July 16, 2021

Nihon Kohden Corporation
% Sandra Gadeyne
Sr. Director, Quality and Regulatory Affairs
Nihon Kohden America
15353 Barranca Pkwy
Irvine, California 92618

Re: K203435
Trade/Device Name: Nihon Kohden Life Scope G5 Bedside Monitoring System, Nihon Kohden Life Scope G7 Bedside Monitoring System
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
Dated: June 14, 2021
Received: June 16, 2021

Dear Sandra Gadeyne:

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,

Jennifer Shih Kozen
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*

Device Name
Nihon Kohden Life Scope G5 Bedside Monitoring System CSM-1501and CSM-1502
Nihon Kohden Life Scope G7 Bedside Monitoring System CSM-1701and CSM-1702

Indications for Use *(Describe)*
The Nihon Kohden Life Scope® G5 and Nihon Kohden Life Scope® G7 Bedside Monitoring System 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 (O2), 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 modules, CCO/SvO2 monitors, and EEG measuring units.
The device may generate an 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.

A-fib detection, ST measurement and QTc/QRSd monitoring are intended for adult patients only. Arrhythmia detection function is intended for child, adolescent, and adult patients.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Sponsor: Nihon Kohden Corporation
1-31-4 Nishiochiai, Shinjuku-Ku
Tokyo, Japan 161-8560

Initial Importer: Nihon Kohden America
15353 Barranca Parkway
Irvine, CA, 92618
Sandra Gadeyne

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510(k) Submission Type: Traditional 510(k)

Date Prepared: June 14, 2021

DEVICE INFORMATION:

Proprietary Name:	Nihon Kohden Life Scope® G5 Bedside Monitoring System and Nihon Kohden Life Scope® G7 Bedside Monitoring System
Common Name:	Multiparameter Patient Monitor
Marketing Names:	Life Scope® G5L, Life Scope®, G5-HD, G5 All-in-one Patient Monitor Life Scope® G7H; Life Scope® G7 with (DAU) Data Acquisition Module, Life Scope® G7 High Acuity Monitor
Classification:	Class II
Product Codes:	MHX
Regulations:	§870.1025
Classification Panel:	Cardiovascular

11.1 PRODUCT DESCRIPTION:

The Nihon Kohden Life Scope® G5 and Life Scope® G7 Bedside Monitoring System are an LCD touchscreen bedside monitoring system. These bedside monitors are installed near the patient and are intended to display the patient's vital signs such as ECG (basic and 12 lead), NIBP, temperature, SpO_2, respiration, and CO_2 and generate alarms from the bedside monitor. Additional parameters can be measured such as arrhythmia detection, ST elevation, and Train of Four (TOF) measuring parameters. Apnea and arrhythmia can also be monitored. The configuration of the bedside monitor can be adapted by the health care professionals to meet the clinical setting requirements.

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.

The bedside monitor is designed so the operator can directly touch the screen from the operator position. Other optional accessories can also be used with the bedside monitor to add other parameters, allowing it to be used in a wide range of sites, such as operating rooms and intensive care units (ICU). The bedside monitor can also be connected to a network to communicate with central monitors and other Nihon Kohden devices.

The Life Scope® G5 Bedside Monitoring System consists of two models, those models are offered in two sizes:

- CSM-1501 bedside monitoring with core unit (CU) model CU-151R: 12.1-inch display
- CSM-1502 bedside monitoring with core unit (CU) model CU-152R: 15.6-inch display

The Life Scope G7 Bedside Monitoring System consists of two models, those models are offered in two sizes:

- CSM-1701 bedside monitoring with core unit (CU) model CU-171R: 15.6-inch display
- CSM-1702 bedside monitoring with core unit (CU) model CU-172R: 19.0-inch display

The Life Scope G7 Bedside Monitoring System consists of an input unit and a data acquisition unit with either the CU-171R or the CU-172R core unit.

The differences between the hardware for Life Scope brands is that:

- The Life Scope® G5 comes in two sizes and is smaller than the Life Scope G7.
- The Life Scope® G5 has a handle and the G7 does not.
- The Life Scope® G5 connects directly to the input unit.
- The Life Scope® G7 has the Data Acquisition Unit and the G5 does not. The Data Acquisition Unit directly connects to the input unit.

The similarities between Life Scope® G5 and Life Scope® G7 brands are that:

- Both platforms have the same software and have the same performance specification.
- Both of the platforms core unit calculates and displays the parameters of Heart Rate, NIBP, IBP, Body Temperature, Cardiac Output, and Respiratory Rate (from the impedance of the ECG electrodes) from the physiological signals (waveforms) sent from the input unit. All other parameters are calculated from an external device and the platform only displays the parameter on the monitor.

11.1.1 Principles of Operation

The Life Scope® G5 and Life Scope® G7 Bedside Monitoring Systems are intended to monitor, record, and display (local and remotely) physiological data including electrocardiogram (ECG), blood oxygen saturation (SpO_2), non-invasive blood pressure (NIBP), invasive blood pressure (IBP), body temperature, Cardiac Output (CO), Carbon Dioxide (CO_2), End Tidal Carbon Dioxide ($EtCO_2$), Respiratory Rate (RR), BIS and inspired and expired anesthetic agents and gases including CO_2, O_2, N_2, Halothane, Isoflurane, Enflurance, Sevoflurance, and Desflurane. These features are currently available in the legally marketed Nihon Kohden predicate devices.

11.1.2 Indications for Use/Intended Use:

The Nihon Kohden Life Scope® G5 and Nihon Kohden Life Scope® G7 Bedside Monitoring System 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 (SpO_2), non-invasive blood pressure (NIBP), invasive blood pressure (IBP), body temperature, BIS, cardiac output (CO), oxygen concentration (O_2), carbon dioxide concentration (CO_2), $EtCO_2$, respiratory rate, inspired and expired anesthetic agents and anesthetic gases including N_2O, halothane, isoflurane, enflurane, sevoflurane, and desflurane. The device also displays patient data from external devices such as ventilators, TOF modules, CCO/SvO_2 monitors, and EEG measuring units.

The device may generate an 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.

A-fib detection, ST measurement and QTc/QRSd monitoring are intended for adult patients only. Arrhythmia detection function is intended for child, adolescent, and adult patients.

