December 29, 2021

Nihon Kohden Corporation
% Sunita Teekasingh
Sr. Regulatory Affairs Consultant - GSA2 Group LLC
Nihon Kohden America, Inc
15353 Barranca Parkway
Irvine, California 92618

Re: K213316
Trade/Device Name: Life Scope PT BSM-1700 Series, AY Series, Data Acquisition Unit, LIFE SCOPE BSM 6000 SERIES BEDSIDE MONITORING SYSTEM, Nihon Kohden CSM-1901 BEDSIDE MONITORING SYSTEM
Regulation Number: 21 CFR 868.2775
Regulation Name: Electrical Peripheral Nerve Stimulator
Regulatory Class: Class II
Product Code: KOI, MHX
Dated: November 26, 2021
Received: November 29, 2021

Dear Sunita Teekasingh:

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,

Todd Courtney
Assistant Director
DHT1C: Division of Sleep Disordered
Breathing, Respiratory and
Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213316

Device Name
Smart Cable™ NMT Module and Accessories; Life Scope® BSM-6000 Series Bedside Monitoring Systems; Life Scope® CSM-1901 Bedside Monitoring Systems; Life Scope ® PT BSM-1700 Series and Accessories and AY Series And Accessories.

Indications for Use *(Describe)*
The Smart Cable NMT Module and Accessories are indicated for monitoring the relaxation of the patient when neuromuscular blockades are administered.

The Smart Cable NMT Module and Accessories are comprised of:

- AF-201P NMT Module with Smart Cable
- Disposable Electrodes
- Main cable
- Holder (optional)

The Smart Cable NMT Module and Accessories are intended to be used as a system that requires Nihon Kohden compatible electrodes and bedside monitoring systems. The Smart Cable NMT Module and Accessories are intended for use by medical personnel in clinical settings and are available by prescription only.

Life Scope® BSM-6000 Series Bedside Monitoring Systems

The Life Scope® BSM-6000 Series Bedside Monitoring Systems are intended to monitor, display, and record physiological data to provide cardiac and vital signs monitoring within a medical facility. The device is intended to produce a visual record of the electrical signals produced by the heart and monitor the electrocardiogram to generate visible and/or audible alarms when an arrhythmia exists.

The device is also intended to monitor heart rate, pulse rate, blood oxygen saturation (SpO2), non- invasive blood pressure (NIBP), invasive blood pressure (IBP), body temperature, BIS, cardiac output (CO), oxygen concentration (FiO2), carbon dioxide concentration (CO2), EtCO2, respiratory rate and inspired and expired anesthetic agents and anesthetic gases including N2O, Halothane, Isoflurane, Enflurane, Sevoflurane and Desflurane.
The device may generate an audible and/or visual alarm when a measured rate falls outside preset limits. The device may also be used to condition and transmit physiological signals via radio frequency. The device can interface to external equipment to display numerical and waveform data and alarms from the external devices. Supported external devices include CO2 monitors, BIS monitors, Anesthetic agents/gases detection system, Anesthesia machine, Ventilators, CCO monitors, TOF monitors, CCO/SvO2 Monitors, EEG monitoring device, tcPO2/tcPCO2 monitors, rSO2 monitors and external devices which output analog voltage signal.

The device will be available for use by medical personnel on patients within a medical facility on all patient populations. The system requires a BSM-6000 core unit with a compatible input unit: AY Series or Life Scope® PT BSM-1700 Series.

Life Scope® CSM-1901 Bedside Monitoring Systems

The Life Scope® CSM-1901 Bedside Monitoring Systems are intended to monitor, display and record physiological data to provide cardiac and vital signs monitoring within a medical facility. The device is intended to produce a visual record of the electrical signal produced by the heart and monitor the electrocardiogram to generate visible and/or audible alarms when an arrhythmia exists. The device is also intended to monitor heart rate, pulse rate, blood oxygen saturation (SpO2),

non-invasive blood pressure (NIBP), invasive blood pressure (IBP), body temperature, BIS, cardiac output (CO), oxygen concentration (FiO2), carbon dioxide concentration (CO2), EtCO2, respiratory rate, inspired and expired anesthetic agents and anesthetic gases including N2O, halothane, isoflurane, enflurane, sevoflurane and desflurane. The device also displays patient data from external devices such as ventilators, TOF monitors, CCO/SvO2 monitors, and EEG measuring unit. The device may generate and audible and/or visual alarm when a measured rate falls outside preset limits.
The device will be available for use by trained medical personnel within a medical facility on all patient populations, including adult, neonate, infant, child, and adolescent subgroups.

