October 19, 2018

Nihon Kohden Corporation
% Thomas Bento
St. Vice President, Quality and Regulatory Affairs
Nihon Kohden America, Inc.
15353 Barranca Parkway
Irvine, California 92618

Re: K171765
Trade/Device Name: Nihon Kohden CO2 Monitor
Regulation Number: 21 CFR 868.1400
Regulation Name: Carbon dioxide gas analyzer
Regulatory Class: Class II
Product Code: CCK, MNK
Dated: September 5, 2017
Received: September 8, 2017

Dear Thomas Bento:

This letter corrects our substantially equivalent letter of October 11, 2017.

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name
Nihon Kohden CO2 Monitor OLG-3800A

Indications for Use *(Describe)*
The OLG-3800A CO2 monitor is intended to monitor respiratory rate, CO2 partial pressure and EtCO2. The device is also intended to monitor pulse rate and SpO2.

The device may generate an audible and/or visible alarm when a measured physiological rate falls outside preset limits, or when a technical error is detected.

The devices are intended to be used by qualified medical personnel within a medical facility, such as hospital or clinic, on all patient populations including adult, neonate, infant, child, and adolescent subgroups.

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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510(k) Summary

Nihon Kohden CO2 Monitor, Model OLG-3800A

Submitter:	Nihon Kohden Corporation
Address:	1-31-4 Nishiochiai, 1-Chome, Shinjuku-Ku Tokyo, Japan 161-8560
Phone number:	81-3-59968020
Contact person:	Thomas Bento
Office number:	(949) 580-1555 x3324
Mobile number:	(949) 680-9048
Fax number:	(913) 273-0732

Date prepared:	June 12, 2017
Device name:	Nihon Kohden CO2 Monitor, Model OLG-3800A
Common name:	Carbon Dioxide (CO2) Gas Analyzer
Device classification:	Class II
Primary Product code:	CCK
Secondary Product code (for Cap-ONE Biteblock, YG-227T):	MNK
Regulation:	21 CFR 868.1400
CO2 Monitor, OLG-3800A	
Predicate:	Nihon Kohden CO2 Monitor, OLG-2800A (K062115)
Reference:	Nihon Kohden Bedside Monitor, BSM-6000 series (K080342)
Biteblock, YG-227T	
Predicate:	Oridion/Covidien/Medtronic Smart CapnoLine Guardian (K093388)

Description:

The Nihon Kohden OLG-3800A is a compact CO2 monitor with a 7-inch display and is designed so the operator can directly touch the screen from the operator position. The CO2 monitor displays the patient's vital signs (CO2, RR, SpO2, PR) on the screen and generates an alarm according to the setting. Alarms are indicated with a screen message, sound, blinking or lighting of the alarm indicator. The device is used with commercially available sensors for intubated and non-intubated patients. The CO2 monitor is intended to be used in an ER, OR, ICU, CCU or general ward on all patient populations, depending on the accessories used with the device. The OLG-3800A is AC and/or battery operated.

When the operation mode is set to Network mode, the CO2 monitor can connect to a Nihon Kohden monitoring system network and communicate with the central monitor and bedside monitor on the network.

A new optional accessory, single-use adult cap-ONE Biteblock YG-227T can be used together with OLG-3800. YG-227T is inserted between the patient's teeth to prevent closure of the patient's jaws. It connects to a specified Nihon Kohden CO2 sensor kit to measure the partial pressure of the expired CO2 of a patient. Also, it allows oxygen (including an oxygen-air mixture) to be provided to the patient during endoscopy.

Indications for Use:

The OLG-3800A CO2 monitor is intended to monitor respiratory rate, CO2 partial pressure and EtCO2. The device is also intended to monitor pulse rate and SpO2.

The device may generate an audible and/or visible alarm when a measured physiological rate falls outside preset limits, or when a technical error is detected.

The devices are intended to be used by qualified medical personnel within a medical facility, such as hospital or clinic, on all patient populations including adult, neonate, infant, child, and adolescent subgroups.