11.1.3 Predicate Device

Table11-1 lists the basic information about the CSM-1901 (G9) Bedside Monitoring System including 510(k) number, device trade name, 510(k) holder, and clearance date.

Table11-1. Table of CSM-1901 (G9) Bedside Monitoring System Information

510(k)	Product	510(k) Holder	Clearance Date
K201949	CSM-1901	Nihon Kohden Corporation	May 02, 2021

11.1.4 Comparison to Predicate Device

The Nihon Kohden Life Scope® G5 and Life Scope® G7 Bedside Monitoring Systems are substantially equivalent to the Nihon Kohden CSM-1901 Bedside Monitor (K201949). The subject devices have the same intended use, indications for use, principles of operation, and performance specifications as the predicate device, see Table 11-2, for the comparison of the subject devices to the predicate devices.

The similarities between the two (2) subject devices- Life Scope G5 and Life Scope G7 to the predicate devices:

- All the platforms have a similar performance specification.
- All the core units of the platform calculate and display the parameters of Heart Rate, NIBP, IBP, Body Temperature, Cardiac Output, and Respiratory Rate (from the impedance of the ECG electrodes) from the physiological signals (waveforms) sent from the input unit. All other parameters are calculated from an external device and the platform only displays the parameter on the monitor.
- All the platforms use the same common accessories and interfaces with the same external devices.

11.2 COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE:

Table 11-2 is a detailed comparison.

Table 11-2. Comparison of the Life Scope G5 and the Life Scope G7 and to predicate device Life Scope G9

Characteristics	Life Scope G5 (Subject Device)	Life Scope G7 (Subject Device)	CSM-1901 (K#201949) Predicate	Comparison
Trade Name	Life Scope G5 Bedside Monitoring System	Life Scope G7 Bedside Monitoring System	CSM-1901 Bedside Monitor	N/A
Common Name	**G5**	**G7**	**G9**	N/A
Classification Panel	Cardiovascular	Cardiovascular	Cardiovascular	Identical
Regulation Number	870.1025	870.1025	870.1025	Identical
Classification Name	Monitor, Physiological, Patient with Arrhythmia Detection	Monitor, Physiological, Patient with Arrhythmia Detection	Monitor, Physiological, Patient with Arrhythmia Detection	Identical
Regulatory Class	Class II	Class II	Class II	Identical
Product Code	MHX	MHX	MHX	Identical
Patient Population	Neonate, children, and adults	Neonate, children, and adults	Neonate, children, and adults	Identical
Setting	Clinical	Clinical	Clinical	Identical
End-User	Health Care Professionals	Health Care Professionals	Health Care Professionals	Identical
Biocompatibility	N/A	N/A	N/A	Identical
Shelf Life	N/A	N/A	N/A	Identical
Patient Contact	No	No	No	Identical
Single-use	No	No	No	Identical

Characteristics	Life Scope G5 (Subject Device)	Life Scope G7 (Subject Device)	CSM-1901 (K#201949) Predicate	Comparison
Sterile	No	No	No	Identical
Indications for Use/Intended Use				

Indications for Use/Intended Usewavef	The Nihon Kohden Life Scope G5 bedside monitors 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 (SpO_2), non-invasive blood pressure (NIBP), invasive blood pressure (IBP), body temperature, BIS, cardiac output (CO), oxygen concentration (O_2), carbon dioxide concentration (CO_2), $EtCO_2$, respiratory rate, inspired and expired anesthetic agents and anesthetic gases including N_2O, halothane, isoflurane, enflurane, sevoflurane, and desflurane. The device also displays patient data from external devices such as ventilators, TOF modules, CCO/SvO_2 monitors, and EEG measuring units. The device may generate an 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. A-fib detection, ST measurement and QTc/QRSd monitoring are intended for adult patients only. Arrhythmia	The Nihon Kohden Life Scope G7 bedside monitors 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 (SpO_2), non-invasive blood pressure (NIBP), invasive blood pressure (IBP), body temperature, BIS, cardiac output (CO), oxygen concentration (O_2), carbon dioxide concentration (CO_2), $EtCO_2$, respiratory rate, inspired and expired anesthetic agents and anesthetic gases including N_2O, halothane, isoflurane, enflurane, sevoflurane, and desflurane. The device also displays patient data from external devices such as ventilators, TOF modules, CCO/SvO_2 monitors, and EEG measuring units. The device may generate an 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. A-fib detection, ST measurement and QTc/QRSd monitoring are intended for adult patients only. Arrhythmia	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 (SpO_2), non-invasive blood pressure (NIBP), invasive blood pressure (IBP), body temperature, BIS, cardiac output (CO), oxygen concentration (FiO_2), carbon dioxide concentration (CO_2), $EtCO_2$, respiratory rate, inspired and expired anesthetic agents and anesthetic gases including N_2O, halothane, isoflurane, enflurane, sevoflurane, and desflurane. The device also displays patient data from external devices such as ventilators, TOF monitors, CCO/SvO_2 monitors, and EEG measuring units. The device may generate an 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.	Below & Section 5.3-8

Characteristics	Life Scope G5 (Subject Device)	Life Scope G7 (Subject Device)	CSM-1901 (K#201949) Predicate	Comparison
	detection function is intended for child, adolescent, and adult patients.	detection function is intended for child, adolescent, and adult patients.		
Waveform Display	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.	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.	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.	Same

Characteristics	Life Scope G5 (Subject Device)	Life Scope G7 (Subject Device)	CSM-1901 (K#201949) Predicate	Comparison
Numeric Data Display	Heart rate, VPC rate (per minute), ST level, respiration rate, NIBP (Sys, Dia, MAP),IBP (Sys, Dia, Mean), 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,)	Heart rate, VPC rate (per minute), ST level, respiration rate, NIBP (Sys, Dia, MAP),IBP (Sys, Dia, Mean), 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,)	Heart rate, VPC rate (per minute), ST level, respiration rate, NIBP (Sys, Dia, MAP),IBP (Sys, Dia, Mean), 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,)	Same
Alarm Display	Alarm sound, highlighted alarm display, alarm lamp	Alarm sound, highlighted alarm display, alarm lamp	Alarm sound, highlighted alarm display, alarm lamp	Same
Alarm Suspend/Silence Function	Yes	Yes	Yes	Same
ECG				

