May 2, 2021

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

Re: K201949
Trade/Device Name: Smart Cable NMT Module and Accessories, Life Scope BSM 3000 Series Bedside Monitors, Life Scope BSM 6000 Series Bedside Monitors, and Nihon Kohden CSM-1901 Bedside Monitor
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector And Alarm (Including ST-Segment Measurement And Alarm)
Regulatory Class: Class II
Product Code: MHX, KOI
Dated: March 30, 2021
Received: April 2, 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 ENT, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201949

Device Name
Smart Cable NMT Module and Accessories; Life Scope BSM-3000 Series Bedside Monitors; Life Scope BSM-6000 Series Bedside Monitors; and Nihon Kohden CSM-1901 Bedside Monitor

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.

- -

The Life Scope BSM-3000 Series Bedside Monitor 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 audible and/or visible 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 (O2), 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 Life Scope BSM-6000 Series Bedside Monitor 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 audible and/or visible 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 Nihon Kohden CSM-1901 Bedside Monitor 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 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.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

5.0 510(k) Summary – General Provisions

General Provisions	**Manufacturer Name:**	**Nihon Kohden Corporation**
	Address:	1-31-4 Nishiochiai, Shinjuku-Ku Tokyo 161-8560, Japan
	Submitter Name:	Nihon Kohden America
	Address:	15353 Barranca Parkway Irvine, California, USA 92618
	Contact:	Sandra Gadeyne Sr. Director of Quality and Regulatory Affairs
	Phone Number	949-356-3401
	Fax Number:	949-580-1550
	Email	Sandra_Gadeyne@nihonkohden.com
	Date of Preparation	30Apr2021

5.1 Smart Cable NMT Module and Accessories

Subject 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**
	Common Name:	Electrical peripheral nerve stimulator
	Classification Name	Stimulator, Nerve, Peripheral, Electric
	Classification:	Class II
	Product Code:	KOI
	Regulation Number:	21 CFR 868.2775
	510(k) Number	**K201949**
Predicate Device	Trade Name:	**TetraGraph Neuromuscular Transmission Monitor**
	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:	Senzime AB
	510K number:	**K190795**
Reference Device	Trade Name:	**ToFscan**
	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:	Idmed
	510(k):	**K172690**

Subject 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. The 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.
Indications for Use 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.

Characteristics	Subject Device: Smart Cable NMT Module and Accessories	Predicate Device: Tetragraph Neuromuscular Transmission Monitor (K#190795)	Reference Device: ToFscan Neuromuscular Transmission Monitor (K#172690)
Classification Panel	Anesthesiology	Anesthesiology	Anesthesiology
Classification Name	21 CFR 868.2775 Electrical Peripheral Nerve Stimulator	21 CFR 868.2775 Electrical Peripheral Nerve Stimulator	21 CFR 868.2775 Electrical Peripheral Nerve Stimulator
Regulatory Class	Class II	Class II	Class II
Product Code	KOI	KOI	KOI
Indications for 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 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.	The TetraGraph Neuromuscular Transmission (NMT) Monitor is indicated for monitoring the relaxation of the patient when neuromuscular blockade is administered.	ToFscan is a neuromuscular transmission monitor for monitoring the neuromuscular block of a patient in the operating theatre, recovery room or intensive care unit. The effect of neuromuscular blocking agents (NMBA) is monitored by measuring the acceleration of the muscle movement (acceleromyography) or by visually observing muscle contractions consequent to electrical stimulation. The ToFscan has a three-dimensional acceleration sensor (accelerometer) to detect and quantify a patient's thumb movement (contracting adductor pollicis). The sensor is directly integrated into the finger's splint, making it possible to obtain its optimal and reproducible positioning.

Device Description	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.	The TetraGraph Neuromuscular Transmission (NMT) Monitor (TetraGraph) is a portable, battery-operated EMG-based neuromuscular transmission monitor for use perioperative and in recovery and critical care environments following or during the application of Neuromuscular block. Neuromuscular Transmission (NMT) is the transfer of an electrical impulse between a motor nerve and its associated muscle. The NMT is blocked by neuromuscular blocking agents ("NMBAs") which cause transient muscle paralysis preventing the patient from moving and breathing spontaneously. Muscle relaxation is used during general anesthesia to enable endotracheal intubation and mechanical ventilation and to provide optimal surgical conditions. Muscle relaxation may also be used in critical care during mechanical ventilation. In these circumstances, TetraGraph can be used as an objective monitor of neuromuscular transmission. TetraGraph undertakes this function by electrical stimulation of the peripheral nerve and directly measuring the evoked response of the muscles (Muscle Action Potential (MAP)), thus providing a quantitative and automatic measurement of muscle response to a stimulus using electromyography (EMG). The TetraGraph is a prescription-only medical device and is indicated for use in hospitals. TetraGraph supplements the use of clinical information/data obtained from other monitors, such as peripheral oxygen	The effect of neuromuscular blocking agents (NMBAs) is monitored by measuring the acceleration of the muscle movement (acceleromyography) or by visually observing muscle contractions consequent to electrical stimulation. The ToFscan has a three-dimensional acceleration sensor (accelerometer) to detect and qualify a patient's thumb movement (contracting adductor pollicis). The sensor is directly integrated into the finger's splint, making it possible to obtain it's optimal and reproducible positioning.

