July 21, 2022

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

Re: K220976
Trade/Device Name: Life Scope PT BSM-1700 Series Bedside Monitor
Regulation Number: 21 CFR 868.2775
Regulation Name: Electrical Peripheral Nerve Stimulator
Regulatory Class: Class II
Product Code: KOI
Dated: June 14, 2022
Received: June 16, 2022

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,

for Todd Courtney
Assistant Director
DHT1C: Division of Sleep Disordered Breathing,
Respiratory and Anesthsia 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)*
K220976

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

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 Beside Monitor and Accessories are intended acquire and transfer electrical impulses from the patient to the main unit of the device. The BSM-1700 Series has both an input and transport/standalone mode. 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 or when disconnected from the core unit of the device. The input unit can be removed from one core unit and connected to another device's 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. In standalone mode, the device does not require a core unit. The BSM-1700 Series 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). When the BSM-1700 Series is used in transport or standalone mode, the following can be analyzed and displayed: 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), 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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NIHON KOHDEN

510(k) Summary

1 GENERAL PROVISIONS

ADMINISTRATIVE INFORMATION	
Sponsor	Nihon Kohden Corporation 1-31-4 Nishiochiai, Shinjuku-Ku Tokyo, Japan 161-8560
Initial Importer	Nihon Kohden America 15353 Barranca Parkway Irvine, CA
Primary Contact/Official Correspondent	Sunita Teekasingh RN, BSN, CCRN, MSc GSA2 Group LLC Mobile: 612-814-7999 Email: Sunita_Teekasingh@nihonkohden.com
Secondary Contact/Company Representative	Sandra Gadeyne, MBA, ASQ-CQA Sr. Director, Quality Assurance and Regulatory Affairs 15353 Barranca Parkway Irvine, CA Office Phone: 949-268-7708 Mobile Phone: 949-356-3401 Email: Sandra_Gadeyne@nihonkohden.com
SUBMISSION INFORMATION	
Submission Type	Special 510(k)
Product Names	Life Scope® PT BSM-1700 Series Bedside Monitor and Accessories Life Scope® BSM-6000 Series Bedside Monitoring Systems Life Scope® G5 Series Bedside Monitoring Systems Life Scope® G7 Series Bedside Monitoring Systems Life Scope® CSM-1901 Bedside Monitoring Systems AY Series and Accessories, Data Acquisition Unit Smart Cable™ NMT Module and Accessories
Common Names	Bedside Monitor, Patient Monitor, Cardiac Monitor, Vital Signs Monitor Stimulator, Nerve, Peripheral, Electric
Classification	Class II
Predicate 510(k) **Product Code**	K213316 KOI
Primary Product Code **KOI Products**	KOI: **Smart Cable™ NMT Module and Accessories**
Secondary Product Code **MHX Products**	MHX: **Life Scope® BSM-6000 Series Bedside Monitoring Systems** **Life Scope® G5 Series Bedside Monitoring Systems** **Life Scope® G7 Series Bedside Monitoring Systems** **Life Scope® CSM-1901 Bedside Monitoring Systems** **AY Series and Accessories, Data Acquisition Unit** **Life Scope® PT BSM-1700 Series and Accessories**
Submission Basis	Labeling Modification to Nihon Kohden's legally authorized device: Life Scope® PT BSM-1700 Series Bedside Monitor
Submission Date	1 June 2022

2 KOI: SMART CABLE NMT MODULE AND ACCESSORIES

The Smart Cable NMT Module and Accessories were previously cleared under K213316. This system requires a compatible monitoring system for the NMT Module to work. There has been no modification to the Smart Cable NMT Module's intended Use, safety or performance to as a result of the inclusion of standalone for the BSM-1700 Series labeling update.

2.1 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.

2.2 Indications for Use/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.

2.3 Equivalent device

There have been no modifications the Smart Cable NMT Module and Accessories in this submission and this device is the equivalent to the device presented under K213316.

2.4 Performance Results

The device performance and software have not changed from the original submission K213316.

