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

Capsule Technologie SAS
Peter Kelley
Director of QA/RA
300 Brickstone Square, Suite 203
Andover, Massachusetts 01810

Re: K151071
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
Dated: August 5, 2015
Received: August 12, 2015

Dear Peter Kelley:

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 yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): __K151071_____

Device Name: SmartLinx Vitals Plus Patient Monitoring System

Indications for Use:

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

Prescription Use _X__ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

_____

Submitter	Capsule Technologie SAS 9 villa Pierre Ginier 75018 Paris, FR
Contact Person	Peter Kelley Director QA/RA 300 Brickstone Square, Suite 203 Andover, MA 01810 Phone: 978-482-2309 Email: peterk@capsuletech.com
Date Prepared	MAY 21, 2015
Device 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
Predicate Device	GE Carescape V100 Vital Signs Monitor K102426 This predicate has not been subject to a design-related recall.
Reference Devices	Zoll R Series Monitor Defibrillators K120907 Masimo uSpO2 Pulse Oximetry Cable K121914 Exergen TAT-5000S K011291

Device Description

The SmartLinx Vitals Plus Patient Monitoring System consists of the SmartLinx Vitals Plus mobile medical application and externally integrated vital signs modules operating on the SmartLinx Neuron 2 mobile platform. The application controls the modules at the point of care through interfaces on the SmartLinx Neuron 2 mobile platform and presents this to the user for active monitoring purposes. The supported physiological parameters are: non-invasive blood pressure (systolic, diastolic, mean arterial pressure (MAP)), pulse rate, functional arterial oxygen saturation (SpO2), and temperature.

The SmartLinx Vitals Plus Patient Monitoring System is composed of multiple products:

- The SmartLinx Vitals Plus mobile medical application
- The SmartLinx Vitals Plus NIBP Module with SunTech Medical cuffs and hoses
- The Masimo SET uSpO2 Pulse Oximetry Cable
- The Exergen TAT-5000S infrared thermometer
- The SmartLinx Neuron 2 Mobile Platform
- The SmartLinx Vitals Plus Roll Stand

SmartLinx Vitals Plus mobile medical application

The SmartLinx Vitals Plus mobile medical application is a new mobile medical application which operates on the SmartLinx Neuron 2 mobile platform. It provides command/control of user features of vital signs modules, actuators and medical devices. SmartLinx Vitals Plus mobile medical application

collects vital signs and medical device data at the point of care through sensor, actuator and medical device interfaces on the SmartLinx Neuron 2 mobile platform and presents this to the user for active monitoring purposes. The supported physiological parameters are: NIBP (systolic, diastolic, mean arterial pressure (MAP)), Pulse Rate, SpO2 and Temperature. The SmartLinx Vitals Plus mobile medical application is used by healthcare providers.

SmartLinx Vitals Plus NIBP Module

The SmartLinx Vitals Plus NIBP Module is a new hardware component, which incorporates the SunTech Medical Advantage A+ NIBP module and associated blood pressure cuffs and hoses, which measure systolic, diastolic and mean arterial (MAP) blood pressures, and pulse rates for adult, pediatric and neonatal patients. This same module is used in the previously cleared Zoll R Series Monitor Defibrillator (K120907), which is cited as a reference device in this 510(k) filing. The module is controlled by the SmartLinx Vitals Plus mobile medical application to manage the inflation and deflation of blood pressure cuffs, and to measure blood pressures and pulse rates. The SmartLinx Vitals Plus NIBP module is used by healthcare providers.

Masimo uSpO2 Pulse Oximetry Cable

The Masimo uSpO2 Pulse Oximetry Cable, and associated sensors are an in-line patient cable that provides continuous noninvasive monitoring of functional oxygen saturation (SpO2) and pulse rate when installed in a compatible OEM host system, and has its own regulatory clearance (K121914). The SmartLinx Vitals Plus application will control the operation of the uSpO2 to measure SpO2 in adult, pediatric and neonatal patients. The uSpO2 is used by healthcare providers.

Exergen TAT-5000S

The Exergen TAT-5000S is an infrared thermometer which has its own regulatory clearances (K011291). It is capable of being used independently or through an interface with other products. The SmartLinx Vitals Plus application will control the operation of the TAT-5000S to measure temperatures in adult, pediatric and neonatal patients. The TAT-5000S is used by healthcare providers.

SmartLinx Neuron 2 Mobile Platform

The SmartLinx Neuron 2 is a mobile computer which utilizes industry standard PC architecture and components, with touch-screen capabilities, and serial, USB, network and Bluetooth interfaces for device connectivity, and which runs a Microsoft Windows operating system. It provides connectivity for SmartLinx applications to vital signs modules and medical devices.

SmartLinx Vitals Plus Roll Stand

The SmartLinx Vitals Plus Roll Stand is an accessory provided to allow the users to ergonomically move and manage the SmartLinx Vitals Plus System and its components. It provides a platform for mounting the Neuron 2 and mechanical interfaces to all of the system components.

Indications for Use

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.