Characteristics	Life Scope G5 (Subject Device)	Life Scope G7 (Subject Device)	CSM-1901 (K#201949) Predicate	Comparison
Number of ECG Electrodes	3, 6 or 10	3, 6 or 10	3, 6 or 10	Identical
ECG Leads	I, II, III, aVR, aVL, aVF, V1 to V6	I, II, III, aVR, aVL, aVF, V1 to V6	I, II, III, aVR, aVL, aVF, V1 to V6	Identical
Input Impedance	5 M ohm	5 M ohm	5 M ohm	Identical
Frequency Response	3.2 Time Constant = 0.05 to 150Hz	3.2 Time Constant = 0.05 to 150Hz	3.2 Time Constant = 0.05 to 150Hz	Identical
Display Sensitivity	x1/8, x1/4, x1/2, x1, x2, x4, Auto	x1/8, x1/4, x1/2, x1, x2, x4, Auto	x1/8, x1/4, x1/2, x1, x2, x4, Auto	Identical
Defibrillation Discharge Protection	Yes	Yes	Yes	Identical
Electrosurgery Interface filter	Yes	Yes	Yes	Identical
Pacing detection	Yes	Yes	Yes	Identical
Leads OFF Detector	Yes	Yes	Yes	Identical
Filters	Diag, Mon, ST, Max + AC	Diag, Mon, ST, Max + AC	Diag, Mon, ST, Max + AC	Identical
Heart Rate Counting Method	Average, instantaneous (beat to beat)	Average, instantaneous (beat to beat)	Average, instantaneous (beat to beat)	Identical
Heart Rate Counting Range	0, 15 to 300 bpm	0, 15 to 300 bpm	0, 15 to 300 bpm	Identical
Counting Accuracy	± 2 bpm	± 2 bpm	± 2 bpm	Identical
Alarm Limits: Upper Lower	 16 to 300 bpm, OFF 15 to 299 bpm, OFF	 16 to 300 bpm, OFF 15 to 299 bpm, OFF	 16 to 300 bpm, OFF 15 to 299 bpm, OFF	Identical
ST Level Measuring Range (adults only)	-2.5 to +2.5 mV	-2.5 to +2.5 mV	-2.5 to +2.5 mV	Identical
QTc/QRSd Monitoring (adult only)	Yes	Yes	No	Below
QRS Sync Tone	Yes	Yes	Yes	Identical

Characteristics	Life Scope G5 (Subject Device)	Life Scope G7 (Subject Device)	CSM-1901 (K#201949) Predicate	Comparison
Arrhythmia Detection				
Detection Method	Multi-template software algorithm Multi-lead analysis	Multi-template software algorithm Multi-lead analysis	Multi-template software algorithm Multi-lead analysis	Identical
VPC Counting Range	0 to 99 per min	0 to 99 per min	0 to 99 per min	Identical
Arrhythmia Alarms	Yes	Yes	Yes	Identical
Arrhythmia Recall	Yes	Yes	Yes	Identical
Number of Arrhythmia Recall Files	16,384 files	16,384 files	20,000 files	Below
Number of Arrhythmia Recall Files (hrs)	168 hrs	168 hrs	168 hrs	Identical
Length of Recall Files	12 seconds	12 seconds	12 seconds	Identical
Arrhythmia Graphic Trend	Yes	Yes	Yes	Identical
Number of Arrhythmia types	25	25	25	Identical
Arrhythmia Graphic Trend	Yes	Yes	Yes	Identical
ECAPS- 12 Lead Analysis				
Acquisition and Processing	Simultaneous Acquisition and Processing for 12 Lead Development with Calculations and Resting ECG Analyses	Simultaneous Acquisition and Processing for 12 Lead Development with Calculations and Resting ECG Analyses	Simultaneous Acquisition and Processing for 12 Lead Development with Calculations and Resting ECG Analysis	Identical
ECG Interpretation Program	ECAPS12C	ECAPS12C	ECAPS12C	Identical
12 lead ST Analysis	Yes	Yes	Yes	Identical
QTc/QRSd Measurement	Yes	Yes	Yes	Identical

Characteristics	Life Scope G5 (Subject Device)	Life Scope G7 (Subject Device)	CSM-1901 (K#201949) Predicate	Comparison
Patient Age: 12 Lead Acquisition 12 Lead Interpretation	All ages 3 Years and older	All ages 3 Years and older	All ages 3 Years and older	Identical
Respiration				
Method	Impedance, CO_2	Impedance, CO_2	Impedance, thermistor, CO_2	Below
Respiration Rate Display	0 to 150 bpm	0 to 150 bpm	0 to 150 bpm	Identical
Respiration Rate Alarm Limits: Upper Lower	 2 to 150 bpm, OFF 0 to 148 bpm, OFF	 2 to 150 bpm, OFF 0 to 148 bpm, OFF	 2 to 150 bpm, OFF 0 to 148 bpm, OFF	Identical
No breath time Limit	5 to 40 seconds, OFF	5 to 40 seconds, OFF	5 to 40 seconds, OFF	Identical
Waveform Display	Yes	Yes	Yes	Identical
Connector Insertion Detection	Yes	Yes	Yes	Identical
Apnea Detection	Yes	Yes	Yes	Identical
Apnea Alarm Limit:	5 to 40s, OFF	5 to 40s, OFF	5 to 40s, OFF	Identical
Apnea methods	Impedance from ECG and Resp waveform, CO_2 waveform	Impedance from ECG and Resp waveform, CO_2 waveform	Impedance from ECG and Resp waveform, CO_2 waveform	Identical
Oxygen Saturation - SpO_2				
Probe Type	Nihon Kohden (NK), Nellcor (NL) or Masimo (MS)	Nihon Kohden (NK), Nellcor (NL) or Masimo (MS)	Nihon Kohden (NK), Nellcor (NL) or Masimo (MS)	Identical
Input Unit	AY Series and BSM-1700 Series	AY Series and BSM-1700 Series	AY Series and BSM-1700 Series	Identical
Displayed Range	0 to 100%	0 to 100%	0 to 100%	Identical