2.5 Summary

Based on the intended use, product, performance and software information provided in this notification, the subject device has been shown to be substantially equivalent to the currently marketed predicate devices.

3 MHX:BSM-6000 Series

There are no changes to the Life Scope® BSM-6000 from K213316.

3.1 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, BIS, Cardiac Output (CO), oxygen concentration (FiO2), carbon dioxide concentration (CO2), EtCO2, respiratory rate and inspired and expired anesthetic agents and anesthetic 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 radio frequency.
The system requires a BSM 6000 core unit with a compatible input unit: AY Series or Life Scope® PT BSM-1700 Series.

Table 1: Compatible Input Unit and Core Units

Compatible Parent Bedside Monitoring Configurations			
Core Unit	**Input Model**	**Multi-Connector**	**Spo2 Probe**
Life Scope® BSM-6000 Series Bedside Monitoring Systems	AY-631P	1	Masimo
	AY-633P	3	
	BSM-1733	3	
	AY-651P	1	Nellcor
	AY-653P	3	
	BSM-1753	3	
	AY-661P	1	Nihon Kohden
	AY-663P	3	
	BSM-1763	3	
	AY-671P	1	
	AY-673P	3	
	BSM-1773	3	
	Data Acquisition Unit	Multi-Connector	SpO2 Probe
	JA 690PA	N/A	N/A
	JA-694PA	4	N/A

3.2 Indications For Use/Intended Use

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.

3.3 Equivalent device

There have been no modifications the Life Scope® BSM-6000 Series in this submission and this device is the equivalent to the device presented under K213316.

3.4 Performance Results

The device performance and software have not changed from the original submission K213316.

3.5 Summary

Based on the intended use, product, performance and software information provided in this notification, the subject device has been shown to be substantially equivalent to the currently marketed predicate devices.

3.6 Summary

Based on the intended use, product, performance and software information provided in this notification, the subject device has been shown to be substantially equivalent to the currently marketed predicate devices.

4 MHX: LIFE SCOPE® CSM-1901 BEDSIDE MONITORING SYSTEMS

There have been no modifications to the Life Scope® CSM-1901 as a result of the addition of the standalone mode on the BSM-1700 Series. The technological, Safety and Performance is the same o the previous submission K213316.

4.1 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.

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.

Table 2:Compatible Input Unit and Core Units

Compatible Parent Bedside Monitoring Configurations			
Core Unit	**Input Model**	**Multi-Connector**	SpO2 Probe
	AY-631P	1	Masimo

Life Scope® CSM-1901 Bedside Monitoring Systems	AY-633P	3	
	BSM-1733	3	
	AY-651P	1	Nellcor
	AY-653P	3	
	BSM-1753	3	
	AY-661P	1	Nihon Kohden
	AY-663P	3	
	BSM-1763	3	
	AY-671P	1	
	AY-673P	3	
	BSM-1773	3	
	Data Acquisition Unit	Multi-Connector	SpO2 Probe
	JA 690PA	N/A	N/A
	JA-694PA	4	N/A

4.2 Indications for Use/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.

4.3 Equivalent device

There have been no modifications the Life Scope® CSM-1901 and Accessories in this submission and this device is the equivalent to the device presented under K213316.

4.4 Performance Results

The device performance and software have not changed from the original submission K213316.

4.5 Summary

Based on the intended use, product, performance and software information provided in this notification, the subject device has been shown to be substantially equivalent to the currently marketed predicate devices.

5 MHX: AY SERIES AND ACCESSORIES

5.1 Device Description

The AY Series Input unit is used with the monitoring systems platforms, when connected to the core unit of the parent device, the input unit collects electrical impulses, and the core units calculates and displays on the core unit's screen.

5.2 Indications for Use/Intended Use

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.

5.3 Equivalent device

There have been no modifications the AY Series and Accessories in this submission and this device is the equivalent to the device presented under K213316.

5.4 Performance Results

The device performance and software have not changed from the original submission K213316.

