June 10, 2020

Capsule Technologie SAS
Peter Kelley
Director, Quality & Regulatory
300 Brickstone Square, Suite 203
Andover, Massachusetts 01810

Re: K200856
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, CCK
Dated: June 5, 2020
Received: June 8, 2020

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

LT Stephen Browning
Assistant Director
Division of Cardiac Electrophysiology, Diagnostics, and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200856

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), end-tidal and fractional concentration of inspired CO2, respiration, and temperature, on adult, pediatric, and neonatal patients in health care facilities 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

Per 21 CFR 807.92

Submitter's Name and Address	Capsule Technologies, SAS 76-78 avenue de France CS21416 75644 Paris Cedex 13
Contact Name and Information	Peter Kelley Director Quality & Regulatory Capsule Tech, Inc 300 Brickstone Square, Suite 203 Andover, MA 01810 Phone: 978-482-2365 e-mail: pkelley@capsuletech.com
Date Prepare	March 30, 2020
Device Trade Name	SmartLinx Vitals Plus Patient Monitoring System
Common Name	Physiological or Vital Signs Monitor, Patient Monitor
Class and Classification Name	Class II, 21 CFR Part 870.2300 – Cardiac monitor (including cardiotachometer and rate alarm)
Product Code	MWI, DXN, DQA, FLL, CCK
Predicate Devices	Primary: SmartLinx Vitals Plus Patient Monitoring System, K183638. Cleared April 19, 2019. Secondary: Masimo NomoLine Infrared Sidestream Gas Analyzer ISA C02, K171121, (originally K103064). Cleared April 6, 2011.

Device Description

The primary predicate device, SmartLinx Vitals Plus Patient Monitoring System, was cleared in K183638. The secondary predicate device, the Masimo NomoLine ISA CO2 Gas Analyzer was cleared with the Root Monitoring System and Accessories (K171121).

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), end-tidal and fractional concentration of inspired CO2, respiration, and temperature, on adult, pediatric, and neonatal patients in health care facilities when used by clinical physicians or appropriate medical staff under the direction of physicians.

The SmartLinx Vitals Plus Patient Monitoring System operates with the SmartLinx Medical Device Information Platform (MDIP) a Medical Device Data System to present patient information to the clinical user for active monitoring purposes at the point of care.

The proposed SmartLinx Vitals Plus Patient Monitoring System consists of the following components:

- SmartLinx Neuron Mobile Platform
- SmartLinx Vitals Plus Application
- SmartLinx Vitals Plus NIBP Monitoring Module
- Masimo NomoLine Infrared Sidestream Gas Analyzer ISA C02
- Nellcor SpO2 Oximetry Module
- Masimo uSpO2 Pulse Oximetry Cable
- Exergen TAT-5000S Temperature Scanner
- SmartLinx Early Warning Scoring System

SmartLinx Neuron Mobile Platform

The SmartLinx Neuron is a mobile computer which utilizes industry standard PC architecture and components, with touch-screen capabilities, and serial, USB, network and RFID interfaces and which runs a Microsoft Windows operating system. It is used by healthcare providers through the applications running on it, and it is accessed by IT administrators during management and maintenance. The SmartLinx Neuron provides connectivity to medical devices through five isolated serial ports and two isolated USB ports. It also communicates with other IT systems through Ethernet or Wi-Fi network connection. The SmartLinx Neuron is IEC 60601-1 compliant for use in Medical Electrical Systems. The SmartLinx Neuron is utilized as part of an active monitoring system when running the SmartLinx Vitals Plus Application.

SmartLinx Vitals Plus Application

The SmartLinx Vitals Plus Application is a mobile medical application operating on the SmartLinx Neuron Mobile Platform. The Vitals Plus Application controls the externally integrated vital signs modules through interfaces on the SmartLinx Neuron and the SmartLinx Vital Plus NIBP Monitoring Module and presents patient information to the user for active monitoring purposes at the point of care. The supported physiological parameters are: non-invasive blood pressure (systolic, diastolic, and mean arterial pressure), pulse rate, functional arterial oxygen saturation (SpO2), temperature, end-tidal and fractional concentration of inspired CO2 and respiration rate.