Technological Characteristics – Substantial Equivalence Discussion:

The Nihon Kohden CO2 Monitor OLG-3800A is substantially equivalent to the predicate device, Nihon Kohden CO2 Monitor Model OLG-2800A (K062115). The Nihon Kohden BSM 6000 Series Bedside Monitor is shown as a reference device for comparison. Differences between the devices are minor and do not raise questions regarding safety or efficacy.

These differences include:

1. The OLG-3800A is substantially equivalent to the OLG-2800A other than the additional function of blood oxygen saturation (SpO2) measurement.

2. The OLG-3800A has a new added feature to measure SpO2. The SpO2 measurement method is the same as that of the reference device, BSM-6000 series bedside monitor. It has been verified using standard ISO 80601-2-61:2011.

The following table shows a comparison of the subject device, and the predicate and reference devices.

Specification	OLG-2800A Predicate (K062115)	BSM-6000 Series Reference Device (K080342)	OLG-3800A New Device
Indications for Use			
	The OLG-2800A is a portable monitor that measures respiration status of patients at a medical facility setting. The device is used with commercially available sensors for intubated and non-intubated patients. The device displays waveforms and numeric data of monitored parameters, such as CO2, EtCO2, respiratory rate and trendgraphs. The device may generate an audible and/or visible alarm when a measured parameter falls outside preset limits. The device LED display showsEtCO2 value and respiration rate and the LCD display shows CO2 waveforms, and alarms settings. The device is AC and/or battery operated. The device will be available for use by medical personnel on all patient populations depending on the CO2 sensor kit.	The device is intended to monitor, display and record physiological data to provide cardiac and vital signs monitoring within a medical facility. The device is intended to produce a visual record of the electrical signals produced by heart and monitor the electrocardiogram to generate audible and/or visible alarms when an arrhythmia exists. The device is also intended to monitor heart rate, pulse rate, blood oxygen saturation (SpO_2), noninvasive 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, and inspired and expired anesthetic agents and anesthetic gases including N_2O, 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 will be available for use by medical personnel on patients within a medical facility on all patient populations.	The OLG-3800A CO2 monitor is intended to monitor respiratory rate, CO2 partial pressure and EtCO2. The device is also intended to monitor pulse rate and SpO2. The device may generate an audible and/or visible alarm when a measured physiological rate falls outside preset limits, or when a technical error is detected. The devices are intended to be used by qualified medical personnel within a medical facility, such as hospital or clinic, on all patient populations including adult, neonate, infant, child, and adolescent subgroups.

Specification	OLG-2800A Predicate (K062115)	BSM-6000 Series Reference Device (K080342)	OLG-3800A New Device
Display			
Type	FSTN monochrome LCD, 7 segment LED, 3 digits display $EtCO_2$	TFT Color LCD, 10.4" (BSM-6301A) 12.1" (BSM-6501A) 15.0" (BSM-6701A)	7-inch, color TFT type LCD
Resolution	200 x 108	800x600 (BSM-6301A/6501A); 1024x768 (BSM-6701A)	800 (H) × 480 (V)
Waveform Display	CO_2	ECG (12 leads), respiration, pulse, CO2, cardiac output, external input, O2, EEG (BISx) , IBP(7)	CO2, SpO2
Numeric Data Display	$EtCO_2$, respiration rate	Heart Rate, Pulse Rate, VPC rate, ST level (12 leads), Respiration Rate, NIBP (SYS/DIA/MAP) Temperature (4), SpO_2, $EtCO_2$, $FiCO_2$,FiO_2, cardiac output, O_2, BIS, IBP(7) (sys/dia/mean)	ETCO2, FiCO2, INST CO2, RR, SpO2, PR, PI
Alarm			
Vital Signs Alarm Parameters	$ETCO_2$, FiCO2 RR, No breath	HR, PR, VPC, ST, RR, Apnea, SpO2, NIBP, PRESS, TEMP, CO2(E), CO2(I), O2(E), O2(I), N2O(E), N2O(I), HAL(E), HAL(I), ISO(E), ISO(I), ENF(E), ENF(I), DES(E), DES(I), SEV(E), SEV(I), MV, PEEP, Ppeak, SEF, TP, CCO, CCI	CO2(E), CO2(I),INST CO2,RR,NO BREATH,SpO2,PR
Respiration			
Method	CO_2	Impedance, thermistor, CO2	CO_2
Respiration Rate Display	0 to 150 bpm	0 to 150 bpm	0 to 150 bpm
Alarm Limits: Upper Lower	2 to 150 bpm, off 0 to 148 bpm, off	2 to 150 bpm, OFF 0 to 148 bpm, OFF	Upper limit: 2 to 150 bpm, OFF Lower limit: OFF, 0 to 148 bpm
No Breath Detection Time Limit	5 to 40 seconds, off	5 to 40 seconds, OFF	5 to 40 seconds, off
No breath Detection	Yes	Yes (Displayed as "Apnea")	Yes
CO2			
Display range	0 to 150 mmHg	0 to 150 mmHg	0 to 150 mmHg