		saturation (SpO2), end-tidal carbon dioxide (ETCO2), as well as clinical assessment, to determine the adequacy of ventilation. The level of neuromuscular block is routinely measured by stimulating a peripheral nerve, usually in the forearm and by evaluating the muscle response typically in the thumb or little finger. The TetraGraph controls the level of electrical stimulation applied to the nerve and monitors the muscle response by the use of Electromyography (EMG) detected by electrodes on the muscle. TetraGraph consists of the following main components TetraGraph Monitor The TetraGraph Monitor is used to control the electrical stimulation and to measure the EMG- response. The Monitor is controlled via a touch screen and a power button. The Senzime AB Traditional 510(k) Premarket Submission TetraGraph Page 005-3TetraGraph Monitor is connected to the electrode via a cable (the TetraCord Cable). The battery in the TetraGraph Monitor is charged via a communication port connected to a USB- supply adapter. TetraSens Electrode The TetraSens Electrode is a single-use electrode array. Each array includes two stimulating electrodes (applied along the ulnar nerve at the wrist) and two recording electrodes (applied on the hand). The TetraGraph Monitor can transmit stimulation pulses to the patient and can receive EMG signals via the electrode array. The electrodes are neither supplied sterile nor intended to be sterilized by	

		the user. The TetraSens Electrodes are sold separately from the TetraGraph monitor and are available in boxes of 20 pcs. TetraCord Cable The TetraCord Cable is connected to the TetraGraph Monitor via a port and is connected to the TetraSens Electrode via the cable connector at the other end of the TetraCord Cable. The TetraCord Cable is supplied in together with the TetraGraph monitor as part of the kit and can also be sold separately as a spare part. TetraGraph Pole Clamp kit A Pole clamp kit is available for mounting the TetraGraph on a pole stand. The kit includes a mounting device and an attachment to the Tetragraph. The Pole clamp kit is supplied separately from the Tetragraph kit. Rechargeable lithium-polymer battery A re-chargeable lithium-polymer battery is included in the TetraGraph, and also available as spare part. The rechargeable battery is charged using the USB power supply adapter. USB power supply adapter and USB cable The rechargeable battery is charged using the USB power supply adapter. The adapter is configured for local power outlets and connects to the TetraGraph using a USB cable. Data can also be transferred to a PC via the USB-port by using the USB-cable.	
Muscle movement detection technology	Electromyography (EMG)	Electromyography (EMG)	Acceleromyography
Electrode Connection	Reusable Cable	Reusable Cable	Reusable Cable
Electrode for Stimulation	Single-use electrode array (5 electrodes on an	Single-use electrode array (4 electrodes on an array)	Uses 3D Accelerometer Sensor to measure thumb movement instead of

	array)		electrode
Electrode applied part	Total of 5: Two stimulating electrodes are applied along the ulnar nerve at the wrist and two recording electrodes are applied on the hand. One grounding electrode applied on the hand	Total of 4: Two stimulating electrodes are applied along the ulnar nerve at the wrist and two recording electrodes are applied on the hand.	Not Applicable (Uses D Accelerometer Sensor to measure thumb movement instead of the electrode)
Stimulation Patterns	Single stimulation, TOF (Train Of Four), PTC (Post Tetanic Count), TET (tetanic stimulation), DBS (Double Burst Stimulation)	Single Twitch (ST), Train- of-Four (TOF), Post- tetanic Count (PTC)	TOF (Train Of Four) - PTC (Post Tetanic Count) - ATP (Automated TOF PTC) - DBS (Double Burst) (3,3) (3,2) - ST (Single Twitch) 0.1 Hz and 1 Hz - TET (Tetanus) 50 Hz
Stimulating Current Range	10-60 mA	10-60 mA	0-60 mA
Stimulation Pulse Width	Square wave, constant current: 200µs or 300µs	Square wave, constant current: 200µs or 300µs	Constant current, 0-60 mA, monophasic 200µsec pulse width
Power source	Power is supplied from the Monitoring System.	Battery operated	AC Power Supply
Compatibility	Works only with Nihon Kohden Monitoring System: BSM-6000, BSM-3000 CSM-1901	Tetragraph Neuromuscular Transmission Monitor consists of a monitor, electrode, and other components.	The ToFscan system is composed of the monitor, the hand sensor, and the US AC power supply unit.
General Safety	IEC 60601-1, IEC-60601-1-2, IEC 60601-2-40	IEC 60601-1, IEC-60601-1-2, IEC 60601-2-40	IEC 60601-1, IEC 60601-1-2, IEC 60601-2-10
Intended Use	There are differences in the indications for use statement, but the differences do not result in new intended use.		
Technological Characteristics	Both Smart Cable NMT Module and Accessories and the predicate device, Tetragraph Neuromuscular Transmission Monitor, measure muscle response based on electromyography (EMG) technology and have reusable cables for the electrode connection. The electrode used for the stimulation are single use. There are minor technological differences in number of electrodes and stimulation settings. Both devices utilize two stimulating electrodes which are applied along the ulnar nerve at the wrist and two recording electrodes are applied on the hand. One grounding electrode applied on the hand. The Smart Cable NMT Module and Accessories incorporates the stimulation patterns of both the predicate and the reference device.		