SmartLinx Vitals Plus NIBP Monitoring Module

The SmartLinx Vitals Plus NIBP Monitoring Module integrates the SmartLinx Vitals Plus NIBP Module and the SmartLinx Vitals Plus Alarm Hub into a single 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. 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.

The SmartLinx Vital Plus 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 secondary speaker), watchdog functionality, and a USB hub for expansion.

Masimo NomoLine Infrared Sidestream Gas Analyzer ISA C02

The Masimo NomoLine ISA™ CO2 Gas Analyzer is part of the ISA product family and is a sidestream analyzer intended to be connected to a host instrument for monitoring of CO2 and respiratory rate. NomoLine ISA CO2™ is intended to be connected to a patient breathing circuit for monitoring of inspired/expired gases during anesthesia, recovery and respiratory care.

NomoLine sampling cannulas are intended to be used as accessories to the NomoLine ISA™ gas analyzers. They are connected to the nostrils or to the nostrils and mouth of spontaneously breathing patients for sampling of CO2.

The SmartLinx Vitals Plus Application controls the operation of the ISA CO2 to measure COS and respiration rate in adult, pediatric, and neonatal patients.

Nellcor SpO2 Oximetry Module

The Nellcor SpO2 Oximetry Module connects with Nellcor SpO2 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 Nellcor SpO2 Oximetry Module to measure SpO2 and pulse rate in adult, pediatric, and neonatal patients.

Masimo uSpO2 Pulse Oximetry Cable

The Masimo uSpO2 Pulse Oximetry Cable is a 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 Temperature Scanner

The Exergen TAT-5000S thermometer is a component of Vitals Plus. 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.

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 physiological 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), end-tidal and fractional concentration of inspired CO2, respirations, and temperature, on adult, pediatric, and neonatal patients in health care facilities when used by clinical physicians or appropriate medical staff under the direction of physicians.

Comparison of Similarities and Differences

This discussion of substantial equivalence follows the guidelines published in: The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications Guidance for Industry and Food and Drug Administration Staff July 28, 2014. This submission uses two predicate devices, the current SmartLinx Patient Monitoring System (K183638) as the primary predicate, and the Masimo NomoLine ISA CO2 Gas Analyzer as the secondary predicate device. The Masimo NomoLine ISA CO2 Gas Analyzer was cleared with the Root Monitoring System and Accessories (K171121). The proposed device consists of the integration of the secondary predicate device with the first predicate device.

The proposed SmartLinx Vital Plus Patient Monitoring System is substantially equivalent to the combined predicate devices, in terms of classification **(Table 1**), intended use (***Table 2***) and technical characteristics (***Table 3***), as described below.

Table 1 Comparison of Classification of Proposed Device to Predicate Devices

Attrubute	Predicate SmartLinx Vitals Plus	Predicate NomoLine ISA CO2	Proposed SmartLinx Vitals Plus
Manufacturer	Capsule Technologies	Masimo Corporation	Capsule Technologies
Regulation Number	870.2300	868.1400	870.2300 *Same as primary predicate*
Regulation Name	Cardiac monitor (including cardiotachometer and rate alarm)	Carbon dioxide gas analyzer	Cardiac monitor (including cardiotachometer and rate alarm) *Same as primary predicate*
Product Codes	MWI, DQA, DXN, FLL	CCK	MWI, DQA, DXN, FLL, CCK *Same as combined predicates*
510(k) Number	K183638	K171121	K200856
Class	II	II	II