The system requires a CSM-1901 core unit with a compatible input unit: AY Series or Life Scope® PT BSM-1700 Series.

Life Scope® PT BSM-1700 Series and Accessories

The Life Scope® PT BSM-1700 Series and Accessories are intended acquire and transfer electrical impulses from the patient to the main unit of the device. The BSM-1700 Series input unit monitors physiological data and may generate an audible and/or visual alarm when a measured rate falls outside preset limits when disconnected from the core unit of the device. The input unit can be removed from one core unit and connected to another devices core unit. The Life Scope® PT BSM-1700 Series can be used in transport mode where data is transferred from one device to another device by using with or without WLAN technology. The input unit can acquire the following parameter signals: Electrocardiogram (ECG), Impedance respiration (Imp Resp), Non-invasive blood pressure (NIBP), Arterial oxygen saturation (SpO2), Carbon dioxide concentration (CO2), Invasive blood pressure (IBP), Temperature (Temp), Cardiac Output (CO), TOF and Bispectral Index (BIS).

The Data Acquisition Unit (DAU) is an optional accessory. The DAU is used to communicate between the compatible parent core unit and the input unit using connection cables. The keys on the DAU allow operation of the bedside monitor remotely. The DAU is only compatible with the Life Scope® PT BSM-1700 Series and the AY Series Input Units.

AY Series and Accessories

AY Series and Accessories are intended to acquire and transfer electrical impulses from the patient to the core unit of the device. The input unit can acquire the following parameter signals: Electrocardiogram (ECG), Impedance respiration (Imp Resp), Non-invasive blood pressure (NIBP), Arterial oxygen saturation (SpO2), Carbon dioxide concentration (CO2), Invasive blood pressure (IBP), Temperature (Temp), Cardiac Output (CO), TOF and Bispectral Index (BIS). AA Series smart expansion unit adds additional MULTI sockets to an AY Series input unit and can only be used with compatible monitoring systems.

The Data Acquisition Unit (DAU) is an optional accessory. The DAU is used to communicate between the compatible parent core unit and the input unit using connection cables. The keys on the DAU allow operation of the bedside monitor remotely. The DAU is only compatible with the Life Scope® PT BSM-1700 Series and the AY Series Input Units.

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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SECTION 5 510(K) SUMMARY OR 510(K) STATEMENT

NIHON KOHDEN

General Provisions	**Manufacturer Name:**	**Nihon Kohden Corporation**
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	Submitter Name:	Nihon Kohden America
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	Date of Preparation	27-Dec-2021
	Submission Type	Special 510(K)
	Type of Modification	Software Modification
	Predicate	K201949 – cleared 2 May2021 • Life Scope® BSM-6000 Series Bedside Monitors; • Nihon Kohden CSM-1901 Bedside Monitor

5.1 GENERAL PROVISIONS

5.2 INTRODUCTION

This submission is to obtain clearance for the software modification to the input units for Life Scope® PT BSM 1700 Series and AY Series Input Units , see Table 5-1 for the summary. The input units required an updated software package to work with the Smart Cable NMT Module and Accessories (K201949).

The software modifications on the input units does not change the safety, performance of the predicate devices.

