DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

November 5, 2015

Nihon Kohden
% Al Pacheco
Sr. Quality Engineer
Certified Compliance Solutions, Inc.
11665 Avena Place, Suite 203
San Diego, California 92128

Re: K151080
Trade/Device Name: Nihon Kohden CSM-1901 Bedside Monitor
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector and Alarm (Including ST-Segment Measurement and Alarm)
Regulatory Class: Class II
Product Code: MHX
Dated: October 6, 2015
Received: October 7, 2015

Dear Al Pacheco:

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.

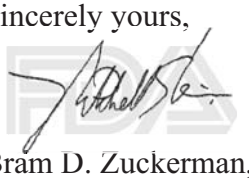
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular 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)*
K151080

Device Name
Nihon Kohden CSM-1901 Bedside Monitor

Indications for Use *(Describe)*
The Nihon Kohden CSM-1901 Bedside Monitor is intended to monitor, display and record physiological data to provide cardiac and vital signs monitoring within a medical facility. The device is intended to produce a visual record of the electrical signal produced by the heart and monitor the electrocardiogram to generate visible and/or audible alarms when an arrhythmia exists. The device is also intended to monitor heart rate, pulse rate, blood oxygen saturation (SpO2), non-invasive blood pressure (NIBP), invasive blood pressure (IBP), body temperature, BIS, cardiac output (CO), oxygen concentration (FiO2), carbon dioxide concentration (CO2), EtCO2, respiratory rate, inspired and expired anesthetic agents and anesthetic gases including N2O, halothane, isoflurane, enflurane, sevoflurane and desflurane. The device also displays patient data from external devices such as ventilators, TOF monitors, CCO/SvO2 monitors, and EEG measuring unit.

The device may generate and audible and/or visual alarm when a measured rate falls outside preset limits.

The device will be available for use by trained medical personnel within a medical facility on all patient populations, including adult, neonate, infant, child, and adolescent subgroups.

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary for Nihon Kohden CSM-1901 Bedside Monitor

Submitter: Nihon Kohden Corporation
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Phone number: (949) 580-1555 x3324
Fax number: (949) 580-1550

Contact person: Tom Bento
Phone number: (949) 580-1555 x3324
Fax number: (949) 580-1550

Date prepared: October 2, 2015

Device name: Nihon Kohden CSM-1901 Patient Monitor
Common name: Monitor Physiological Patient (with Arrhythmia Detection or Alarms)
Product Code: MHX
Regulation: 21 CFR 870.1025

Substantial equivalence claimed to: K082785 BSM-9100A Series Bedside Monitor

Description:
The Bedside monitor CSM-1901 is a device which continuously monitors physiological information of a patient and is used in an operation room, a recovery room, general wards, ICU, CCU, HCU, NICU and an emergency room. This bedside monitor is placed near the patient and is intended to display patient's vital signs. This device can also be connected to other external patient monitoring devices. In addition, this device can communicate patient's data to a central monitoring station via network to monitor multiple patients.

Indications for Use:
The Nihon Kohden CSM-1901 Bedside Monitor is intended to monitor, display and record physiological data to provide cardiac and vital signs monitoring within a medical facility. The device is intended to produce a visual record of the electrical signal produced by the heart and monitor the electrocardiogram to generate visible and/or audible alarms when an arrhythmia exists. The device is also intended to monitor heart rate, pulse rate, blood oxygen saturation (SpO2), non-invasive blood pressure (NIBP), invasive blood pressure (IBP), body temperature, BIS, cardiac output (CO), oxygen concentration (FiO2), carbon dioxide concentration (CO2), EtCO2, respiratory rate, inspired and expired anesthetic agents and anesthetic gases including N2O, halothane, isoflurane, enflurane, sevoflurane and desflurane. The device also displays patient data from external devices such as ventilators, TOF monitors, CCO/SvO2 monitors, and EEG measuring unit.

The device may generate and audible and/or visual alarm when a measured rate falls outside preset limits.

The device will be available for use by trained medical personnel within a medical facility on all patient populations, including adult, neonate, infant, child, and adolescent subgroups.

Technological Characteristics - Substantial Equivalence Discussion

The Nihon Kohden CSM-1901 Bedside Monitor is substantially equivalent to the predicate Device, the Nihon Kohden BSM-9100A Bedside Monitor. Differences between the devices are minor and do not raise questions regarding safety or efficacy. These differences include:

- The CSM-1901 includes an interface to the AE-918P EEG monitor Neuro Unit
- The CSM-1901 has modified the ECG display sensitivity including adding x8 sensitivity and deleting the x4 sensitivity setting
- The CSM-1901 has increased storage capacity for Arrhythmia Recall Files
- The CSM-1901 has added pulse rate display with NIBP data
- The CSM-1901 has enhanced display features including improved resolution, increased number of traces, increased number of sweep speeds, and the addition of a moving trace capability

Test Summary

Performance testing for the Nihon Kohden CSM-1901 Bedside Monitor includes software unit testing, system validation testing, and testing to compliance standards for electrical and electromagnetic safety. Traceability has been documented between all system specifications to validation test protocols.

Standards testing includes:

1. ANSI/AAMI ES 60601-1:2005/(R)2012 and A1 2012, C1:2009/(R)2012 and A2:2010/(R)2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
2. IEC 60601-1-2: 2007-03 Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility – Requirements and tests
3. IEC 60601-1-8:2012-11 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
4. IEC 60601-2-27:2011-03 Medical electrical equipment Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment
5. IEC 60601-2-34:2011-03 Medical electrical equipment Part 2-34: Particular requirements for the basic safety and essential performance of invasive blood pressure monitoring equipment
6. IEC 60601-2-55:2011-12 Medical electrical equipment Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors
7. IEC 60601-2-56:2009-10 Medical electrical equipment Part 2-56: Particular requirements for the basic safety and essential performance of clinical thermometers for body temperature measurement
8. IEC 60601-2-61:2009-10 Medical electrical equipment Part 2-61: Particular requirements for the basic safety and essential performance of pulse oximeter equipment

Verification and validation testing includes:

1. Software unit testing
2. Integration test (functional testing)
3. System verification test (GUI test)
4. System validation test

Conclusion:
The performance of the Nihon Kohden CSM-1901 Bedside Monitor is substantially equivalent to the predicate Device, the Nihon Kohden BSM-9100A Bedside Monitor and raises no safety or effectiveness issues and performs as well or better than the predicate device.