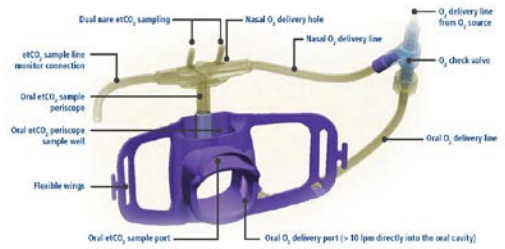
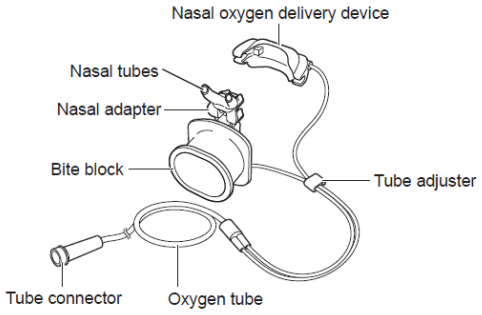
Specification	OLG-2800A Predicate (K062115)	BSM-6000 Series Reference Device (K080342)	OLG-3800A New Device
Declared range and accuracy with sensor	TG-900P: ±3 mmHg (0 ≤ CO_2 ≤ 10 mmHg) ±4mmHg (10 ≤ CO_2 ≤ 40 mmHg) ±10% reading (40 ≤ CO_2 ≤ 100 mmHg) (At 1 atmospheric pressure, air inspiration, no condensation) TG-920P: ±3 mmHg (0 ≤ CO_2 ≤ 10 mmHg) ±4mmHg (10 ≤ CO_2 ≤ 40 mmHg) ±10% reading (40 ≤ CO_2 ≤ 100 mmHg) (At 1 atmospheric pressure, air inspiration, no condensation, 7 minutes passed after stabilization of the sensor temperature) TG-970P, TG-980P: ±2 mmHg (0 ≤ CO_2 ≤ 40 mmHg) ±5% reading (40 < CO_2 ≤ 70 mmHg) ±7% reading (70 < CO_2 ≤ 100 mmHg) ±10% reading (100 < CO_2 ≤ 150 mmHg) (When no condensation)	TG-900P: ±3 mmHg (0 ≤ CO_2 ≤ 10 mmHg) ±4mmHg (10 ≤ CO_2 ≤ 40 mmHg) ±10% reading (40 ≤ CO_2 ≤ 100 mmHg) (At 1 atmospheric pressure, air inspiration, no condensation) TG-920P: ±3 mmHg (0 ≤ CO_2 ≤ 10 mmHg) ±4mmHg (10 ≤ CO_2 ≤ 40 mmHg) ±10% reading (40 ≤ CO_2 ≤ 100 mmHg) (At 1 atmospheric pressure, air inspiration, no condensation, 7 minutes passed after stabilization of the sensor temperature) TG-970P, TG-980P: ±2 mmHg (0 ≤ CO_2 ≤ 40 mmHg) ±5% reading (40 < CO_2 ≤ 70 mmHg) ±7% reading (70 < CO_2 ≤ 100 mmHg) ±10% reading (100 < CO_2 ≤ 150 mmHg) (When no condensation)	TG-900P: ±3 mmHg (0 ≤ CO_2 ≤ 10 mmHg) ±4mmHg (10 ≤ CO_2 ≤ 40 mmHg) ±10% reading (40 ≤ CO_2 ≤ 100 mmHg) (At 1 atmospheric pressure, air inspiration, no condensation) TG-920P: ±3 mmHg (0 ≤ CO_2 ≤ 10 mmHg) ±4mmHg (10 ≤ CO_2 ≤ 40 mmHg) ±10% reading (40 ≤ CO_2 ≤ 100 mmHg) (At 1 atmospheric pressure, air inspiration, no condensation, 7 minutes passed after stabilization of the sensor temperature) TG-970P, TG-980P: ±2 mmHg (0 ≤ CO_2 ≤ 40 mmHg) ±5% reading (40 < CO_2 ≤ 70 mmHg) ±7% reading (70 < CO_2 ≤ 100 mmHg) ±10% reading (100 < CO_2 ≤ 150 mmHg) (When no condensation)
Alarm Limits, CO_2: Upper Lower	2 to 99 mmHg, off 1 to 98 mmHg, off	2 to 99mmHg, OFF 1 to 98 mmHg, OFF	Upper limit: 2 to 99 mmHg, OFF Lower limit: 1 to 98 mmHg, OFF
Respiration Detection From CO_2	Yes	Yes	Yes
$EtCO_2$ Numeric Display	Yes	Yes	Yes
Respiratory synchronization sound($ETCO_2$)	Fixed	No	Fixed, 5 levels
SpO_2			
Probe type	N/A	Nihon Kohden (NK), Nellcor (NL) or Masimo (MS)	Nihon Kohden (NK)
Displayed Range (NK type)	N/A	0 to 100%	0 to 100%SpO_2