Comparison of the Subject and Predicate Devices

Table 1 Technological Characteristics Comparison

Characteristic	SmartLinx Vitals Plus	GE Carescape V100	Discussion of Differences
Intended Use	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.	The CARESCAPE VI00 Vital Signs Monitor is intended to monitor a single adult, pediatric or neonatal patient's vital signs at the bedside or during intra-hospital transport. Vital signs parameters include non-invasive blood pressure (systolic, diastolic, and mean arterial pressure), pulse rate, and/or oxygen saturation (pulse oximetry) and/or temperature. The portable device is designed for use in numerous clinical settings in various hospital departments such as emergency, radiology, recovery, medical/surgical, labor and delivery, endoscopy, cardiac step-down. The CARESCAPE VI00 Vital Signs Monitor can also be used in satellite areas, physicians' office, or alternate care settings.	Same
Design	**NIBP**: Suntech Advantage A+ oscillometric OEM NIBP technology module.	**NIBP**: Proprietary oscillometric design.	The NIBP functions use the same mechanism of action, oscillimetry. Both devices have the same questions of safety and effectiveness regarding energy transfer to the patient.
	SPO2: Masimo uSpO2 Oximetry Cable using SET pulse oximetry technology.	**SPO2**: Masimo SET pulse oximetry technology.	Same
	TEMP: Exergen TAT-5000S temporal artery scanner thermometer	**TEMP**: Exergen TAT-5000 temporal artery scanner thermometer	Same
Applied Part Materials	**NIBP**: SunTech Durable, Disposable, and Vinyl blood pressure cuffs and hoses	**NIBP**: GE CRITIKON Blood Pressure Cuffs and hoses	The applied parts in both devices have the same questions of safety and effectiveness regarding

Characteristic	SmartLinx Vitals Plus	GE Carescape V100	Discussion of Differences
			biocompatibility of patient applied parts.
	SPO2: Masimo LNCS and LNOP family of SpO2 sensors	**SPO2**: Masimo LNCS and LNOP family of SpO2 sensors	Same
	TEMP: Exergen TAT-5000S temporal artery scanner thermometer	**TEMP**: Exergen TAT-5000 temporal artery scanner thermometer	Same
Energy Source	12.6V, 2600 mAh, Lithium-Ion Battery Pack. 9V alkaline battery powers the optional Exergen TAT-5000s	6V, 3300 mAh, sealed lead acid battery powers the main unit. A 9V alkaline battery powers the Exergen TAT-5000	Questions of safety related to lithium ion batteries are the same as for lead acid and alkaline batteries, and thus do not raise different questions of safety and effectiveness.

Performance Testing

Performance testing ensures that the SmartLinx Vitals Plus Patient Monitoring System performs as well as the indicated predicate device and meets all of its functional requirements and performance specifications. Safety testing assures that the device complies with applicable sections of recognized industry and safety standards. The SmartLinx Vitals Plus Patient Monitoring System performance testing is summarized in Table 2.

Table 2 SmartLinx Vitals Plus Patient Monitoring System Performance Testing

Category	Testing Summary
Sterilization Validation	The SmartLinx Vitals Plus Patient Monitoring System is not designed to be sterilized. All patient applied parts used with the SmartLinx Vitals Plus Patient Monitoring System are sourced from the vendors of the vital signs modules. The sterilization issues related to these patient applied parts were addressed in the predicate or reference device submissions, and were cleared by FDA.
Shelf Life Testing	The SmartLinx Vitals Plus Patient Monitoring System does not have a shelf-life. All patient applied parts used with the SmartLinx Vitals Plus Patient Monitoring System are sourced from the vendors of the vital signs modules. The shelf life issues related to these patient applied parts were addressed in the predicate or reference device submissions, and were cleared by FDA. The SmartLinx Neuron battery has a shelf life of three months. This limit applies to batteries that are not in use.

	The Exergen TAT-5000S uses a 9 volt alkaline battery which typically has a shelf life of seven years.
Biocompatibility Testing	All patient applied parts used with the SmartLinx Vitals Plus Patient Monitoring System are sourced from the vendors of the vital signs modules. The biocompatibility issues related to these patient applied parts were addressed in the predicate or reference device submissions, and were cleared by FDA.
Software Testing	Software for the SmartLinx Vitals Plus Patient Monitoring System was designed and developed in accordance with Capsule Technologie software development processes, and was verified and validated. Test results indicated that the SmartLinx Vitals Plus Patient Monitoring System complies with its predetermined specification.
Electrical Safety	The SmartLinx Vitals Plus Patient Monitoring System was tested for patient safety in accordance with the following applicable standards: • IEC 60601-1:2005 • IEC 60601-1-6:2013 • IEC 60601-1-8:2012 • IEC 80601-2-30:2013 • ISO 80601-2-56:2009 • ISO 80601-2-61:2011 • ISO 81060-2:2013 • IEC 62304:2006 • IEC 62366:2014 • IEC 62133:2012 Test results indicated that the SmartLinx Vitals Plus Patient Monitoring System complies with its predetermined specification.
Electromagnetic Compatibility Testing	The SmartLinx Vitals Plus Patient Monitoring System was tested for EMC in accordance with IEC 60601-1-2:2007. Test results indicated that the SmartLinx Vitals Plus Patient Monitoring System complies with its predetermined specification.
Performance Testing – Bench	The SmartLinx Vitals Plus Patient Monitoring System was tested in accordance with internal Capsule Technologie requirements and procedures. Test results indicated that the SmartLinx Vitals Plus Patient Monitoring System complies with its predetermined specification. This testing includes performance, functional, reliability, environmental, and packaging testing .
Performance Testing – Animal	Animal performance testing was not performed and is not necessary to demonstrate safety and effectiveness of the SmartLinx Vitals Plus Patient Monitoring System.
Performance Testing – Clinical	The SmartLinx Vitals Plus Patient Monitoring System was tested for clinical performance in accordance with the following applicable standard: • ISO 81060-2:2013 Test results indicated that the SmartLinx Vitals Plus Patient Monitoring System complies with its predetermined specification.

Conclusions

Capsule Technologie SAS considers the SmartLinx Vitals Plus Patient Monitoring System to be as safe, as effective, and its performance is substantially equivalent to the predicate device.