Safety & Performance Tests	The Smart Cable NMT Module and Accessories have been subjected to design verification and validation testing for electrical safety, electromagnetic compatibility, software V&V, operational performance, and operational and storage environmental performance. These tests verified and validated the proper operation of the system. Conformance to 21 CFR Part 898 Performance Standard for Electrode Lead Wires and Patient Cables was met with compliance to IEC 60601-1 3rd edition clause 8.5.2.3. Patient contacting accessories have demonstrated acceptable biocompatibility and where applicable, shelf life. Performance testing has been made for the TetraGraph which supports substantial equivalence between the TetraGraph and the predicate device. The performance testing for the Smart Cable NMT Module and Accessories are summarized below: • Software performance testing • Electrical safety (in accordance with IEC 60601-1) • Electromagnetic compatibility (in accordance with IEC 60601-1-2 and IEC 60601-2-40) • Biocompatibility testing (in accordance with ISO10993-1) • Mechanical strength • Environmental testing • Usability testing • Shelf life testing • Performance testing of electrodes; including tensile testing as well as electrical performance (as specified in the ANSI/AAMI EC12:2000 standard) The performance testing shows that Smart Cable NMT Module and Accessories has met all the acceptance criteria and are equivalent or similar to the predicate device's specifications. Thus, the test data demonstrates that Smart Cable NMT Module and Accessories is as safe and as effective in monitoring the relaxation of the patient when neuromuscular blockade is administered as the predicate. No clinical tests have been submitted, referenced or relied on in the premarket notification submission for a determination of substantial equivalence. The device and the components are not MR compatible.
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 device, the TetraGraph Neuromuscular Transmission Monitor.

5.2 Life Scope BSM-3000 Series Bedside Monitoring System

Subject Device	Trade Name:	**Life Scope BSM-3000 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
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
	510(K):	K080342
Device Description	The Life Scope BSM-3000 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, Cardiac Output (CO), oxygen concentration (O2), 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, EEG monitoring device, tcPO2 monitors, rSO2 monitors and external devices with output analog voltage signal 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 radio frequency.	

Indications for Use and Intended Use	The Life Scope BSM-3000 Series Bedside Monitor 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 audible and/or visible 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 (O2), 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.
Technological Characteristics	The BSM-3000 Bedside Monitoring System was a letter to file to the BSM-6000 Bedside Monitoring Systems. The dimensions and weight of the monitoring systems are different, but the performance, technological features are the same. The difference between the systems are that the BSM-3000 has an integrated input system, and BSM-6000 has a interchangeable input unit. Each of the monitoring systems measure the same parameters and interface with the same accessories. There have been no significant hardware changes. The indications for use statement/intended use statement have been updated to include the interface with other external devices. There have been software updates to the system to integrate the Smart Cable NMT Module and accessories. The performance of the device is listed in Section 5.5 of this document.
Safety & Performance Tests	The Life Scope BSM-3000 Series Bedside Monitoring System 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-3000 Series Bedside Monitoring System is equivalent to the Life Scope BSM- 6000 Series Bedside Monitoring System, the only difference is that the indications for Use have been updated to include the interface with other external devices.

5.3 Life Scope BSM-6000 Series Bedside Monitoring System

Subject 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
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
	510(K):	K080342

Device Description	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, 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.
Indications for Use and Intended Use	The Life Scope BSM-6000 Series Bedside Monitor 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 audible and/or visible 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.