Table 5-1: **Software submission Scope**

Smart Cable NMT Module and Accessories K201949	**Parent device Core Unit software version**	**Input Unit Software version AY Series or BSM-1700 Series**		
AF-201P Software Version 3.0- no changes to the original software under K201949	Life Scope®BSM-6000 Series Bedside Monitoring Systems (K201949) Software v08-31	**AY Series v08-31** AY-631P AY-633P AY-651P AY-653P AY-671P AY-673P	**OR**	**BSM-1700 Series** v02-66 BSM-1733 BSM-1753 BSM-1773
	Life Scope® CSM-1901 Bedside Monitoring Systems (K201949) Software v01-32			
	Life Scope® BSM-3000 Series Bedside Monitors (K201949) Software v08-31			

In addition to the software changes, Nihon Kohden (NK) is updating the intended use for the Life Scope® BSM-6000 Series Bedside Monitoring Systems, and Life Scope® CSM-1901 Bedside Monitoring Systems:

- A statement was added to the parent devices to clarify these systems require both a core unit and an input unit.
- The Life Scope® PT BSM-1700 Input unit and the AY Series Input unit and accessories were added to the parent device intended use.

Table 5-2: Parent Devices: Core Unit and Input unit configurations

Compatible Parent Bedside Monitoring Core Units	Input Model	Configuration	
		Multi Connector	SpO_2 Probe
Life Scope® BSM 6000 Series Bedside Monitoring Systems (K201949)	AY-631P	1	Masimo
	AY-633P	3	
	BSM-1733	3	
Life Scope® CSM-1901 Bedside Monitoring Systems (K201949)	AY-651P	1	Nellcor
	AY-653P	3	
	BSM-1753	3	
Life Scope® G5 Series Bedside Monitoring Systems (K203435)	AY-671P	1	Nihon Kohden
	AY-673P	3	
	BSM-1773	3	
Life Scope® G7 Series Bedside Monitoring Systems (K203435)			
Life Scope® CSM-1901 and BSM-6000 Series Bedside Monitoring Systems (K201949) **Data Acquisition Unit**	JA 690PA	N/A	Unit only used with CSM-1901 and BSM-6000
	JA-694PA	4	

5.3 SMART CABLE NMT MODULE AND ACCESSORIES

The Smart Cable NMT Module and Accessories were previously cleared under K201949, this system requires a compatible monitoring system for the NMT module to work. The input unit software has been updated to recognize the Smart Cable NMT Module connection. There have been no modifications to the Intended Use, safety or performance for Smart Cable NMT Module and Accessories as a result of the input unit software update.

Subject Device	Trade Name:	**Smart Cable NMT Module and Accessories**
	Common Name:	Electrical peripheral nerve stimulator
	Classification Name	Stimulator, Nerve, Peripheral, Electric
	Classification:	Class II
	Product Code:	KOI
	Regulation Number:	21 CFR 868.2775
Predicate Device	Trade Name:	Smart Cable NMT Module and Accessories
	Marketing Names:	NMT Smart Cable TOF Pod; Smart Cable NMT Pod, with EMG Support; NMT Pod TOF Pod; TOF Smart Pod; NMT Smart Pod, NMT Module, AF-201P, Smart Cable NeuroMuscular Transmission Pod, NMT Pod and Train of Four Pod, Disposable electrodes, EMG electrodes, NMT electrodes
	Classification Name:	Electrical peripheral nerve stimulator
	Premarket Notification	Stimulator, Nerve, Peripheral, Electric
	Product Code:	KOI
	Device Classification:	Class II
	Regulation Number:	21 CFR 868.2775
	Manufacturer:	**Nihon Kohden**
	510K number:	**K201949**
Device Description	The Nihon Kohden Smart Cable NMT Module (NMT Module) and Accessories is an optional accessory for the Nihon Kohden bedside monitoring systems. The Smart Cable NMT Module and Accessories TOF (Train of Four) are based on EMG technology. With this system, the user can apply electrical stimulation on the ulnar nerve to detect the muscle's action potential. The reaction to the electrical impulse can be visualized on the connected monitoring system. The Smart Cable NMT Module and Accessories can assist medical personnel to quantitatively determine the level of muscle relaxation. This information can be used to determine the dose of muscle relaxants and regional anesthetics when performing anesthesia in a clinical setting. It is intended for use by medical personnel in the operating room, recovery room, or intensive care unit. NMT Module is a system comprised of NMT Module, Main Cable, Holder, and EMG Electrode. The NMT module is connected to an electrode via Main Cable. The electrode is a single-use electrode array and each array includes two stimulating electrodes, two recording electrodes, and one ground electrode. The NMT module can transmit an electrical	