Characteristics	Life Scope G5 (Subject Device)	Life Scope G7 (Subject Device)	CSM-1901 (K#201949) Predicate	Comparison
Nihon Kohden Declared Range, type and Accuracy with sensor	70 to 100% (with sensor) 80 to 100% ± 2 %SpO_2 70 to 80% ± 3 %SpO_2	70 to 100% (with sensor) 80 to 100% ± 2 %SpO_2 70 to 80% ± 3 %SpO_2	70 to 100% (with sensor) 80 to 100% ± 2 %SpO_2 70 to 80% ± 3 %SpO_2	Identical
Nellcor Declared Range, type and Accuracy with sensor (K060576)	70 to 100% 70 to 100% ± 2 %SpO_2 (adult) 70 to 100% ± 3 %SpO_2 (neonatal)	70 to 100% 70 to 100% ± 2 %SpO_2 (adult) 70 to 100% ± 3 %SpO_2 (neonatal)	70 to 100% 70 to 100% ± 2 %SpO_2 (adult) 70 to 100% ± 3 %SpO_2 (neonatal)	Identical
Masimo Declared Range, MS type and Accuracy with sensor (K053269)	No motion condition 70 to 100% ± 2 %SpO_2 (adult) 70 to 100% ± 3 %SpO_2 (neonatal) motion condition 70 to 100% ± 3 %SpO_2 (adult) 70 to 100% ± 3 %SpO_2 (neonatal)	No motion condition 70 to 100% ± 2 %SpO_2 (adult) 70 to 100% ± 3 %SpO2 (neonatal) motion condition 70 to 100% ± 3 %SpO_2 (adult) 70 to 100% ± 3 %SpO_2 (neonatal)	No motion condition 70 to 100% ± 2 %SpO_2 (adult) 70 to 100% ± 3 %SpO2 (neonatal) motion condition 70 to 100% ± 3 %SpO_2 (adult) 70 to 100% ± 3 %SpO_2 (neonatal)	Identical
Display Sensitivity	x1/8, x1/4, x1/2, x1, x2, x4, x8, Auto	x1/8, x1/4, x1/2, x1, x2, x4, x8, Auto	x1/8, x1/4, x1/2, x1, x2, x4, x8, Auto	Identical
Pulse Sync Tone	Yes	Yes	Yes	Identical
Audible Indication to SpO2 Variation	Yes	Yes	Yes	Identical
SpO_2 Alarm Limits: Upper Lower	 51 to 100%, OFF 50 to 99%, OFF	 51 to 100%, OFF 50 to 99%, OFF	 51 to 100%, OFF 50 to 99%, OFF	Identical
Pulse Rate Count Range:	0, 30 to 300 bpm (NK) 0, 20 to 300 bpm (NL) 0, 25 to 240 bpm (MS)	0, 30 to 300 bpm (NK) 0, 20-300 bpm (NL) 0, 25-240 bpm (MS)	0, 30-300 bpm (NK) 0, 20-300 bpm (NL) 0, 25-240 bpm (MS)	Identical
Pulse Rate Counting Accuracy	±3% ±1 beat/min (NK) ±3 beat/min (NL) ±3 beat/min No motion (MS) ±5 beat/min Motion (MS)	±3% ±1 beat/min (NK) ±3 beat/min (NL) ±3 beat/min No motion (MS) ±5 beat/min Motion (MS)	±3% ±1 beat/min (NK) ±3 beat/min (NL) ±3 beat/min No motion (MS) ±5 beat/min Motion (MS)	Identical
Non- Invasive Blood Pressure (NIBP)				
Measuring Method	Oscillometric	Oscillometric	Oscillometric	Identical

Characteristics	Life Scope G5 (Subject Device)	Life Scope G7 (Subject Device)	CSM-1901 (K#201949) Predicate	Comparison
Pressure Data Display	Systolic, Diastolic, Mean, Cuff pressure, Pulse Rate	Systolic, Diastolic, Mean, Cuff pressure, Pulse Rate	Systolic, Diastolic, Mean, Cuff pressure, Pulse Rate	Identical
Measuring Range, Adult/Pediatric	0 to 300 mmHg	0 to 300 mmHg	0 to 300 mmHg	Identical
Measuring Range, Neonates	0 to 150 mmHg	0 to 150 mmHg	0 to 150 mmHg	Identical
Measuring Accuracy	±3 mmHg (0 mmHg ≤ NIBP ≤ 300 mmHg)	±3 mmHg (0 mmHg ≤ NIBP ≤ 300 mmHg)	±3 mmHg (0 mmHg ≤ NIBP ≤ 300 mmHg)	Identical
Measurement Mode	Manual, STAT, Periodic, SIM	Manual, STAT, Periodic, SIM	Manual, STAT, Periodic, SIM	Identical
Maximum Cuff Inflation Pressure: Adult/Pediatric Neonate	300 mmHg 150 mmHg	300 mmHg 150 mmHg	300 mmHg 150 mmHg	Identical
Rapid Deflation If Power Failure	Yes	Yes	Yes	Identical
Alarm Limits: Upper Lower	15 to 260 mmHg, OFF 10 to 255 mmHg, OFF	15 to 260 mmHg, OFF 10 to 255 mmHg, OFF	15 to 260 mmHg, OFF 10 to 255 mmHg, OFF	Identical
Invasive Pressure (IBP)				
Measuring Method	Pressure transducer	Pressure transducer	Pressure transducer	Identical
Number of Channels	8	8	8	Identical
Measuring Range	-50 to 300 mmHg	-50 to 300 mmHg	-50 to 300 mmHg	Identical
Measuring Accuracy	±1mmHg, ±1digit (-50 to100 mmHg) ±1%, ±1digit (100 to 300 mmHg)	±1mmHg, ±1digit (-50 to100 mmHg) ±1%, ±1digit (100 to 300 mmHg)	±1mmHg, ±1digit (-50 to100 mmHg) ±1%, ±1digit (100 to 300 mmHg)	Identical
Input Sensitivity	50 µV/V/10mmHg	50 µV/V/10mmHg	50 µV/V/10mmHg	Identical
Connector Insertion Detection	Yes	Yes	Yes	Identical