Technological Characteristics	The indications for use/intended use statement have been updated to include the interface with other external devices. There are no hardware changes compared to the predicate devices. There have been software updates to the system to integrate the Smart Cable NMT Module and accessories.
Safety & Performance Tests	The Life Scope BSM-6000 Series Bedside Monitoring System 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 is equivalent to the Life Scope BSM-6000 Series. The indications for Use have been updated to include the interface with other external devices. The BSM-6000 and the BSM-6000 Bedside Monitoring System can measure oxygen concentration, the BSM-6000 when connected to an external device, can also measure fractionated oxygen.

5.4 CSM 1901 Bedside Monitoring System

Subject Device	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):	K151080
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):	K151080
Device Description	The Nihon Kohden CSM-1901Series is a device 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. This bedside monitor is placed near the patient and is intended to display patient's vital signs. This device can also be connected	

	to other external patient monitoring devices. In addition, this device can communicate patient's data to a central monitoring station via network to monitor multiple patients.
Indications for Use and Intended Use	The Nihon Kohden CSM-1901 Bedside Monitor 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 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.
Technological Characteristics	There are no hardware changes to the predicate devices. Both the predicate and the subject device measure the same functions. Both devices can measure Oxygen concentration but when connected to an external adapter (JO-900P) can measure FiO2. The JO-900P is not been validated on the BSM-3000. There have been software updates to the system to integrate the Smart Cable NMT Module and accessories.
Safety & Performance Tests	The Nihon Kohden CSM-1901 Bedside Monitoring System 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 Nihon Kohden CSM-1901 Series is equivalent to the Nihon Kohden CSM-1901 Series. There have been no changes on the indications for use. The software was updated to incorporate the Smart Cable NMT Module and Accessories.

5.5 Bedside Monitoring Systems Technological Specifications

The compatible bedside Monitoring systems features were unchanged as a result of the incorporation of the Smart Cable NMT Module and Accessories. See table below for the product features and technological specifications.

	Life Scope BSM-6000 Series Bedside Monitoring System	Life Scope BSM-3000 Series Bedside Monitoring System	Nihon Kohden CSM - 1901 Bedside Monitoring System
Device Description	The Life Scope 6000 Series Bedside Monitoring 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, Cardiac Output (CO), oxygen concentration (FiO2), CO2 and EtCO2, respiratory rate, BIS and inspired and expired anesthetic agents and gases including CO2, O2, N20, 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/SvO 2 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 radio frequency	The Life Scope BSM-3000 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, Cardiac Output (CO), oxygen concentration (O2), 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, EEG monitoring device, tcPO2 monitors, rSO2 monitors and external devices with output analog voltage signal and continuous NIBP Monitors. The device may generate an audible and/or visual alarm when a measured rate falls outside preset limits. This	The Nihon Kohden CSM-1901 is a device 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. This bedside monitor is placed near the patient and is intended to display patient's vital signs. This device can also be connected to other external patient monitoring devices. In addition, this device can communicate patient's data to a central monitoring station via network to monitor multiple patients.

	Life Scope BSM-6000 Series Bedside Monitoring System	Life Scope BSM-3000 Series Bedside Monitoring System	Nihon Kohden CSM - 1901 Bedside Monitoring System
		device may also be used to condition and transmit physiological signals via radio frequency.	
Intended Use	The Life Scope BSM-6000 Series Bedside Monitor 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 audible and/or visible 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	The Life Scope BSM-3000 Series Bedside Monitor 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 audible and/or visible 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 (O2), 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,	The Nihon Kohden CSM-1901 Bedside Monitor 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 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

	Life Scope BSM-6000 Series Bedside Monitoring System	Life Scope BSM-3000 Series Bedside Monitoring System	Nihon Kohden CSM - 1901 Bedside Monitoring System
	analog voltage signal. The device will be available for use by medical personnel on patients within a medical facility on all patient populations.	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.	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.
Display			
Type	TFT Color LCD, 10.4" (BSM-6301A) TFT Color LCD, 12.1" (BSM-6501A) TFT Color LCD, 15.0" (BSM-6701A)	TFT Color LCD, 12.1" (BSM-35xx) TFT Color LCD, 15.0" (BSM-37xx)	TFT Color LCD, 19.0"
Resolution	800 x 600 (BSM-6301A/BSM-6501A) 1024 x 768 (BSM-6701A)	800 x 600 (BSM-35xx) 1024 x 768 (BSM-37xx)	1680 x 1024, 1280 x 1024
Number Of Traces	15	15	17
Trace Movement	Moving or fixed	Same	Same
Waveform Display	ECG (12 leads), respiration, SpO2, CO2, Cardiac output, external input, O2, N2O, anesthesia agents, EEG(BISx), IBP (7)	ECG (12 leads), respiration, SpO2, CO2, Cardiac output, external input, O2, N2O, anesthesia agents, EEG(BISx), IBP (2) (BSM-35xx) IBP (3) (BSM-37xx)	ECG, respiration curve, IBP waveform, SpO2 pulse waveform, CO2 partial pressure curve, EEG waveform, respiratory flow curve, airway pressure curve, respiratory volume curve, EEG waveform (BIS), O2 concentration curve, CO2 concentration curve, anesthetic agent concentration curve.
Numeric Data Display	Heart Rate, Pulse Rate, VPC rate, ST level (12 leads), Respiration Rate, NIBP (sys/dia/mean), Temperature (4), SpO2, EtCO2, FiO2, Cardiac output, O2, N2O,	Heart Rate, Pulse Rate, VPC rate, ST level (12 leads), Respiration Rate, NIBP (sys/dia/mean), Temperature (2), SpO2,	Heart rate, VPC rate (per minute), ST level, respiration rate, NIBP (Sys, Dia, MAP), IBP (Sys, Dia, Mean),