	stimulation pulse to the patient and can receive EMG signals via the electrode array. The captured data from the disposable electrode is sent to the monitoring system via the Smart Cable interface connector. The various stimulation settings are also sent to the monitoring system to display. The AF-201P NMT Module is used to control the electrical stimulation and to measure the response. The operational setting is controlled via buttons on the module or a touch screen.
Indication for Us and Intended Use	The Smart Cable NMT Module and Accessories are indicated for monitoring the relaxation of the patient when neuromuscular blockades are administered. The Smart Cable NMT Module and Accessories are comprised of: • AF-201P NMT Module with Smart Cable • Disposable Electrodes • Main cable • Holder (optional) The Smart Cable NMT Module and Accessories are intended to be used as a system that requires Nihon Kohden compatible electrodes and bedside monitoring systems. The Smart Cable NMT Module and Accessories are intended for use by medical personnel in clinical settings and are available by prescription only.
Modification	There are no changes to the Smart Cable NMT Module and Accessories as a result of the software update to the Life Scope® PT BSM-1700 Series and or the AY Series input units.
Summary of Substantial Equivalence	The device comparison and the results of the safety and performance tests indicate that the Nihon Kohden Smart Cable NMT Module and Accessories is substantially equivalent to the predicate devices.

5.4 LIFE SCOPE® BSM-6000 SERIES BEDSIDE MONITORING SYSTEM

The intended Use for BSM-6000 was updated to include the statement "*The system requires a BSM 6000 core unit with a compatible input unit: AY Series or Life Scope® PT BSM-1700 Series"*.

The Life Scope® BSM-6000 Series Bedside Monitoring System, the input unit software has been updated to recognize the connection to the Smart Cable NMT Module and Accessories. There are no changes to the specifications or performance from the predicate device under K201949.

The Intended Use further clarifies the addition of Life Scope® BSM-1700 Series and the AY Series Input Units to BSM-6000 Intended Use is substantially equivalent to the predicate K201949.

Subject Device	Trade Name:	**Life Scope BSM-6000 Series Bedside Monitoring Systems**
	Common Name:	Bedside Monitor, Patient Monitor, Cardiac Monitor, Vital Signs Monitor and Anesthesia Monitor
	Classification Name	Monitor, Physiological Patient Monitor with Arrhythmia Detection and Alarms
	Classification:	Class II
	Product Code:	MHX
	Regulation Number:	21 CFR 870.1025
Predicate Device	Trade Name:	**Life Scope BSM-6000 Series Bedside Monitoring System**
	Common Name:	Bedside Monitor, Patient Monitor, Cardiac Monitor, Vital Signs Monitor and Anesthesia Monitor
	Classification Name	Monitor, Physiological Patient Monitor with Arrhythmia Detection and Alarms
	Classification:	Class II
	Product Code:	MHX
	Regulation Number:	21 CFR 870.1025
	Manufacturer	**Nihon Kohden**
	510(K):	**K201949**
Device Description	The Life Scope BSM-6000 Series Bedside Monitoring Systems are intended to monitor, display and record physiological data to provide cardiac and vital signs monitoring within a medical facility. The device is intended to produce a visual record of the electrical signals produced by the heart and monitor the electrocardiogram to generate visible and/or audible alarms when an arrhythmia exists. The device is also intended to monitor heart rate, pulse rate, blood oxygen saturation (SpO2), non- invasive blood pressure (NIBP), invasive blood pressure (IBP), body temperature, Cardiac Output (CO), oxygen concentration (FiO2), CO2 and EtCO2, respiratory rate, BIS and inspired and expired anesthetic agents and gases including CO2, O2, N2O, Halothane, Isoflurane, Enflurane, Sevoflurane and Desflurane. Anesthetic agents and gases are detected using the cleared AG-920RA Anesthetic Agent Detection System. The device can interface to external equipment to display numerical and waveform data and alarms from the external devices. Supported external devices include AG-920RA Anesthetic Agent Detection System, Ventilators, CO2 Monitors, TOF Monitors, BIS Monitors, CCO/SvO2 Monitors and continuous NIBP Monitors. The device may generate an audible and/or visual alarm when a measured rate falls outside preset limits. This device may also be used to condition and transmit physiological signals via radiofrequency. The system requires a BSM 6000 core unit with a compatible input unit: AY Series or Life Scope® PT BSM-1700 Series.	