5.5 Summary

Based on the intended use, product, performance and software information provided in this notification, the subject device has been shown to be substantially equivalent to the currently marketed predicate devices.

6 MHX:BSM-1700 SERIES BEDSIDE MONITOR

For this submission the BSM-1700 Bedside Monitor labeling has been updated to include the standalone mode. There are no specification changes, technological changes or safety and Performance claims. The indications for use and labeling have been updated to include the standalone mode

6.1 Device Description

The BSM-1700 Series Bedside Monitor is a multifunctional device used as an input unit, transport/standalone monitor.

- Input unit for other monitoring systems platforms, when connected to the core unit of the parent device, the input unit collects electrical impulses, and the core units calculates and displays on the core unit's screen.
- When the patient needs to be transported, the BSM-1700 Series can be removed from the core unit, transport mode can be enabled and can be used with or without WLAN. When WLAN is enabled real time data viewing on the Nihon Kohden network or if it is disabled the BSM-1700 Series will display monitoring data and store the review data.
- When the device is removed from the core unit it functions as a standalone or independent monitoring system.

The BSM-1700 Series has a display monitor that is disabled when connect to a core unit. Each monitor has a color display and is intended for one patient. When used as an input unit with the core unit, the system monitors advanced parameters. The intended populations are all patient populations under the care of health professionals.

In all modes, the BSM-1700 Series uses the Smart Cable technology that is used to connect to other accessories used to collect electrical impulses. The BSM-1700 Series interprets the electrical impulses from the patient's body. When connected to a core unit, advanced calculations can be achieved. The device may generate an audible and/or visual alarm when a measured rate falls outside preset limits

When the input unit is connected to a core unit the core unit calculates and displays the electrical impulses.

Table 3 BSM-1700 Series with Compatible Core Units

BSM-1700 Series with Core Units			
Core Units	**Input Model**	**Configuration**	
		Multi-Connector	**SpO_2 Probe**
Life Scope® BSM 6000 Series Bedside Monitoring Systems (K213316) Life Scope® CSM-1901 Series Bedside Monitoring Systems (K213316) Life Scope® G5 Series Bedside Monitoring Systems (K203435) Life Scope® G7 Series Bedside Monitoring Systems (K203435)	BSM-1733	3	Masimo
	BSM-1753	3	Nellcor
	BSM-1763 BSM-1773	3	Nihon Kohden
Data Acquisition Unit Life Scope® CSM-1901 Bedside Monitoring Systems (K213316)	JA 690PA JA-694PA	N/A 4	Unit only used with CSM-1901 and BSM-6000

As an input unit, the device can interface with external accessories to display numerical and waveform data and alarms from the external accessories. The Core unit supports external devices including 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.

When used as an input unit, the device can be removed from the core unit, and transport mode can be enabled. The device in transport mode can be used with or without WLAN. When WLAN is enabled, real time data can be seen on the Nihon Kohden network monitors. When WLAN is disabled, the BSM-1700 Series will display the monitoring data and store the review data. When used in a transport/standalone mode, the device can store the review data while transferring the patient. The review data can be transmitted via a direct network connection when the device is connected to a host monitor. When used in transport/standalone mode, the following can be analyzed and displayed: 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), 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.

Table 4: Predicate Device Comparison

	Subject Device: Life Scope BSM-1700 Series Bedside Monitor Input Unit and Transport/Standalone Mode	**Predicate Device: BSM 1700 Series Bedside Monitoring System K213316-** Input Unit and Transport Mode
Intended Use/ Indications for Use	The Life Scope® PT BSM-1700 Series Beside Monitor and Accessories are intended acquire and transfer electrical impulses from the patient to the main unit of the device. The BSM-1700 Series has both an input and transport/standalone mode. 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 or when disconnected from the core unit of the device. The input unit can be removed from one core unit and connected to another device's 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. *In standalone mode, the device does not require a core unit.* The *BSM-1700 Series* 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). *When the BSM-1700 Series is used in transport or standalone mode, the following can be analyzed and displayed: 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), 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.	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.
System Configuration- When connected to a Core Unit (Input Unit)		