	Life Scope BSM-6000 Series Bedside Monitoring System	Life Scope BSM-3000 Series Bedside Monitoring System	Nihon Kohden CSM - 1901 Bedside Monitoring System
	Anesthesia agents, BIS, IBP (7) (sys/dia/mean)	EtCO2, Cardiac output, O2, N2O, Anesthesia agents, BIS, IBP (2) (sys/dia/mean) (BSM-35xx) IBP (3) (sys/dia/mean) (BSM-37xx)	SpO2, pulse rate, temperature, cardiac output (CO), cardiac index (CI),injectate temperature (Ti), blood temperature (Tb), O2 concentration (O2), end tidal CO2 partial pressure (ETCO2), BIS, inspired/expired N2O concentration, inspired/expired CO2 partial pressure, inspired/expired CO2 concentration,inspired/expired O2 concentration, inspired/expired anesthetic agent concentration (Halothane, Enflurane, Isoflurane, Sevoflurane, Desflurane), minimum alveolar concentration (MAC), peak airway pressure (Ppeak), positive end expiratory pressure (PEEP), mean airway pressure (Pmean), minute volume (MV), inspiratory tidal volume (TVi), expiratory tidal volume (TVe), compliance (C), airway resistance (R), inspiratory airway resistance (Ri), expiratory airway resistance (Re), inspiration expiration ratio (I:E), 90 or 95% spectral edge frequency (SEF), median frequency (MDF), peak power frequency (PPF), total power (TP), power of frequency (Abs δ, Abs θ, Abs α, Abs β, Abs γ), power ratio of frequency (% δ,
Alarm Display	Alarm sound, highlighted alarm display, alarm lamp	Same	Same

	Life Scope BSM-6000 Series Bedside Monitoring System	Life Scope BSM-3000 Series Bedside Monitoring System	Nihon Kohden CSM - 1901 Bedside Monitoring System
Alarm Suspend/ Silence Function	Yes	Same	Same
ECG			
Number Of ECG Electrodes	3, 6 or 10	Same	Same
Defibrillation Discharge Protection	Yes	Same	Same
Electrosurgery Interface filter	Yes	Same	Same
Pacing detection	Yes	Same	Same
Heart Rate Counting Method	Average, instantaneous (beat to beat)	Same	Same
Heart Rate Counting Range	0, 15 to 300 bpm	Same	Same
Counting Accuracy	±2 bpm	Same	Same
Alarm Limits: Upper Lower	16 to 300 bpm, OFF 15 to 299 bpm, OFF	Same	Same
ST Level Measuring Range	-2.5 to +2.5 mV	Same	Same
QRS Sync Tone	Yes	Same	Same
Arrhythmia Detection			
Detection Method	Multi-template software algorithm Multi-lead analysis	Same	Same
VPC Counting Range	0 to 99 per min	Same	Same
Arrhythmia Alarm	Yes	Same	Same
Arrhythmia Recall	Yes	Yes	Yes
Number Of Arrhythmia Recall Files	Up to 72 hours	Up to 72 hours	168 hours

	Life Scope BSM-6000 Series Bedside Monitoring System	Life Scope BSM-3000 Series Bedside Monitoring System	Nihon Kohden CSM - 1901 Bedside Monitoring System
Number of arrhythmia type	23	23	25
Arrhythmia Graphic Trend	Yes	Same	Same
Respiration			
Method	Impedance, thermistor, CO2	Impedance, CO2	Impedance, thermistor, CO2
Respiration Rate Display	0 to 150 bpm	Same	Same
Alarm Limits: Upper Lower	2 to 150 bpm, OFF 0 to 148 bpm, OFF	Same	Same
No breath time Limit	5 to 40 seconds, OFF	Same	Same
Waveform Display	Yes	Same	Same
Connector Insertion Detection	Yes	Same	Same
Apnea Detection	Yes	Same	Same
SpO2			
Probe Type	Nihon Kohden, Nellcor (NL) or Masimo (MS)	Same	Same
Displayed Range, NK type	0 to 100%	Same	Same
Displayed Range, NL type	1 to 100%	Same	Same
Displayed Range, MS type	1 to 100%	Same	Same
Declared Range, NK type and Accuracy with sensor	70 to 100% (with sensor) 80 to 100% ± 2 %SpO2 70 to 80% ± 3 %SpO2	Same	Same
Declared Range, NL type and Accuracy with	70 to 100% 70 to 100% ± 2 digits(adult)	Same	Same