Table 5-3: Compatible Input Unit and Core units

Compatible Parent Bedside Monitoring Configurations			
Core Units	Input Model	Multi Connector	SpO2 Probe
Life Scope® BSM-6000 Series Bedside Monitoring Systems	AY-631P AY-633P BSM-1733	1 3 3	Masimo
	AY-651P AY-653P BSM-1753	1 3 3	Nellcor
	AY-671P AY-673P BSM-1773	1 3 3	Nihon Kohden
Life Scope® BSM-6000 Series Data Acquisition Unit	JA 690PA JA-694PA	N/A 4	Unit only used with BSM-6000

The input units are common to NK parent devices that require both a core unit and an input unit. NK manufactures the input units with three (3) SpO2 options. The Life Scope® BSM-6000 Series (K201949) have an interchangeable input units that contains the MULTI socket ports. For larger monitoring systems is data acquisition unit is required to transmit data from the input unit to the core unit.

The input unit interprets the electrical impulses from the patient's body and transfers this data into the core unit. The core unit calculates the electrical impulses. Each monitor has a color display and is intended for one patient. The intended populations are all patient populations under the care of health professionals.

Proposed Indications for Use and Intended Use

The Life Scope® BSM-6000 Series Bedside Monitoring System is intended to monitor, display, and record physiological data to provide cardiac and vital signs monitoring within a medical facility. The device is intended to produce a visual record of the electrical signals produced by the heart and monitor the electrocardiogram to generate visible and/or audible alarms when an arrhythmia exists.

The device is also intended to monitor heart rate, pulse rate, blood oxygen saturation (SpO2), non- invasive blood pressure (NIBP), invasive blood pressure (IBP), body temperature, BIS, cardiac output (CO), oxygen concentration (FiO2), carbon dioxide concentration (CO2), EtCO2, respiratory rate and inspired and expired anesthetic agents and anesthetic gases including N2O, Halothane, Isoflurane, Enflurane, Sevoflurane and Desflurane.

The device may generate an audible and/or visual alarm when a measured rate falls outside preset limits. The device may also be used to condition and