	Subject Device: Life Scope BSM-1700 Series Bedside Monitor Input Unit and Transport/Standalone Mode	**Predicate Device: BSM 1700 Series Bedside Monitoring System K213316-** Input Unit and Transport Mode
Compatible Core Unit Options: requires Input Unit	Life Scope® BSM-6000 Bedside Monitoring Systems; Life Scope® CSM-1901 Bedside Monitoring Systems; Life Scope® G5 Series Bedside Monitoring System, Life Scope® G7 Series Bedside Monitoring System.	Same
BSM-1700 Touchscreen Display	Disabled	Same
Measuring Parameters as a Bedside Monitoring System (Core unit + Input Unit)	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).	Same
Touchscreen Display	Default to Core unit Monitor	Same
Resolution	Default to Core unit Monitor Resolution	Same
System Configuration - Transport mode/Standalone Mode only		
BSM-1700 Touchscreen Display	Enabled	Same
BSM-1700 Resolution	640 x 480	Same
Number Of Traces in transport/standalone	9 12 (when 12 leads ECG is displayed)	Same
Waveform Display	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), and Bispectral Index (BIS).	Same
Functions - Transport mode/Standalone Mode only		
Trace Movement	Fixed	Same
Numeric Data Display	Heart Rate, Pulse Rate, VPC rate, ST level (12 leads), Respiration Rate, NIBP (sys/dia/mean), Temperature (2), SpO2, EtCO2, FiCO2, Cardiac output, BIS, IBP (3) (sys/dia/mean)	Same
Alarm Display	Alarm sound, highlighted alarm display, alarm lamp	Same
Alarm Suspend/ Silence Function	Yes	Same
ECG- All Modes		
Number Of ECG Electrodes	3, 6 or 10	Same
Defibrillation Discharge Protection	Yes	Same

		Subject Device: Life Scope BSM-1700 Series Bedside Monitor Input Unit and Transport/Standalone Mode	**Predicate Device: BSM 1700 Series Bedside Monitoring System K213316-** Input Unit and Transport Mode
Electrosurgery Interface filter		Yes	Same
Pacing detection		Yes	Same
Heart Rate Counting Method		Average, instantaneous (Beat to beat)	Same
Heart Rate Counting Range		0, 15 to 300 bpm	Same
Counting Accuracy		±2 bpm	Same
Alarm Limits: Upper Lower		16 to 300 bpm, OFF 15 to 299 bpm, OFF	Same
ST Level Measuring Range		-2.5 to +2.5 mV	Same
QRS Sync Tone		Yes	Same
Detection Method		Multi-template software algorithm multi-lead analysis	Same
VPC Counting Range		0 to 99 per min	Same
Arrhythmia Alarm		Yes	Same
Arrhythmia Recall		Yes	Same
Number of Arrhythmia Recall files as input unit		Defaults to core unit	Defaults to core unit
Number Of Arrhythmia Recall Files in transport/standalone mode		32768 items,72hours (Standalone Mode) 8192 items ,24hours (Transport Mode)	8192 items ,24hours (Transport Mode)
Respirations- All modes			
Respiration		Yes	Same
Respiration Rate Display		0 to 150 bpm	Same
Alarm Limits: Upper Lower		2 to 150 bpm, OFF 0 to 148 bpm, OFF	Same
No breath time Limit		5 to 40 seconds, OFF	Same
Waveform Display		Yes	Same
Connector Insertion Detection		Yes	Same
Apnea Detection		Yes	Same
SpO2 – All modes			
Probe Type		Nihon Kohden, Nellcor (NL) or Masimo (MS)	Same
N K	Displayed Range,	0 to 100%	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

