuous SpO2 Monitoring, Masimo® or Nellcor® SpO_2 algorithms (optional) – same as ***proposed*** device
	Alarms: Configuration, annunciation, and acknowledgement of physiological (Sys, Dia, MAP, Pulse Rate, SpO2, and TEMP) and technical alarms.	Same as ***predicate*** device and reference device	Physiological Alarms: same as ***predicate*** and ***proposed*** device
	Temporal Artery TEMP Measurement: Exergen TAT-5000S Thermometer (temporal)	Same as ***predicate*** device and reference device	Probe TEMP Measurement: same as ***predicate*** and ***proposed*** device
	Probe TEMP Measurement: FILAC 3000 Thermometer (oral / axillary / rectal)	Same as ***predicate*** device and same as reference device	Probe TEMP Measurement: same as ***predicate*** and ***proposed*** device
	N/A	Minor software / hardware changes under Design Control program	N/A
Applied Part Materials	NIBP: SunTech Durable One-Piece, Disposable, and Vinyl blood pressure cuffs and hoses, and GE CRITIKON SOFT-CUF cuffs	Same as ***predicate*** device and similar to reference device	NIBP: • Oscillometric step-deflation • Manual, Auto and STAT modes • Systolic, diastolic, MAP & pulse pressure • Adaptive NIBP measurement • Start BP options for spot-checking or continuous workflow • NIBP Signal Quality Status indicator (SQS)
	SpO2: Masimo LNCS family of reusable and disposable SpO2 sensors	Same as ***predicate*** device and reference device	SpO2: same as ***predicate*** and ***proposed*** device

	UNMODIFIED Device SmartLinx Vitals Plus Patient Monitoring System	**MODIFIED Device** SmartLinx Vitals Plus Patient Monitoring System	**Reference Device** 740 Select
Applied Parts, continued	SpO2: Nellcor OxiMax family of reusable and disposable SpO2 sensors	Different from ***predicate*** device but same as reference device	Masimo® or Nellcor® SpO_2 algorithms (optional)—both sensors and signal processing
	TEMP: Exergen disposable probe covers and sheaths	Same as ***predicate*** device and reference device	TEMP: same as ***predicate*** and ***proposed*** device
	Probe TEMP Measurement: Covidien FILAC probe covers	Same as ***predicate*** device and reference device	TEMP: same as ***predicate*** and ***proposed*** device
Energy Source	Main Battery Neuron 2: Lithium-Ion 3S1P 2600 mAh or 3050 mAh	Same as ***predicate*** device and similar to reference device	Li-Ion battery: 12 hour run time (continuous SpO2, NIBP/ temperature every 15 minutes); similar to the ***predicate*** and ***proposed*** device
	Extended Battery Neuron 2: Lithium-Ion 3S2P 5200 mAh or 6100 mAh (1 or 2 depending on use of Dual Battery Dock)	Same as ***predicate*** device and similar to reference device	N/A
	Exergen: 9V alkaline	Same as ***predicate*** device and reference device	Exergen: same as ***predicate*** and ***proposed*** device
	Power Supply: 100-240 V AC, 2.0-1.0 A, 50-60 Hz, 65 W max, Class I	Same as ***predicate*** device and reference device	Power Supply: same as ***predicate*** and ***proposed*** device

The discussion of similarities and differences is structured in accordance with FDA's guidance document "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications Guidance for Industry and Food and Drug Administration Staff", July 28, 2014.

Decision 1: Is the predicate device legally marketed?

YES: the unmodified, primary predicate device SmartLinx Vitals Plus Patient Monitoring System is legally marketed and was cleared in K171751.

YES: the reference device, the 740 Select is legally marketed and was cleared in K130411.

Decision 2: Do the devices have the same intended use?

YES: as shown in Table 6 above, the intended use/indication statement for the ***proposed*** SmartLinx Vitals Plus Patient Monitoring System is **identical** to the indication statement for the ***predicate***, primary predicate device SmartLinx Vitals Plus Patient Monitoring System.

Although the intended use / indications for use of the reference device, the 740 Select is worded differently from that of the ***predicate*** and ***proposed*** SmartLinx Vitals Plus Patient Monitoring System, the intended use is similar in that both devices are used by healthcare professionals for monitoring of neonatal, pediatric and adult patients for non-invasive blood pressure, pulse rate, noninvasive functional oxygen saturation of arteriolar hemoglobin (SpO2) and body temperature.

Decision 3: Do the devices have the same technological characteristics?