	transmit physiological signals via radio frequency. The device can interface to external equipment to display numerical and waveform data and alarms from the external devices. Supported external devices include CO2 monitors, BIS monitors, Anesthetic agents/gases detection system, Anesthesia machine, Ventilators, CCO monitors, TOF monitors, CCO/SvO2 Monitors, EEG monitoring device, tcPO2/tcPCO2 monitors, rSO2 monitors and external devices which output analog voltage signal. The device will be available for use by medical personnel on patients within a medical facility on all patient populations. The system requires a BSM-6000 core unit with a compatible input unit: AY Series or Life Scope® PT BSM-1700 Series.
Intended Use: Life Scope® PT BSM-1700 Series and Accessories Updated from the Predicate device	The Life Scope® PT BSM-1700 Series and Accessories are intended acquire and transfer electrical impulses from the patient to the main unit of the device. The BSM-1700 Series input unit monitors physiological data and may generate an audible and/or visual alarm when a measured rate falls outside preset limits when disconnected from the core unit of the device. The input unit can be removed from one core unit and connected to another devices core unit. The Life Scope® PT BSM-1700 Series can be used in transport mode where data is transferred from one device to another device by using with or without WLAN technology. The input unit can acquire the following parameter signals: Electrocardiogram (ECG), Impedance respiration (Imp Resp), Non-invasive blood pressure (NIBP), Arterial oxygen saturation (SpO2), Carbon dioxide concentration (CO2), Invasive blood pressure (IBP), Temperature (Temp), Cardiac Output (CO), TOF and Bispectral Index (BIS). The Data Acquisition Unit (DAU) is an optional accessory. The DAU is used to communicate between the compatible parent core unit and the input unit using connection cables. The keys on the DAU allow operation of the bedside monitor remotely. The DAU is only compatible with the Life Scope® PT BSM-1700 Series and the AY Series Input Units.
Intended Use: AY Series and Accessories Updated from the Predicate Device	AY Series and Accessories are intended to acquire and transfer electrical impulses from the patient to the core unit of the device. The input unit can acquire the following parameter signals: Electrocardiogram (ECG), Impedance respiration (Imp Resp), Non-invasive blood pressure (NIBP), Arterial oxygen saturation (SpO2), Carbon dioxide concentration (CO2), Invasive blood pressure (IBP), Temperature (Temp), Cardiac Output (CO), TOF and Bispectral Index (BIS). AA Series smart expansion unit adds additional MULTI sockets to an AY Series input unit and can only be used with compatible monitoring systems. The Data Acquisition Unit (DAU) is an optional accessory. The DAU is used to communicate between the compatible parent core unit and the input unit using connection cables. The keys on the DAU allow operation of the bedside monitor remotely. The DAU is only compatible with the Life Scope® PT BSM-1700 Series and the AY Series Input Units.
Modification	The input units software has been updated to work with the Smart Cable NMT Module and Accessories. The indication for use was updated to include a description of the input units and accessories.

Technological Characteristics	The indications for use/intended use statement have been updated to include the description of the input units and core units. There are no hardware changes compared to the predicate devices. There has been software updates to the input units to integrate with the Smart Cable NMT Module and accessories.
Safety & Performance Tests	The Life Scope® BSM-6000 Series Bedside Monitoring Systems incorporated all software changes in the integration testing. The testing confirmed the operation of the device when the Smart Cable NMT software was integrated into the system. The results confirmed that the device performed within specifications. No clinical tests have been submitted, referenced or relied on in this premarket notification submission for a determination of substantial equivalence.
Summary of Substantial Equivalence	The Life Scope® BSM-6000 Series Bedside Monitoring Systems are equivalent to the Life Scope BSM-6000 Series (K201949). The indications for use have been updated to include a description of the core unit and the input units, the software verification and validation confirmed performance and technological equivalency.

5.5 LIFE SCOPE® CSM-1901 BEDSIDE MONITORING SYSTEM

The intended Use for CSM-1901 was updated to include the statement, "*The system requires a CSM-1901 core unit with a compatible input unit: AY Series or Life Scope® PT BSM-1700 Series.*"

The Life Scope® CSM-1901 Bedside Monitoring System, the input unit software has been updated to recognize the connection to the Smart Cable NMT Module and Accessories. There are no changes to the specifications or performance from the predicate device under K201949.

The Intended Use further clarifies the addition of Life Scope® BSM-1700 Series and the AY Series Input unit and Accessories to CSM-1901 Intended Use. The Life Scope® CSM-1901 Bedside Monitoring System, Intended Use is substantially equivalent to the predicate K201949.

Subject Device	**Trade Name:**	**Life Scope CSM-1901 Bedside Monitoring Systems**
	Common Name:	Bedside Monitor, Patient Monitor, Cardiac Monitor, Vital Signs Monitor and Anesthesia Monitor
	Classification Name	Monitor, Physiological Patient Monitor with Arrhythmia Detection and Alarms
	Classification:	Class II
	Product Code:	MHX
	Regulation Number:	21 CFR 870.1025
Predicate Devices	Trade Name	Nihon Kohden CSM-1901 Bedside Monitor
	Common Name:	Bedside Monitor, Patient Monitor, Cardiac Monitor, Vital Signs Monitor and Anesthesia Monitor