Characteristics	Life Scope G5 (Subject Device)	Life Scope G7 (Subject Device)	CSM-1901 (K#201949) Predicate	Comparison
Alarm Limits: Upper Lower	 -48 to 300 mmHg, OFF -50 to 298 mmHg, OFF	 -48 to 300 mmHg, OFF -50 to 298 mmHg, OFF	 -48 to 300 mmHg, OFF -50 to 298 mmHg, OFF	Identical
Pulse Rate Count Range:	0, 30 to 300 bpm	0, 30 to 300 bpm	0, 30 to 300 bpm	Identical
Pulse Rate Counting Accuracy	± 2 bpm	± 2 bpm	± 2 bpm	Identical
Pulse Sync Tone	Yes	Yes	Yes	Identical
Body Temp				
Number of channels	4 ch	4 ch	8 ch	Below
Measuring Range	0 to 45 °C	0 to 45 °C	0 to 45 °C	Identical
Display Units	°C or °F	°C or °F	°C or °F	Identical
Accuracy	± 0.1 °C (25 to 45 °C) ± 0.2 °C (0 to 25 °C)	± 0.1 °C (25 to 45 °C) ± 0.2 °C (0 to 25 °C)	± 0.1 °C (25 to 45 °C) ± 0.2 °C (0 to 25 °C)	Identical
Alarm Limits: Upper Lower	 0.1 to 45.0 °C, OFF 0.0 to 44.9 °C, OFF	 0.1 to 45.0 °C, OFF 0.0 to 44.9 °C, OFF	 0.1 to 45.0 °C, OFF 0.0 to 44.9 °C, OFF	Identical
Connector Insertion Detection	Yes	Yes	Yes	Identical
Numeric Display	Yes	Yes	Yes	Identical
Carbon Dioxide (CO2) Gas Monitoring				
Measuring Method CO_2 (1)	Main Stream with the following sensor: TG-900P/TG-920P/TG-980P	Main Stream with the following sensor: TG-900P/TG-920P/TG-980P	Main Stream with the following sensor: TG-900P/TG-920P/TG-980P	Identical

Characteristics	Life Scope G5 (Subject Device)	Life Scope G7 (Subject Device)	CSM-1901 (K#201949) Predicate	Comparison
Rise Time	TG-900P: 160ms(typical) for 10 to 90% TG-920P: 120ms(typical) for 10 to 90% TG-980P: < 60ms for 10 to 90% (excluding connected instruments)	TG-900P: 160ms(typical) for 10 to 90% TG-920P: 120ms(typical) for 10 to 90% TG-980P: < 60 ms for 10 to 90% (excluding connected instruments)	TG-900P: 160ms(typical) for 10 to 90% TG-920P: 120ms(typical) for 10 to 90% TG-980P: < 60 ms for 10 to 90% (excluding connected instruments)	Identical
Measuring Method CO_2 (2)	Main Stream, Side Stream (when GF-210RA connected)	Main Stream, Side Stream (when GF-210RA connected)	Main Stream, Side Stream (when GF-210RA connected)	Identical
Measuring Range, CO_2	TG-900P/TG-920P: 0 to 100mmHg TG-980P: 0 to 150mmHg	TG-900P/TG-920P: 0 to 100mmHg TG-980P: 0 to 150mmHg	TG-900P/TG-920P: 0 to 100mmHg TG-980P: 0 to 150mmHg	Identical
Display Values	EtCO2, CO2, Resp. rate Inspired CO2	EtCO2, CO2, Resp. rate Inspired CO2	EtCO2, CO2, Resp. rate Inspired CO2	Identical
Response Time	Depends on CO2 unit 160msec (TG-900P) 120msec (TG-920P/970P) < 60msec (TG-980P)	Depends on CO2 unit 160msec (TG-900P) 120msec (TG-920P/970P) < 60msec (TG-980P)	Depends on CO2 unit 160msec (TG-900P) 120msec (TG-920P/970P) < 60msec (TG-980P)	Identical
Alarm Limits- CO_2: Upper Lower	2 to 99 mmHg, OFF 1 to 98 mmHg, OFF	2 to 99 mmHg, OFF 1 to 98 mmHg, OFF	2 to 99 mmHg, OFF 1 to 98 mmHg, OFF	Identical
Accuracy CO_2	TG-900P/TG-920P ± 3 mmHg ($0 \leq CO_2 \leq 10$mmHg) ± 4 mmHg ($10 < CO_2 \leq 40$mmHg) ± 10% reading ($40 < CO_2 \leq 100$mmHg) (At 1 atmospheric pressure, air inspiration, no condensation) TG-980P ± 2 mmHg ($0 \leq CO_2 \leq 40$mmHg) ± 5% reading ($40 < CO_2 \leq 70$mmHg) ± 7% reading ($70 < CO_2 \leq 100$mmHg) ± 10% reading ($100 < CO_2 \leq$ 150mmHg) (When no condensation)	TG-900P/TG-920P ± 3 mmHg ($0 \leq CO_2 \leq 10$mmHg) ± 4 mmHg ($10 < CO_2 \leq 40$mmHg) ± 10% reading ($40 < CO_2 \leq 100$mmHg) (At 1 atmospheric pressure, air inspiration, no condensation) TG-980P ± 2 mmHg ($0 \leq CO_2 \leq 40$mmHg) ± 5% reading ($40 < CO_2 \leq 70$mmHg) ± 7% reading ($70 < CO_2 \leq 100$mmHg) ± 10% reading ($100 < CO_2 \leq$ 150mmHg) (When no condensation)	TG-900P/TG-920P ± 3 mmHg ($0 \leq CO_2 \leq 10$mmHg) ± 4 mmHg ($10 < CO_2 \leq 40$mmHg) ± 10% reading ($40 < CO_2 \leq 100$mmHg) (At 1 atmospheric pressure, air inspiration, no condensation) TG-980P ± 2 mmHg ($0 \leq CO_2 \leq 40$mmHg) ± 5% reading ($40 < CO_2 \leq 70$mmHg) ± 7% reading ($70 < CO_2 \leq 100$mmHg) ± 10% reading ($100 < CO_2 \leq$ 150mmHg) (When no condensation)	Identical