Table 2 Comparison of Intended Use of Proposed Device to Predicate Devices

Intended Use / Indications for Use	
Proposed SmartLinx Vitals Plus	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), end-tidal and fractional concentration of inspired CO2, respiration, and temperature, on adult, pediatric, and neonatal patients in health care facilities when used by clinical physicians or appropriate medical staff under the direction of physicians.
Predicate SmartLinx Vitals Plus	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.
Predicate NomoLine ISA CO2	The optional ISA product family consists of three types of sidestream gas analyzers (ISA CO2, ISA AX+ and ISA OR+) and accessories including Nomoline, intended to be connected to other medical backboard devices for monitoring of breath rate and the following breathing gases: ISA CO2: CO2 ISA AX+: CO2, N2O, Halothane, Isoflurane, Enflurane, Sevoflurane and Desflurane ISA OR+: CO2, O2, N2O, Halothane, Isoflurane, Enflurane, Sevoflurane and Desflurane ISA CO2, ISA AX+ and ISA OR+ are intended to be connected to a patient breathing circuit for monitoring of inspired/expired gases during anesthesia, recovery and respiratory care. The intended environment is the operating suite, intensive care unit and patient room. ISA CO2 is also intended to be used in road ambulances. The intended patient population is adult, pediatric, infant, and neonatal patients.
Discussion	The proposed SmartLinx Vital Plus Patient Monitoring System intended use incorporates all the predicate Vitals Plus intended use plus the monitoring of inspired and expired CO2 intended use of the ISA CO2 predicate device. The differences between the proposed and predicate intended use are not critical for the intended use of the proposed device, and do not affect the safety and effectiveness of the device when used as labeled.

Table 3 Comparison of Technical Characteristics of Proposed Device to Predicate Devices

Attribute	Primary Predicate: SmartLinx Vitals Plus	Secondary Predicate: NomoLine ISA CO2	Proposed Device: SmartLinx Vitals Plus	Discussion
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		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 primary predicate
	SpO2 Measurement: Masimo or Nellcor Continuous SpO2 Monitoring: Pulse tone pitch xxx, sensor off alarmSpO2 alarm delay: Selectable time (secs) for Masimo, SatSeconds for Nellcor		SpO2 Measurement: Masimo or Nellcor Continuous SpO2 Monitoring: Pulse tone pitch xxx, sensor off alarmSpO2 alarm delay: Selectable time (secs) for Masimo, SatSeconds for Nellcor	Same as primary predicate
	Alarms: Configuration, annunciation, and acknowledgement of physiological (Sys, Dia, MAP, Pulse Rate, SpO2, and TEMP) and technical alarms		Alarms: Configuration, annunciation, and acknowledgement of physiological (Sys, Dia, MAP, Pulse Rate, SpO2, and TEMP) and technical alarms	Same as primary predicate

Attribute	Primary Predicate: SmartLinx Vitals Plus	Secondary Predicate: NomoLine ISA CO2	Proposed Device: SmartLinx Vitals Plus	Discussion
	TEMP: Exergen TAT-5000S temporal artery scanner thermometer		TEMP: Exergen TAT-5000S temporal artery scanner thermometer	Same as primary predicate
		CO2: Infrared spectroscopy	CO2: Infrared spectroscopy	Same as secondary predicate
Applied Parts	NIBP: SunTech Durable One-Piece, Disposable, and Vinyl blood pressure cuffs and hoses, and GE CRITIKON SOFT-CUF cuffs		NIBP: SunTech Durable One-Piece, Disposable, and Vinyl blood pressure cuffs and hoses, and GE CRITIKON SOFT-CUF cuffs	Same as primary predicate
	SpO2: Masimo LNCS family of reusable and disposable SpO2 sensors		SpO2: Masimo LNCS family of reusable and disposable SpO2 sensors	Same as primary predicate
	Masimo® or Nellcor® SpO_2 algorithms (optional)—both sensors and signal processing		Masimo® or Nellcor® SpO_2 algorithms (optional)—both sensors and signal processing	Same as primary predicate
	TEMP: Exergen disposable probe covers and sheaths		TEMP: Exergen disposable probe covers and sheaths	Same as primary predicate
		CO2 Canulla: Soft PVC	CO2 Canulla: Soft PVC	Same as secondary predicate