	Classification Name	Monitor, Physiological Patient Monitor with Arrhythmia Detection and Alarms
	Classification:	Class II
	Product Code:	MHX
	Regulation Number:	21 CFR 870.1025
	510(K):	K201949

Device Description

The Life Scope® CSM-1901 Bedside Monitoring Systems are systems which continuously monitors physiological information of a patient and is used in an operation room, a recovery room, general wards, ICU, CCU, HCU, NICU and an emergency room. These systems are placed near the patient and is intended to display patient's vital signs. These systems can also be connected to other external patient monitoring devices. In addition, these systems can communicate patient's data to a central monitoring station via network to monitor multiple patients.

Table 5-4: Compatible Input Unit and Core units

Compatible Parent Bedside Monitoring Configurations			
Core Units	**Input Model**	**Multi Connector**	**SpO_2 Probe**
Life Scope® CSM-1901 (K201949)	AY-631P AY-633P BSM-1733	1 3 3	Masimo
	AY-651P AY-653P BSM-1753	1 3 3	Nellcor
	AY-671P AY-673P BSM-1773	1 3 3	Nihon Kohden
Data Acquisition Unit Life Scope® CSM-1901 (K201949)	JA 690PA JA-694PA	N/A	Unit only used with CSM-1901 Data Acquisition

The input unit is common to NK parent devices that require both a core unit and input unit. NK manufactures the input units with three (3) SpO2 options . The Life Scope® CSM-1901 Bedside Monitoring Systems have interchangeable input units that contains the MULTI socket ports. For larger monitoring systems is data acquisition unit is required to transmit data from the input unit to the core unit.

The bedside monitoring systems require both a core unit and an input unit. The input unit interprets the electrical impulses from the patient's body and transfers this data into the core unit. The core unit calculates the electrical impulses. Each monitor has a color display and is intended for

	one patient. The intended populations are all patient populations under the care of health professionals.
Proposed Indications for Use and Intended Use-	The Life Scope® CSM-1901 Bedside Monitoring Systems are intended to monitor, display and record physiological data to provide cardiac and vital signs monitoring within a medical facility. The device is intended to produce a visual record of the electrical signal produced by the heart and monitor the electrocardiogram to generate visible and/or audible alarms when an arrhythmia exists. The device is also intended to monitor heart rate, pulse rate, blood oxygen saturation (SpO2), non-invasive blood pressure (NIBP), invasive blood pressure (IBP), body temperature, BIS, cardiac output (CO), oxygen concentration (FiO2), carbon dioxide concentration (CO2), EtCO2, respiratory rate, inspired and expired anesthetic agents and anesthetic gases including N2O, halothane, isoflurane, enflurane, sevoflurane and desflurane. The device also displays patient data from external devices such as ventilators, TOF monitors, CCO/SvO2 monitors, and EEG measuring unit. The device may generate and audible and/or visual alarm when a measured rate falls outside preset limits. The device will be available for use by trained medical personnel within a medical facility on all patient populations, including adult, neonate, infant, child, and adolescent subgroups. The system requires a CSM-1901 core unit with a compatible input unit: AY Series or Life Scope® PT BSM-1700 Series.
Intended Use: Life Scope® PT BSM-1700 Series and Accessories UPDATED from the predicate	The Life Scope® PT BSM-1700 Series and Accessories are intended acquire and transfer electrical impulses from the patient to the main unit of the device. The BSM-1700 Series input unit monitors physiological data and may generate an audible and/or visual alarm when a measured rate falls outside preset limits when disconnected from the core unit of the device. The input unit can be removed from one core unit and connected to another devices core unit. The Life Scope® PT BSM-1700 Series can be used in transport mode where data is transferred from one device to another device by using with or without WLAN technology. The input unit can acquire the following parameter signals: Electrocardiogram (ECG), Impedance respiration (Imp Resp), Non-invasive blood pressure (NIBP), Arterial oxygen saturation (SpO2), Carbon dioxide concentration (CO2), Invasive blood pressure (IBP), Temperature (Temp), Cardiac Output (CO), TOF and Bispectral Index (BIS). The Data Acquisition Unit (DAU) is an optional accessory. The DAU is used to communicate between the compatible parent core unit and the input unit using connection cables. The keys on the DAU allow operation of the bedside monitor remotely. The DAU is only compatible with the Life Scope® PT BSM-1700 Series and the AY Series Input Units.
Intended Use: AY Series and Accessories UPDATED from the predicate	AY Series and Accessories are intended to acquire and transfer electrical impulses from the patient to the core unit of the device. The input unit can acquire the following parameter signals: Electrocardiogram (ECG), Impedance respiration (Imp Resp), Non-invasive blood pressure (NIBP),