Characteristics	Life Scope G5 (Subject Device)	Life Scope G7 (Subject Device)	CSM-1901 (K#201949) Predicate	Comparison
Connector Insertion Detection	Yes	Yes	Yes	Identical
Rise Time	CO_2: ≤ 350 ms N_2O: ≤ 500 ms O_2: ≤ 500 ms Volatile anesthetic agent: ≤ 500 ms	CO_2: ≤ 350 ms N_2O: ≤ 500 ms O_2: ≤ 500 ms Volatile anesthetic agent: ≤ 500 ms	CO_2: ≤ 350 ms N_2O: ≤ 500 ms O_2: ≤ 500 ms Volatile anesthetic agent: ≤ 500 ms	Identical
Displayed Numerical data	Inspiratory/expiratory CO_2 Inspiratory/expiratory N_2O Inspiratory/expiratory O_2 Inspiratory/expiratory agent (Halothane, Enflurane, Isoflurane, Sevoflurane, Desflurane) (Up to two types) Respiration rate MAC	Inspiratory/expiratory CO_2 Inspiratory/expiratory N_2O Inspiratory/expiratory O_2 Inspiratory/expiratory agent (Halothane, Enflurane, Isoflurane, Sevoflurane, Desflurane) (Up to two types) Respiration rate MAC	Inspiratory/expiratory CO_2 Inspiratory/expiratory N_2O Inspiratory/expiratory O_2 Inspiratory/expiratory agent (Halothane, Enflurane, Isoflurane, Sevoflurane, Desflurane) (Up to two types) Respiration rate MAC	Identical
Measuring Range, CO_2	0 to 10 vol%	0 to 10 vol%	0 to 10 vol%	Identical
Accuracy CO_2	± (0.43 vol% + 8 % rel.)	± (0.43 vol% + 8 % rel.)	± (0.43 vol% + 8 % rel.)	Identical
Alarm Limits- CO_2: Upper Lower	2 to 99 mmHg, OFF 1 to 98 mmHg, OFF	2 to 99 mmHg, OFF 1 to 98 mmHg, OFF	2 to 99 mmHg, OFF 1 to 98 mmHg, OFF	Identical
Measuring Range, N_2O	0 to 100 vol%	0 to 100 vol%	0 to 100 vol%	Identical
Accuracy N_2	± (2 vol% + 8 % rel.)	± (2 vol% + 8 % rel.)	± (2 vol% + 8 % rel.)	Identical
Alarm Limits- N_2O: Upper Lower	1 to 100 %, OFF 0 to 99 %, OFF	1 to 100%, OFF 0 to 99%, OFF	1 to 100 %, OFF 0 to 99 %, OFF	Identical
Measuring range O_2	0 to 100 %	0 to 100 %	0 to 100 %	Identical
Accuracy O_2	± (2.5 vol% + 2.5% rel.)	± (2.5 vol% + 2.5% rel.)	± (2.5 vol% + 2.5% rel.)	Identical
Alarm Limits - O_2: Upper Lower	11 to 100 %, OFF 10 to 99 %	11 to 100 %, OFF 10 to 99 %	11 to 100 %, OFF 10 to 99 %	Identical

Characteristics	Life Scope G5 (Subject Device)	Life Scope G7 (Subject Device)	CSM-1901 (K#201949) Predicate	Comparison
Accuracy Anesthetic agent	± (0.2 vol% + 15 % rel.)	± (0.2 vol% + 15 % rel.)	± (0.2 vol% + 15 % rel.)	Identical
Alarm Limits-Anesthetic agent (HAL-I/E, ISO-I/E, ENF-I/E): Upper Lower	 0.1 to 7.0 %, OFF 0.0 to 6.9 %, OFF	 0.1 to 7.0 %, OFF 0.0 to 6.9 %, OFF	 0.1 to 7.0 %, OFF 0.0 to 6.9 %, OFF	Identical
Alarm Limits-Anesthetic agent (SEV-I/E): Upper Lower	 0.1 to 8.5 %, OFF 0.0 to 8.4 %, OFF	 0.1 to 8.5 %, OFF 0.0 to 8.4 %, OFF	 0.1 to 8.5 %, OFF 0.0 to 8.4 %, OFF	Identical
Alarm Limits-Anesthetic agent (DES-I/E): Upper Lower	 0.1 to 20.0 %, OFF 0.0 to 19.9 %, OFF	 0.1 to 20.0 %, OFF 0.0 to 19.9 %, OFF	 0.1 to 20.0 %, OFF 0.0 to 19.9 %, OFF	Identical
Cardiac Output				
Measuring Method	Thermodilution	Thermodilution	Thermodilution	Identical
Measuring Range: Cardiac Output Injection Temp Blood Temp	 0.5 to 20 L/min 0 to 27 °C 15 to 45 °C	 0.5 to 20 L/min 0 to 27 °C 15 to 45 °C	 0.5 to 20 L/min 0 to 27 °C 15 to 45 °C	Identical
Accuracy: Cardiac Output Injection Temp Blood Temp	 ± 5 % ± 0.2 °C ± 0.2 °C (15 to 45°C) ± 0.1 °C (25 to 45°C)	 ± 5 % ± 0.2 °C ± 0.2 °C (15 to 45°C) ± 0.1 °C (25 to 45°C)	 ± 5 % ± 0.2 °C ± 0.2 °C (15 to 45°C) ± 0.1 °C (25 to 45°C)	Identical
Catheter Coefficient	Auto or Manual	Auto or Manual	Auto or Manual	Identical
Alarm Limits - Blood Temp: Upper Lower	 15.1 to 45.0°C 15.0 to 44.9°C	 15.1 to 45.0°C 15.0 to 44.9°C	 15.1 to 45.0°C 15.0 to 44.9°C	Identical