Specification	OLG-2800A Predicate (K062115)	BSM-6000 Series Reference Device (K080342)	OLG-3800A New Device
Declared Range (NK type) and Accuracy with Sensor	N/A	70 to 100% (with sensor) 80 to 100% ±2% SpO2 70 to 80% ±3% SpO2	70 to 100%SpO2 80 to 100%SpO2 ±2% SpO2 70 to 80%SpO2 ±3% SpO2
Alarm Limits (SpO2): Upper Lower	N/A	51 - 100%, OFF 50 - 99%, OFF	Upper limit: 51 to 100% SpO2, OFF Lower limit: 50 to 99% SpO2, OFF
Alarm Limits (PR): Upper Lower	N/A	Upper limit range: When SYNC SOURCE is set to ECG: 16 to 300 beats/min in 1 beat/min steps, OFF When SYNC SOURCE is set to PRESS or SpO2: 31 to 300 beats/min in 1 beat/min steps, OFF Lower limit range: When SYNC SOURCE is set to ECG: OFF, 15 to 299 beats/min in 1 beat/min steps When SYNC SOURCE is set to PRESS or SpO2: OFF, 30 to 299 beats/min in 1 beat/min steps	Upper limit: 31 to 300 bpm, OFF Lower limit: OFF, 30 to 299 bpm
Pulse Rate Count Range:	N/A	0, 30-300 bpm(NK) 0, 20-300 bpm(NL) 0, 25-240 bpm(MS)	30 to 300 bpm
Power Requirements			
Line Voltage	117 VAC	117 VAC	AC 100 to 240 V ±10%
Power Consumption	50 VA	90VA (BSM-6501A) 100VA (BSM-6701A)	45 VA
Safety Standard			
Safety Standard	IEC 60601-1: 1988 IEC 60601-1 Amendment 1: 1991 IEC 60601-1 Amendment 2: 1995 IEC 60601-1-2: 2001	IEC 60601-1: 1988 IEC 60601-1 Amendment 1: 1991 IEC 60601-1 Amendment 2: 1995 IEC 60601-1-2: 2001	IEC 60601-1:2005+Amendment 1:2012 IEC 60601-1-2:2007
Memory			
Full Disclosure Storage	No	24 hours, 5 waves, Standard	120 hours, 2 waves CO2,SpO2
List Capacity	24 hours	24 hours, Standard	120 hours
Dimension and Weight			
Dimensions, mm (H x W x D)	62 x 210 x 164 mm	316 x 325 x 188 (BSM-6301A) 342 x 353 x 183 (BSM-6501A)	140 × 200 × 145 mm