	Life Scope BSM-6000 Series Bedside Monitoring System	Life Scope BSM-3000 Series Bedside Monitoring System	Nihon Kohden CSM - 1901 Bedside Monitoring System
sensor	70 to 100% ± 3 digits (neonatal)		
Declared Range, MS type and Accuracy with sensor	no motion condition 70 to 100% ± 2 digits(adult) 70 to 100% ± 3 digits(neonatal) motion condition 70 to 100% ± 3 digits(adult) 70 to 100% ± 3 digits(neonatal)	Same	Same
Pulse Sync Tone	Yes	Same	Same
Audible Indication to SpO2 Variation	Yes	Same	Same
SpO2 Alarm Limits: Upper Lower	51 - 100%, OFF 50 - 99%, OFF	Same	Same
Pulse Rate Count Range:	0, 30-300 bpm (NK) 0, 20-300 bpm (NL) 0, 25-240 bpm (MS)	Same	Same
Non-Invasive Blood Pressure (NIBP)			
Measuring Method	Oscillometeric	Same	Same
Pressure Data Display	Systolic, Diastolic, Mean, Cuff pressure	Same	Systolic, Diastolic, Mean, Cuff pressure, Pulse Rate
Measuring Range ,Adult/ Pediatric	0 - 300 mmHg	Same	Same
Measuring Range, Neonates	0 - 150 mmHg	Same	Same
Measuring Accuracy	± 3 mmHg ≤ 200mmHg ± 4 mmHg >200mmHg	Same	Same
Invasive Pressure (IBP)			
Measuring Method	Pressure transducer	Same	Same
Number Of Channels	Up to 7	Up to 2 (BSM-35xx) Up to 3 (BSM-37xx)	8

	Life Scope BSM-6000 Series Bedside Monitoring System	Life Scope BSM-3000 Series Bedside Monitoring System	Nihon Kohden CSM - 1901 Bedside Monitoring System
Measuring Range	-50 to 300 mmHg	Same	Same
Measuring Accuracy	±1mmHg, ±1digit (-50 to100 mmHg) ± 1%, ±1 digit (100 to 300 mmHg)	Same	Same
Connector Insertion Detection	Yes	Same	Same
Alarm Limits: Upper Lower	-48 - 300 mmHg, OFF -50 - 298 mmHg, OFF	Same	Same
Pulse Svnc Tone	Yes	Same	Same
Pulse Rate Count Range:	0, 30 - 300 bpm	Same	Same
Temperature			
Number of channels	Up to 4	Up to 2	Up to 8
Measuring Range	0 to 45°C	Same	Same
Display Units	°C or °F	Same	Same
Accuracy	± 0.1 °C (25 to 45°C) ± 0.2 °C (0 to 25°C)	Same	Same
Connector Insertion Detection	Yes	Same	Same
Numeric Display	Yes	Same	Same
Alarm Limits: Upper Lower	0.1 to 45°C, 0.2 OFF 0 to 44.9°C, OFF	Same	Same
Carbon Dioxide (CO2)			
Measuring Method	Main Stream	Same	Main Stream, Side Stream (when GF-210RA connected)
Response Time	Depends on CO2 unit 160msec (TG-900P)	Same	Same

	Life Scope BSM-6000 Series Bedside Monitoring System	Life Scope BSM-3000 Series Bedside Monitoring System	Nihon Kohden CSM - 1901 Bedside Monitoring System
	120msec (TG-920P/970P) < 60msec (TG-980P)		
Measuring Range, CO2	Depends on CO2 unit 0 to 100mmHg (TG-900P/920P) 0 to 150mmHg (TG-970P/980P)	Same	Same
Displayed Values	EtCO2, CO2, Resp. rate	Same	EtCO2, CO2, Resp. rate Inspired CO2
Measuring Range, Respiration	Depends on CO2 unit 3 to 150 counts/min (TG-900P/920P) 0 to 150 counts/min (TG-970P/980P)	Same	Same
Accuracy	Depends on CO2 unit <TG-900P/920P> +/- 3 mmHg (0-10mmHg), +/- 4 mmHg (10-40mmHg), +/- 10% reading (40-100mmHg) <TG-970P/980P> +/- 2 mmHg (0-40mmHg), +/- 5% reading (40-70mmHg), +/- 7% reading (70-100mmHg), +/- 10% reading (100-150mmHg)	Same	Same
Alarm Limits, CO2: Upper Lower	2 to 99mmHg, OFF 1 to 98 mmHg, OFF	Same	Same
Apnea Alarm Limits	5 to 40 seconds, OFF	Same	Same
Anesthetic FiO2			
Measuring range	10 to 100% O2	Not Available	10 to 100% O2
Accuracy	+ 3% Full Scale	Not Available	+ 3% Full Scale
Alarm Limits: Upper Lower	19 to 100%, 18 to 99%	Not Available	19 to 100%, 18 to 99%
Cardiac Output (CO)			