	Arterial oxygen saturation (SpO2), Carbon dioxide concentration (CO2), Invasive blood pressure (IBP), Temperature (Temp), Cardiac Output (CO), TOF and Bispectral Index (BIS). AA Series smart expansion unit adds additional MULTI sockets to an AY Series input unit and can only be used with compatible monitoring systems. The Data Acquisition Unit (DAU) is an optional accessory. The DAU is used to communicate between the compatible parent core unit and the input unit using connection cables. The keys on the DAU allow operation of the bedside monitor remotely. The DAU is only compatible with the Life Scope® PT BSM-1700 Series and the AY Series Input Units.
Modification	The input unit software has been updated to works with the Smart Cable NMT Module and Accessories. The indication for use was updated to include a description of the input units and accessories.
Technological Characteristics	The indications for use/intended use statement have been updated to include the description of the input units and core units. There are no hardware changes compared to the predicate devices. There has been software update to the input units to integrate with the Smart Cable NMT Module and accessories.
Safety & Performance Tests	The Life Scope® CSM-1901 Bedside Monitoring Systems incorporated all software changes in the integration testing. The testing confirmed the operation of the device when the Smart Cable NMT software was integrated into the system. The results confirmed that the device performed within specifications. No clinical tests have been submitted, referenced or relied on in this premarket notification submission for a determination of substantial equivalence.
Summary of Substantial Equivalence	The Life Scope® CSM-1901 Bedside Monitoring Systems are equivalent to the Nihon Kohden CSM-1901 Bedside Monitor. The indications for use have been updated to include a description of the core unit and the input units, the software verification and validation confirmed performance and technological equivalent.

5.6 PERFORMANCE DATA

Software verification and validation testing were conducted, and documentation are provided as recommended by FDA's Guidance for Industry and FDA Staff - Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (2005). Software verification and validation were conducted that included software unit testing, integration level testing, and system-level testing. A system test was also performed based on the software requirements specification. Testing to compliance standards for electrical and electromagnetic safety was also performed.

Electrical safety and electromagnetic compatibility (EMC) testing were conducted. The devices comply with the applicable requirements within the ANSI AAMI ES60601-1 / IEC 60601-1 standards for safety and the IEC 60601-1-2 standard for EMC.

Table 5-5: Standards Used for Compliance Testing

No.	Standard
1.	EN /ISO 14971:2012 Medical Devices - Application of Risk Management to Medical Devices
2.	IEC 60601-1: 2005+Amd.1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
3.	ANSI/AAMI/ES 60601-1:2005 (R2012) with amendments Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD) (Consolidated Text) (includes ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012)
4.	IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
5.	IEC 60601-2-40:2016 Medical electrical equipment - Part 2-40: Particular requirements for the basic safety and essential performance of electromyographs and evoked response equipment.
6.	IEC60601-1-6: 2010+Amd.1:2013 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability.
7.	ISO10993-1: 2009 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
8.	IEC62366:2007+Amd. 1 2014 Amendment 1 - Medical devices - Application of usability engineering to medical devices
9.	IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION - Medical device software – Software life cycle processes

5.7 CONCLUSION

The software input units modifications and labeling modification do not raise different questions of safety and effectiveness when compared to the predicate devices. The devices perform as intended, and have the same performance characteristics and are substantially equivalent to the predicate devices under K201949.