NO: the ***proposed*** SmartLinx Vitals Plus Patient Monitoring System does not have the same technological characteristics as the ***predicate*** SmartLinx Vitals Plus Patient Monitoring System as follows:

- *Changes to add the option of Nellcor SpO2 Pulse Oximetry solution, Rev. 1.0*
- *Changes to upgrade SmartLinx Vitals Plus Patient Monitoring System from version 2.2.1 to version 2.3*
- *Changes to upgrade SmartLinx Vitals Plus Application from version 9.0.3 to version 9.2*
- *Software modifications to the SmartLinx Vital Plus Patient Monitoring System cleared in K171751, documented to file*

The ***proposed*** SmartLinx Vitals Plus Patient Monitoring System can be configured with either the previously cleared Masimo SpO2 solution or with the Nellcor SpO2 solution, subject of this Special 510(k), whereas the unmodified SmartLinx Vitals Plus Patient Monitoring System can only be configured with the Masimo SpO2 solution.

The technological characteristics of the ***proposed*** SmartLinx Vitals Plus Patient Monitoring System are similar to those of the reference device, 740 Select.
Importantly, the ***proposed*** SmartLinx Vitals Plus Patient Monitoring System is the same as the reference device, the 740 Select, in that both devices support the Nellcor SpO2 solution.

Decision 4: Do the different technological characteristics of the device raise different questions of safety and effectiveness?

NO: the design changes as described in this Special 510(k) resulting in the ***proposed*** SmartLinx Vitals Plus Patient Monitoring System do not raise different questions of safety and effectiveness compared to the ***predicate*** SmartLinx Vitals Plus Patient Monitoring System. The ***predicate*** device supports the Masimo SpO2 solution which raised the question of safety regarding energy transfer to the patient. The energy transfer properties of the Nellcor SpO2 solution would be expected to raise the same question of safety concerning energy transfer to the patient. The reference device as mentioned under Decision 3 above also supports the Nellcor SpO2 solution and thus, the same question of safety regarding energy transfer properties is raised.

Decision 5a: Are the proposed scientific methods for evaluating new/different characteristics' effects on safety and effectiveness acceptable?

YES: the safety and effectiveness of the ***proposed*** SmartLinx Vitals Plus Patient Monitoring System have been confirmed through performance testing, i.e., bench testing, testing to FDA recognized consensus standards, and software verification and validation testing.

Decision 5b: 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 drawn from a robust Design Control, Risk Management, Software Development programs, and testing to FDA recognized consensus standards.

Decision 6: Do the data demonstrate substantial equivalence?

YES: The results from performance testing of safety and effectiveness demonstrate that the ***proposed*** SmartLinx Vitals Plus Patient Monitoring System is substantially equivalent to the ***predicate*** SmartLinx Vitals Plus Patient Monitoring System, and the reference device, the 740 Select, with respect to the Nellcor SpO2 solution.

5. Performance Testing

Performance testing assures that essential device characteristics have been appropriately implemented to provide safe and effective function and performance for the device's intended use. The performance testing consists of hardware and software verification and validation, as well as testing to FDA recognized consensus standards.

The SmartLinx Vitals Plus Patient Monitoring System conforms with FDA recognized consensus standards listed in the table below.

Table 2: FDA Recognized Consensus Standards

Category	Standard	Title
Electromagnetic Compatibility, Electrical Safety and Safety Standards	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)
	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 60601-2-49:2011	Medical electrical equipment – Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment
	ISO 80601-2-61:2011	Medical electrical equipment -- Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
Usability	IEC 60601-1-6:2013	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
	IEC 62366-1:2015	Medical devices - Part 1: Application of usability engineering to medical devices
Software	IEC 62304:2006	Medical device software—Software life cycle processes 13-32 Declaration of Conformity
Batteries	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)]
Alarms	IEC 60601-1-8:2012	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

6. Clinical Studies

This Traditional 510(k) for the ***proposed*** SmartLinx Vitals Plus Patient Monitoring System did not require clinical studies to support substantial equivalence.

7. Conclusions

Substantial equivalence of the ***proposed*** SmartLinx Vitals Plus Patient Monitoring System is demonstrated through performance testing and conformance with FDA recognized consensus standards. The ***proposed*** SmartLinx Vitals Plus Patient Monitoring System results in an equivalent design, features and functionality as compared to the ***predicate*** SmartLinx Vitals Plus Patient Monitoring System (primary predicate device) and 740 Select (reference device) with few exceptions that do not raise new questions of safety or effectiveness.

Capsule Tech, therefore, views the ***proposed*** SmartLinx Vitals Plus Patient Monitoring System to be eligible for a decision of substantial equivalence when compared to the ***predicate*** SmartLinx Vitals Plus Patient Monitoring System (primary predicate device) and 740 Select with Nellcor SpO2 solution (reference device)