Attribute	Primary Predicate: SmartLinx Vitals Plus	Secondary Predicate: NomoLine ISA CO2	Proposed Device: SmartLinx Vitals Plus	Discussion
		Co2: Airway Adapter: Hard plastic; methyl methacrylate-acrylonitrite-butadiene-styrene (MABS)	Co2: Airway Adapter: Hard plastic; methyl methacrylate-acrylonitrite-butadiene-styrene (MABS)	Same as secondary predicate
Energy Source	Main Battery Neuron 2: Lithium-Ion 3S1P 2600 mAh or 3050 mAh		Main Battery Neuron 2: Lithium-Ion 3S1P 2600 mAh or 3050 mAh	Same as primary predicate
	Extended Battery Neuron 2: Lithium-Ion 3S2P 5200 mAh or 6100 mAh (1 or 2 depending on use of Dual Battery Dock)		Extended Battery Neuron 2: Lithium-Ion 3S2P 5200 mAh or 6100 mAh (1 or 2 depending on use of Dual Battery Dock)	Same as primary predicate
	Exergen: 9V alkaline		Exergen: 9V alkaline	Same as primary predicate
	Power Supply: 100-240 V AC, 2.0-1.0 A, 50-60 Hz, 65 W max, Class I		Power Supply: 100-240 V AC, 2.0-1.0 A, 50-60 Hz, 65 W max, Class I	Same as primary predicate
		NomoLine: 5V, 160mA typical, 800mA peak.	NomoLine: 5V, 160mA typical, 800mA peak.	Same as secondary predicate

Discussion

The proposed SmartLinx Vital Plus Patient Monitoring System intended use incorporates all the predicate Vitals Plus intended use plus the monitoring of inspired and expired CO2 intended use of the ISA CO2 predicate device. The differences between the proposed and predicate intended use are not critical for the intended use of the proposed device, and do not affect the safety and effectiveness of the device when used as labeled.

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 ***Table 4*** below.

Table 4 FDA Recognized Consensus Performance Standards

FDA Recognition #	Standard Number	Standard Edition / Date	Title
19-10	UL 1642	5th Edition	Lithium Batteries
19-11	UL 2054	2nd Edition	Household and Commercial Batteries
19-13	IEC 62133	Edition 2.0 2012-12	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)]
19-23	IEC 60086-4 Edition 4.0 2014-09	Edition 4.0 2014-09	Primary batteries - Part 4: Safety of lithium
19-4	ANSI AAMI ES60601-1	2005/(R)2012 and A1:2012	C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)

FDA Recognition #	Standard Number	Standard Edition / Date	Title
19-8	IEC 60601-1-2	Edition 4.0 2014-02	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
5-89	IEC 60601-1-6	Edition 3.1 2013-10	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
5-76	IEC 60601-1-8	Edition 2.1 2012-11	Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
5-114	IEC 62366-1	Edition 1.0 2015-02	Medical devices - Part 1: Application of usability engineering to medical devices
13-79	IEC 62304	Edition 1.1 2015-06 CONSOLIDATED VERSION	Medical device software - Software life cycle processes
3-123	IEC 80601-2-30	Edition 2.0 2018-03	Medical electrical equipment Part 2-30: Particular requirements for basic safety and essential performance of automated type non-invasive sphygmomanometers
6-403	ISO 80601-2-56	Second edition 2017-03	Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement.
1-139	ISO 80601-2-61	Second edition 2017-12 (Corrected version 2018-02)	Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment

FDA Recognition #	Standard Number	Standard Edition / Date	Title
1-140	ISO 80601-2-55	Second edition 2018-02	Medical electrical equipment - Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors
2-220	ISO 10993-1	Fourth edition 2009-10-15	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process [Including: Technical Corrigendum 1 (2010)]
5-40	ISO 14971	Second edition 2007/(R)2010	Medical devices - Application of risk management to medical devices

Clinical Studies

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

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 equivalent design, features and functionality as compared with the two predicate devices with few exceptions that do not raise any new questions of safety or effectiveness. Capsule Technologies therefore views the proposed SmartLinx Vitals Plus Patient Monitoring System to be eligible for a decision of substantial equivalence when compared to the primary predicate device, the SmartLinx Vitals Plus Patient Monitoring System and the secondary predicate device, the Masimo NomoLine Infrared Sidestream Gas Analyzer ISA C02.