	Life Scope BSM-6000 Series Bedside Monitoring System	Life Scope BSM-3000 Series Bedside Monitoring System	Nihon Kohden CSM - 1901 Bedside Monitoring System
Measuring Method	Thermodilution	Same	Same
Measuring Range: Cardiac Output Injection Temp. Blood Temp.	0.5 to 20 L/min 0 to 27 °C 15 to 45 °C	Same	Same
Accuracy: Cardiac Output Injection Temp. Blood Temp.	±5% ± 0.2 deg C ± 0.2% (15 to 45 deg C) ± 0.1% (25 to 45 deg C)	Same	Same
Cather Coefficient	Auto or Manual	Same	Same
Injection Temperature Measurement Method	Temperature probe or inline sensor	Same	Same
Alarm Limits, Blood Temp: Upper Lower	15.1 to 45.0 deg C, 15.0 to 44.9 deg C,	Same	Same
External Communication			
Central Station Communications	Yes (Standard)	Same	Same
Communication Method	Ethernet	Same	Same
ECG Output	Yes	Same	Same
IBP Output	Yes	Same	Same
Connector for Transmitter	Yes	Same	Same
External Display Connector	Yes (Option)	Same	Same
Serial Data Interface	Yes (Option)	Same	Same
User Interface			

	Life Scope BSM-6000 Series Bedside Monitoring System	Life Scope BSM-3000 Series Bedside Monitoring System	Nihon Kohden CSM - 1901 Bedside Monitoring System
Touchscreen	Yes	Same	Same
Alarm Indicator Lamp	Yes	Same	Same
Dedicated Function Keys	Yes	Same	Same
Memory			
Full Disclosure Storage	24hours, 5waves, Standard 72hours, 5waves (Option)	Same	168 hours
Trend Display Time	1, 2, 4, 8, 24, (72) hours (Option)	1, 2, 4, 8, 24, (72) hours (Option)	15 min, 30 min, 1, 2, 4, 6, 8, 12, 24, 48 , 72, 96, 120, 144, 168 hours
Vital Sign List Interval	1, 5, 15, 30 ,60 minute NIBP list (Triggered by NIBP measurement)	Same	1, 5, 10, 15, 30, 60 minute
List Capacity	24hours (Standard) 72hours (Option)	24hours (Standard) 72hours (Option)	168 hours
Recorder (Option)			
Type	Thermal Array	Same	Same
Number of channels	3	Same	Same
Waveforms Recorded	ECG, pulse (SpO2), respiration, IBP	ECG, pulse (SpO2), respiration, IBP	ECG, pulse (SpO2), respiration, IBP, CO2, EEG, Gas, waveform from external device
Annotation printing	Patient Name, bed ID, date, recording type, sensitivity, paper speed, parameter data, ECG lead, arrhythmia classification, QRS classification	Same	Same
Recorder Speed	25 mm/sec, 50 mm/sec	25 mm/sec, 50 mm/sec	12.5 mm/sec, 25 mm/sec, 50 mm/sec
Battery Operation			

	Life Scope BSM-6000 Series Bedside Monitoring System	Life Scope BSM-3000 Series Bedside Monitoring System	Nihon Kohden CSM - 1901 Bedside Monitoring System
Type	Ni-MH (Option)	Same	Same (Option)
Number of batteries	2	1	1
Operation Time	90minutes/battery (BSM-6501A/6301A) 60minutes/battery (BSM-6701A)	90minutes/battery (BSM-35xx) 60 minutes/battery (BSM-37xx)	The battery is for power interruption.
Charge time	12 hours max/battery (monitor on) 6 hours max/2batteries (monitor off)	10 hours Typical (monitor on) 2 hours Typical (monitor off)	The battery is for power interruption.
Transmitter			
Transmitted waveforms	ECG, Respiration or CO2, Pulse (SpO2) or IBP (2) or IBP (3)	Same	Not available
Transmitted numerics	SpO2, NIBP (sys/dia/mean), CO2	Same	Not available
12 Lead ECG Acquisition and Analysis			
Acquisition and Processing	Simultaneous Acquisition and Processing for 12 Lead Development with Calculations and Resting ECG Analyses	Same	Same
ECG Interpretation Program	ECAPS12C	Same	Same
12 lead ST Analysis	Yes	Same	Same
Patient Age: 12 Lead Acquisition 12 Lead Interpretation	ALL ages 3 Years and older	Same	Same
Power Requirements			
Line Voltage	100 to 240V	Same	same
Power Consumption	140VA(BSM-6301A) 90 VA (BSM-6501A) 100VA (BSM-6701A)	100VA	220VA