		Subject Device: Life Scope BSM-1700 Series Bedside Monitor Input Unit and Transport/Standalone Mode	**Predicate Device: BSM 1700 Series Bedside Monitoring System K213316-** Input Unit and Transport Mode
NL	Displayed Range,	1 to 100%	Same
	Declared Range, NL type and Accuracy with sensor	70 to 100% 70 to 100% ± 2 digits(adult) 70 to 100% ± 3 digits (neonatal)	Same
MS	Displayed Range,	1 to 100%	Same
	Declared Range, MS type and Accuracy with sensor	no motion conditions 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
Pulse Rate Count		Yes	Same
Pulse Sync Tone		Yes	Same
Audible Indication to SpO2 Variation		Yes	Same
SpO2 Alarm Limits: Upper Lower		 51 - 100%, OFF 50 - 99%, OFF	Same
Pulse Rate Count Range:		0, 30-300 bpm (NK) 0, 20-300 bpm (NL) 0, 25-240 bpm (MS)	Same
NiBP- All modes			
Measuring Method		Oscillometeric	Same
Pressure Data Display		Systolic, Diastolic, Mean, Cuff pressure	Same
Measuring Range, Adult/ Pediatric		10 - 280 mmHg	Same
Measuring Range, Neonates		10 - 140 mmHg	Same
NIBP Measuring Accuracy		± 3 mmHg	Same
Alarm Limits: Adult/ Pediatric Upper Lower		 15 - 260 mmHg, OFF 10 - 255 mmHg, OFF	Same
Alarm Limits: Neonate Upper Lower		 15 - 140 mmHg, OFF 10 - 135 mmHg, OFF	Same
IBP			
Measuring Method		Pressure transducer	Same
Number Of Channels		Up to 3	Same
Measuring Range		-50 to 300 mmHg	Same
Measuring Accuracy		±1mmHg±1digit (-50 to100 mmHg) ±1%±1 digit (100 to 300 mmHg)	Same
Connector Insertion Detection		Yes	Same

	Subject Device: Life Scope BSM-1700 Series Bedside Monitor Input Unit and Transport/Standalone Mode	**Predicate Device: BSM 1700 Series Bedside Monitoring System K213316-** Input Unit and Transport Mode
Alarm Limits: Upper Lower	 -48 - 300 mmHg, OFF -50 - 298 mmHg, OFF	Same
Pulse Svnc Tone	Yes	Same
Pulse Rate Count Range:	0, 30 - 300 bpm	Same
Temperature -All modes		
Number of channels	Up to 2	Same
Measuring Range	0 to 45°C	Same
Display Units	°C or °F	Same
Accuracy	± 0.1 °C (25 to 45°C) ± 0.2 °C (0 to 25°C)	Same
Connector Insertion Detection	Yes	Same
Numeric Display	Yes	Same
Alarm Limits: Upper Lower	 0.1 to 45°C, OFF 0 to 44.9°C, OFF	Same
Carbon Dioxide-All modes		
Measuring Method	Mainstream	Same
Response Time	Depends on CO2 unit 160msec (TG-900P) 120msec (TG-920P/970P) < 60msec (TG-980P)	Same
Measuring Range, CO2	Depends on CO2 unit 0 to 100mmHg (TG-900P/920P) 0 to 150mmHg (TG-970P/980P)	Same
Displayed Values	EtCO2, CO2, Resp. rate	Same
Measuring Range, Respiration	Depends on CO2 unit 3 to 150 counts/min (TG-900P/920P) 0 to 150 counts/min (TG-970P/980P)	Same
Accuracy	Depends on CO2 unit <TG-900P/920P> ± 3 mmHg (0 to 10mmHg), ± 4 mmHg (10 to 40mmHg), ± 10% reading (40 to 100mmHg) <TG-970P/980P> ± 2 mmHg (0 to 40mmHg), ± 5% reading (40 to 70mmHg), ± 7% reading (70 to 100mmHg), ± 10% reading (100 to 150mmHg)	Same
Alarm Limits, CO2: Upper Lower	 2 to 99mmHg, OFF 1 to 98 mmHg, OFF	Same
Apnea Alarm Limits	5 to 40 seconds, OFF	Same
Cardiac Output- All modes		
Measuring Method	Thermodilution	Same
Measuring Range: Cardiac Output	 0.5 to 20 L/min	Same