Characteristics	Life Scope G5 (Subject Device)	Life Scope G7 (Subject Device)	CSM-1901 (K#201949) Predicate	Comparison
List Capacity	72 hours	72 hours	168 hours	Below
Train of Four (TOF)				
Muscle Movement detection	Electromyography (EMG)	Electromyography (EMG)	Electromyography (EMG)	Identical
Stimulation Patterns	Single stimulation, TOF (Train Of Four), PTC (Post Tetanic Count), TET (tetanic stimulation), DBS (Double Burst Stimulation	Single stimulation, TOF (Train Of Four), PTC (Post Tetanic Count), TET (tetanic stimulation), DBS (Double Burst Stimulation	Single stimulation, TOF (Train Of Four), PTC (Post Tetanic Count), TET (tetanic stimulation), DBS (Double Burst Stimulation	Identical
Stimulation Current Range	10-60 mA	10-60 mA	10-60 mA	Identical
Stimulation Pulse width	Square wave, constant current: 200µs or 300µs	Square wave, constant current: 200µs or 300µs	Square wave, constant current: 200µs or 300µs	Identical
EEG				
Alarm Limits – SEF: Upper Lower	 1.0 to 60.0 Hz, OFF 0.5 to 59.5 Hz, OFF	 1.0 to 60.0 Hz, OFF 0.5 to 59.5 Hz, OFF	 1.0 to 60.0 Hz, OFF 0.5 to 59.5 Hz, OFF	Identical
Alarm Limits - TP: Upper Lower	 0.02 to 9.99 nW, OFF 0.01 to 9.98 nW, OFF	 0.02 to 9.99 nW, OFF 0.01 to 9.98 nW, OFF	 0.02 to 9.99 nW, OFF 0.01 to 9.98 nW, OFF	Identical
Number of Channels	8	8	8	Identical
Input Impedance	15 MΩ at 10 Hz	15 MΩ at 10 Hz	15 MΩ at 10 Hz	Identical
Calibration Check	Step square 50 uV	Step square 50 uV	Step square 50 uV	Identical
Impedance Check	>10 kΩ within ± 20 %	>10 kΩ within ± 20 %	>10 kΩ within ± 20 %	Identical
Common-Mode Rejection Ratio (CMRR)	110 dB or more (in isolation mode) 60 dB or more (in balance mode)	110 dB or more (in isolation mode) 60 dB or more (in balance mode)	110 dB or more (in isolation mode) 60 dB or more (in balance mode)	Identical
Noise Level	< 3 uV p-p (0.53 to 30 Hz)	< 3 uV p-p (0.53 to 30 Hz)	< 3 uV p-p (0.53 to 30 Hz)	Identical

Characteristics	Life Scope G5 (Subject Device)	Life Scope G7 (Subject Device)	CSM-1901 (K#201949) Predicate	Comparison
Frequency Response	0.08 to 70 Hz	0.08 to 70 Hz	0.08 to 70 Hz	Identical
High-pass Filter (Low-cut)	0.08 to 5.3 Hz	0.08 to 5.3 Hz	0.08 to 5.3 Hz	Identical
Low-pass Filter (High-cut)	15 to 70 Hz	15 to 70 Hz	15 to 70 Hz	Identical
AC Filter	Rejection ratio: >26dB	Rejection ratio: >26dB	Rejection ratio: >26dB	Identical
Sensitivity	OFF, 1 to 200 uV/mm (14 steps)	OFF, 1 to 200 uV/mm (14 steps)	OFF, 1 to 200 uV/mm (14 steps)	Identical
A-D Conversion	16 bits	16 bits	16 bits	Identical
Sampling	All channels 200 Hz (A-D Conversion: 4 kHz)	All channels 200 Hz (A-D Conversion: 4 kHz)	All channels 200 Hz (A-D Conversion: 4 kHz)	Identical
Trend parameter	DSA aEEG	DSA aEEG	DSA aEEG	Identical
MDF (Median Frequency)	Yes	Yes	Yes	Identical
TP (Total Power Value)	Yes	Yes	Yes	Identical
aEEG	Yes	Yes	Yes	Identical
Display				
Resolution	CSM-1501: 1280 x 800 CSM-1502: 1366 x 768	CSM-1701: 1366 x 768 CSM-1702: 1680 x 1050	1680 x 1050	Below
Sweep Speed	1.56, 6.25, 12.5, 25, 50 mm/s	1.56, 6.25, 12.5, 25, 50 mm/s	1.56, 6.25, 12.5, 25, 50 mm/s	Identical
Trace Movement	Moving or fixed	Moving or fixed	Moving or fixed	Identical
Alarm Display	Alarm sound, highlighted alarm display, alarm lamp	Alarm sound, highlighted alarm display, alarm lamp	Alarm sound, highlighted alarm display, alarm lamp	Identical
Extended Display - Dual	Yes	Yes	Yes	Identical

Characteristics	Life Scope G5 (Subject Device)	Life Scope G7 (Subject Device)	CSM-1901 (K#201949) Predicate	Comparison
Extended Display Triple Display	CSM-1501: No CSM-1502: Yes	Yes	Yes	Below
Remote Control Compatible	Yes	Yes	Yes	Identical
Calculations				
Drug Calculation	Yes	Yes	Yes	Identical
Car Seat Challenge	Yes	Yes	Yes	Identical
Lung Capacity Calculation	Yes	Yes	Yes	Identical
Recorder				
Type	Thermal Array	Thermal Array	Thermal Array	Identical
Number of Channels	3	3	3	Identical
Annotation printing	Patient Name, bed ID, date, recording type, sensitivity, paper speed, parameter data, ECG lead, arrhythmia classification, QRS classification	Patient Name, bed ID, date, recording type, sensitivity, paper speed, parameter data, ECG lead, arrhythmia classification, QRS classification	Patient Name, bed ID, date, recording type, sensitivity, paper speed, parameter data, ECG lead, arrhythmia classification, QRS classification	Identical
Recorder Speed	12.5, 25, 50 mm/sec	12.5, 25, 50 mm/sec	12.5, 25, 50 mm/sec	Identical

11.3 TECHNOLOGICAL CHARACTERISTICS COMPARISON

The Nihon Kohden Bedside Monitors are substantially equivalent to the predicate. The Life Scope® G5 and Life Scope® G7 Bedside Monitoring System share the same Intended Use as the Nihon Kohden CSM-1901 Bedside Monitor. There are slight technological differences described below. Differences between the devices are minor and mainly due to the smaller size of the subject device and do not raise different questions of safety or efficacy.