Specification	OLG-2800A Predicate (K062115)	BSM-6000 Series Reference Device (K080342)	OLG-3800A New Device
		415 x 392 x191 (BSM-6701A)	
Weight (without accessories)	1.3 Kg (including Battery)	6.6 kg (BSM-6301A) 8.3 kg (BSM-6501A) 10.3 kg (BSM-6701A)	1.7 kg (including Battery)

The Nihon Kohden cap-ONE Biteblock, YG-227T is substantially equivalent to the predicate device, Oridion/Covidien/Medtronic Smart CapnoLine Guardian (K093388).

The following table shows a comparison of the subject device and the predicate.

	Smart CapnoLine Guardian (Oridion/Covidien/Medtronic, K093388)	Cap-ONE Biteblock, YG-227T (New device)
IFU	The Smart CapnoLine Guadian is intended to sample CO2 and administer supplemental oxygen, for patients who can wear 60 fr. Bite block, during upper endoscopy type procedures. The set is intended for single patient use only.	The cap-ONE Biteblock is intended to sample CO2 and administer supplemental oxygen, for patients who can wear a 20mm bite block, during endoscopy type procedures. The device is intended for single patient use only.
Patient population	Patients who can wear 60 fr. Bite block	Patients who can wear a 20mm bite block
Components		
Dimension	(W) 120 x (H) 45 x (D) 26mm*	(W) 43 × (H) 70.6 × (D) 39.7mm±10%
Weight		18g±10%

*Manual measurements from actual device

Test Summary:

Performance testing for the Nihon Kohden CO2 Monitor OLG-3800A includes software verification and validation test, software unit test, integration test, system test, and testing to compliance standards for electrical and electromagnetic safety. Traceability has been documented between all system specifications to validation test results.

Standards compliance testing includes:

AAMI/ANSI ES60601-1:2005 /(R)2012 And A1: 2012, C1:2009/(R)2012 And A2:2010/(R)2012 (IEC 60601-1:2005 + A1:2012): Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance
IEC 60601-1-2:2007 Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests
IEC 60601-1-8:2006 & A1:2012 Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
ISO 80601-2-55:2011 Medical Electrical Equipment - Part 2-55: Particular Requirements for the Basic Safety and Essential Performance of Respiratory Gas Monitors
ISO 80601-2-61:2011 Medical electrical equipment – Part 2-61: Particular requirements for the basic safety and essential performance of pulse oximeter equipment
ISO 10993-1:2009 Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing
ISO 14971:2007 Medical Devices – Application of Risk Management to Medical Devices
IEC 62304:2006 Medical Device Software - Software Life-cycle Processes
IEC 62366:2007 + Amendment 1:2014 - Medical devices -- Application of usability engineering to medical devices

Performance testing for the Cap-ONE Biteblock, YG-227T includes compliance to the following standards:

IEC 60601-1:2005 + A1:2012: Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance
IEC 60601-1-6:2010+A1:2013: Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
ISO 80601-2-55:2011 Medical Electrical Equipment - Part 2-55: Particular Requirements for the Basic Safety and Essential Performance of Respiratory Gas Monitors
ISO 10993-1:2009 Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing
IEC 62366:2007 + Amendment 1:2014 - Medical devices -- Application of usability engineering to medical devices

Conclusion:

The performance of the Nihon Kohden CO2 Monitor OLG-3800A is substantially equivalent to the predicate device, the Nihon Kohden CO2 Monitor Model OLG-2800A and does not raise different questions of safety or effectiveness.