	Subject Device: Life Scope BSM-1700 Series Bedside Monitor Input Unit and Transport/Standalone Mode	**Predicate Device: BSM 1700 Series Bedside Monitoring System K213316-** Input Unit and Transport Mode
Injection Temp. Blood Temp.	0 to 27 °C 15 to 45 °C	
Accuracy: Cardiac Output Injection Temp. Blood Temp.	±5% ± 0.2 °C ± 0.2% (15 to 25 °C) ± 0.1% (25 to 45 °C)	Same
Catheter Coefficient	Auto or Manual	Same
Injection Temperature Measurement Method	Temperature probe or inline sensor	Same
Alarm Limits, Blood Temp: Upper Lower	 15.1 to 45.0 °C, OFF 15.0 to 44.9 °C, OFF	Same
Network Connection		
Central Station Communications	Yes (Standard)	Same
Communication Method	Ethernet WLAN	Same
Others		
ECG Output	Yes	Same
IBP Output	Yes	Same
Connector for Transmitter	No	Same
External Display Connector	No	Same
Serial Data Interface	No	Same
Touchscreen	Yes	Same
Alarm Indicator Lamp	Yes	Same
Dedicated Function Keys	Yes	Same
Full Disclosure Storage	72hours, 5waves (Standalone Mode) 24hours, 5waves (Transport Mode)	24hours, 5waves (Transport Mode)
Trend Display Time	1, 2, 4, 8, 24, 72* hours (72 hours: Standalone Mode)	1, 2, 4, 8, 24 hours
Vital Sign List Interval	1, 5, 10, 15, 30 ,60 minute NIBP list (Triggered by NIBP measurement)	Same
List Capacity	72hours (Standalone Mode) 24hours (Transport Mode)	24hours (Transport Mode)
Recorder Type	Network printer	Same
Battery Type	Li-ion (Option)	Same
Number of batteries	1	Same
Battery Operation Time	5 hours	Same
Charge time	4.5 hours Typical	Same
Acquisition and Processing	Simultaneous Acquisition and Processing for 12 Lead Development with Calculations and Resting ECG Analyses	Same

	Subject Device: Life Scope BSM-1700 Series Bedside Monitor Input Unit and Transport/Standalone Mode	**Predicate Device: BSM 1700 Series Bedside Monitoring System K213316-** Input Unit and Transport Mode
ECG Interpretation Program	ECAPS12C	Same
12 lead ST Analysis	Yes	Same
Patient Age: 12 Lead Acquisition 12 Lead Interpretation	ALL ages 3 Years and older	Same
Line Voltage	100 to 240V	Same
Power Consumption	80VA	Same
Operating Temperature	10 to 40 deg C	Same
Operating Relative Humidity	30 to 85% RH	Same
Operating Atmospheric Pressure	70 to 106 kPa	Same
Dimensions, mm (W, H, D)	147 x 194 x 94 (without the wireless LAN station) 147 x 210 x 94 (with the wireless LAN station)	Same
Weight, kg (without options)	1.4 (without the battery and options) 1.57 (with the battery pack)	Same
General Safety	IEC 60601-1: 2005+Amd.1:2012 ANSI/AAMI/ES 60601-1:2005 (R2012)	Same
EMC	IEC60601-1-2:2014	Same

6.2 Technological Characteristics

There are no technological changes to the predicate devices. Both the predicate and the subject device measure the same functions.

6.3 Safety & Performance Tests

The Life Scope BSM-1700 Series 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.

6.4 Summary of Substantial Equivalence

The Life Scope BSM 1700 Series Bedside Monitor is equivalent to the Life Scope BSM-1700 Series and Accessories. The indications for Use have been updated to include the standalone mode.