1. **O_2/FiO_2**: The subject devices and the predicate CSM-1901 both monitor oxygen concentration (O_2) using the same multi-gas unit, GF-210R, which was previously cleared in K110594. The predicate CSM-1901 has an additional option, sensor JO-900P (K074705), that measures the fraction or percentage of oxygen (Fi$O_2$2). But this difference does not affect the O_2 monitoring of the subject device. Thus, this is not considered a technological change.
2. **QTc/QRSd monitoring**: The subject devices and the predicate device have the same ECG interpretation program, ECAPS 12C, and both the subject and the predicate can measure QTc/QRSd (Spot-Check). But the subject device also supports Continuous monitoring of QTc/QRSd. In Continuous monitoring, the QT interval and QRS duration measuring is started automatically when ECG monitoring is started, while the Spot-Check of the QT interval and QRS duration measuring is started manually. This technological difference does not affect the safety and effectiveness of the subject device compared to the predicate.
3. **Arrhythmia Recall Files**: Arrhythmia recall files are created automatically when arrhythmias occur. The subject devices have less storage capacity (16,384 files) than the CSM-1901 (20,000 files): The subject devices and the predicate, CSM-1901, both save arrhythmia recall files for review on the device. The predicate CSM-1901 can store more files than the subject devices. This difference is minor, and this storage difference does not affect the safety and effectiveness of the subject device compared to the predicate.
4. **Respiration**: The subject devices measure respiration using only the impedance and CO_2 method while the CSM-1901 uses the impedance, CO_2, and thermistor method. The subject devices and the predicate CSM-1901 both measure respiration using the ECG impedance and CO_2 method. The predicate CSM-1901 has another option, the thermistor method, but this does not affect the respiration monitoring of the subject device. Thus, this difference is not considered a technological change.
5. **Body Temp Number of Channels**: The subject devices have a smaller number of channels (4 channels) than the CSM-1901 (8 channels). The predicate CSM-1901 has more channels since the CSM-1901 is meant as a high-end model. The number of body temp measurement channels in the subject devices and the predicate CSM-1901 are both sufficient for monitoring a patient for its intended

use. This technological difference does not affect the safety and effectiveness of the subject devices compared to the predicate.

6. **Cardiac Output List Capacity**: The subject devices have a smaller list capacity (72 hours) than the CSM-1901 (168 hours). The subject devices and the predicate CSM-1901 both save the cardiac output list for review on the device. The predicate CSM-1901 has a larger list capacity since the CSM- 1901 is meant as a high-end model. The cardiac output list capacity in the subject devices and the predicate CSM-1901 are both sufficient for checking the data for its intended use. This technological difference does not affect the safety and effectiveness of the subject devices compared to the predicate.
7. **Display**: The resolution is less than the predicate. The CSM-1901 has a resolution of 1680 x 1050. The CSM-1501 has a resolution of 1280 x 800. The CSM-1502 and CSM-1701 have a resolution of 1366 x 768 and the CSM-1702 has a resolution of 1680 x 1050. Although this is a difference, it is due to the size of the monitors. CSM-1501 has a smaller number of displays (up to 2) than CSM-1901 (up to 3) since CSM-1501 is meant as a low-end model. All the systems were tested to IEC 60601-1 and passed.
8. **Indication for Use/Intended Use**: The subject devices have the same intended use/Indication for use as the predicate device. The difference is that the patient population of each ECG analysis functionality of the subject devices has been clarified.

11.4 PERFORMANCE DATA

The Life Scope® G5 and the Life Scope® G7 Bedside Monitoring Systems share the same software. Software verification and validation testing were conducted, and documentation are provided as recommended by FDA's Guidance for Industry and FDA Staff - Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (2005). Software verification and validation were conducted that included software unit testing, integration level testing, and system-level testing. A system test was also performed based on the software requirements specification. Testing to compliance standards for electrical and electromagnetic safety was also performed.

Electrical safety and electromagnetic compatibility (EMC) testing were conducted on the Nihon Kohden Life Scope® G5 and Life Scope® G7 Bedside Monitoring Systems. The devices comply with the applicable requirements within the ANSI AAMI ES60601-1 / IEC 60601-1 standards for safety and the IEC 60601-1-2 standard for EMC. No new issues of safety or effectiveness are introduced as a result of using these devices.

Table 11-3. Standards Used for Compliance Testing

No.	Standard
01	AAMI/ANSI ES 60601-1:2005/(R)2012 & A1: 2012, C1:2009/(R)2012 & A2:2010/(R)2012 (IEC 60601-1:2005 + A1:2012): Medical Electrical Equipment - Part 1: General Requirements for Basic Safety & Essential Performance
02	IEC 60601-1-2:2014 Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety & Essential Performance - Collateral Standard: Electromagnetic Compatibility -Requirements & Tests
03	IEC 60601-1-8:2006 & A1:2012 Medical electrical equipment – Part 1-8: General requirements for basic safety & essential performance - collateral standard: General requirements, tests & guidance for alarm systems in medical electrical equipment & medical electrical systems
04	ISO 80601-2-55:2018 Medical Electrical Equipment - Part 2-55: Particular Requirements for the Basic Safety & Essential Performance of Respiratory Gas Monitors
05	ISO 80601-2-56:2017+Am1:2018 Medical Electrical Equipment - Part 2-56: Particular Requirements for the Basic Safety & Essential Performance of Clinical Thermometers for Body Temperature Measurement
06	ISO 80601-2-61:2017 Medical electrical equipment – Part 2-61: Particular requirements for the basic safety & essential performance of pulse oximeter equipment
07	IEC 60601-2-26:2012 Medical electrical equipment – Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs
08	IEC 60601-2-27:2011 Medical electrical equipment – Part 2-27: Particular requirements for the basic safety & essential performance of electrocardiographic monitoring equipment
09	IEC 60601-2-34:2011 Medical electrical equipment – Part 2-34: Particular requirements for the basic safety & essential performance of invasive blood pressure monitoring equipment
10	IEC 60601-2-49:2011 Medical electrical equipment – Part 2-49: Particular requirements for the basic safety & essential performance of multifunction patient monitoring equipment
11	IEC 80601-2-30:2018 Medical electrical equipment – Part 2-30: Particular requirements for the basic safety & essential performance of automated non-invasive sphygmomanometers
12	ISO 14971:2012 Medical Devices – Application of Risk Management to Medical Devices

No.	Standard
13	IEC 62366:2007 + Amendment 1:2014 - Medical devices -- Application of usability engineering to medical devices
14	IEC 60601-1-6: 2010+A1: 2013 Medical electrical equipment - Part 1-6: General requirements for safety - collateral standard: Usability
15	ANSI/AAMI/EC57:2012 Testing and reporting performance results of cardiac rhythm and ST-segment measurement algorithms

11.5 CONCLUSION

The results of the substantial equivalence assessment, taken together with non-clinical bench testing, electrical safety and electromagnetic compatibility testing, and software verification and validation, demonstrate that the Nihon Kohden Life Scope® G5 and Life Scope®G7 Bedside Monitoring Systems do not raise different questions of safety and effectiveness when compared to the predicate, perform as intended, and have performance characteristics that are substantially equivalent to the Nihon Kohden Life Scope® G9 predicate device.