	Life Scope BSM-6000 Series Bedside Monitoring System	Life Scope BSM-3000 Series Bedside Monitoring System	Nihon Kohden CSM - 1901 Bedside Monitoring System
Environmental Conditions			
Operating Temperature	10 to 40 deg C	10 to 40 deg C	5 to 40 deg C
Operating Relative Humidity	30 to 85% RH	Same	Same
Operating Atmospheric Pressure	68 to 106 kPa	68 to 106 kPa	700 to 1060 hPa
Dimension and Weight			
Dimensions, mm (W,H,D)	316 x 325 x 188 (BSM-6301A) 342 x 353 x 183 (BSM-6501A) 415 x 392 x 191 (BSM-6701A)	370 x 310 x 172 (BSM-35xx) 430 x 350 x 172 (BSM-37xx)	141 W × 322 H × 365 D mm (CU-191R, CU-192R core unit)
Weight, kg (without options)	6.6 (BSM-6301A) 8.3 (BSM-6501A) 10.3 (BSM-6701A)	6.2 (BSM-35xx) 7.4 (BSM-37xx)	12.5 kg (CU-191R, CU-192R core unit)
General Safety	IEC60601-1-2:2014	IEC60601-1-2:2014	IEC 60601-1-2:2007
Technological Characteristics	There are no technological changes to the predicate devices. Both the predicate and the subject device measure the same functions. Both devices can measure Oxygen concentration but when connected to an external adapter (JO-900P) can measure FiO2. The JO-900P is not been validated on the BSM-3000.	The BSM-3000 Bedside Monitoring System was a letter to file to the BSM-6000 Bedside Monitoring Systems. The dimensions and weight of the monitoring systems are different, but the performance, technological features are the same. Each of the monitoring systems measure the same parameters and interface with the same accessories. The indications for use statement/intended use statement have been updated to include the interface with other external devices. There have been software updates to the system	There are no technological changes to the predicate devices. Both the predicate and the subject device measure the same functions. Both devices can measure Oxygen concentration but when connected to an external adapter (JO-900P) can measure FiO2. There have been software updates to the system to integrate the Smart Cable NMT Module and Accessories.

	Life Scope BSM-6000 Series Bedside Monitoring System	Life Scope BSM-3000 Series Bedside Monitoring System	Nihon Kohden CSM - 1901 Bedside Monitoring System
		to integrate the Smart Cable NMT Module and Accessories.	
Safety & Performance Tests	The Life Scope BSM-6000 Series Bedside Monitoring System was subjected to tests to electromagnetic, environmental, safety, and performance testing procedures. These tests verified the operation of the device. The software validation tested the operation of the software function of the device. The results confirmed that the device performed within specifications	The Life Scope BSM-3000 Series Bedside Monitoring Systems was subjected to tests to electromagnetic, environmental, safety and performance testing procedures. These tests verified the operation of the device. The software validation tested the operation of the software function of the device. The results confirmed that the device performed within specifications. No clinical tests have been submitter, referenced or relied on in the premarket notification submission for a determination of substantial equivalence.	The Nihon Kohden CSM-1901 Bedside Monitor was subjected to tests to electromagnetic, environmental, safety, and performance testing procedures. These tests verified the operation of the device. The software validation tested the operation of the software function of the device. The results confirmed that the device performed within specifications.
Summary of Substantial Equivalence	The Life Scope BSM-6000 Series is equivalent to the Life Scope BSM- 6000 Series. The indications for Use have been updated to include the interface with other external devices. The BSM-6000 and the BSM-6000 Bedside Monitoring System can measure oxygen concentration, the BSM-6000 when connected to an external device, can also measure fractionated oxygen.	The Life Scope BSM-3000 Series Bedside Monitoring System is equivalent to the Life Scope BSM- 6000 Series Bedside Monitoring System, the only difference is that the indications for Use have been updated to include the interface with other external devices.	The Nihon Kohden CSM-1901 Bedside Monitor is equivalent to the Nihon Kohden CSM-1901 Bedside Monitor. There have been no changes on the indications for use. The software was updated to incorporate the Smart Cable NMT Module and Accessories.