DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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April 4, 2017

Nihon Kohden Corporation
% Tom Bento
Sr. Vice President, Quality And Regulatory
Nihon Kohden America, Inc.
15353 Barranca Parkway
Irvine, California 92618

Re: K163459
Trade/Device Name: Nihon Kohden Vital Sign Telemeter GZ-140P
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: March 7, 2017
Received: March 8, 2017

Dear Tom Bento:

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,

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)*
K163459

Device Name
Nihon Kohden Vital Sign Telemeter GZ-140P

Indications for Use *(Describe)*
The Nihon Kohden Vital Sign Telemeter GZ-140P is intended to monitor and transmit physiological data from a patient to a Nihon Kohden monitor via radiofrequency in the 802.11 band for continuous monitoring. GZ-140P transmits electrocardiogram (ECG), respiration data, blood oxygen saturation (SpO2) and non-invasive blood pressure (NIBP). The device may generate an audible and/or visible alarm when an arrhythmia exists, when a measured physiological rate falls outside preset limits, or when a technical error is detected. Furthermore, the device can be configured for use as a temporary simple monitor to display the patient's vital signs on the device screen and generate alarms without transmitting the data to other Nihon Kohden monitor.
The device is 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, with the exception of NIBP measurement which is not intended for use on neonates.

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

Nihon Kohden Vital Sign Telemeter GZ-140P

Submitter:	Nihon Kohden Corporation
Address:	1-31-4 Nishiochiai, 1-Chome, Shinjuku-Ku Tokyo, Japan 161-8560
Phone number:	81-2-59968020
Contact person:	Tom Bento
Phone number:	(949) 680-9048
Fax number:	(913) 273-0732

Date prepared:	December 06, 2016
Device name:	Nihon Kohden Vital Sign Telemeter GZ-140P
Common name:	Patient monitor
Device classification:	Monitor, physiological, patient (with arrhythmia detection or alarms), Transmitters and Receivers, Physiological Signal, Radio Frequency
Primary Product code:	MHX
Regulation:	21 CFR 870.1025
Secondary Product Code:	DRG
Regulation:	21 CFR 870.2910
Substantial equivalent claimed to:	Nihon Kohden BSM-6000 Series Bedside Monitor (K080342) and Nihon Kohden Vital Sign Telemeter GZ-120P and GZ-130P (K153707)

Description:

The Nihon Kohden Vital Sign Telemeter GZ-140P is mainly used as a telemetry system within a medical facility. The device transmits patient's vital signs (ECG, SpO_2, respiration, and blood pressure) and alarm information via wireless LAN connection to the central monitoring station. The device can be configured to display the patient's vital signs on the screen and generate alarms and used as a temporary simple monitor.

Indications for Use:

The Nihon Kohden Vital Sign Telemeter GZ-140P is intended to monitor and transmit physiological data from a patient to a Nihon Kohden monitor via radiofrequency in the 802.11 band for continuous monitoring. GZ-140P transmits electrocardiogram (ECG), respiration data, blood oxygen saturation (SpO_2) and non-invasive blood pressure (NIBP). The device may generate an audible and/or visible alarm when an arrhythmia exists, when a measured physiological rate falls outside preset limits, or when a technical error is detected. Furthermore, the device can be configured for use as a temporary simple monitor to display the patient's vital signs on the device screen and generate alarms without transmitting the data to other Nihon Kohden monitor.

The device is 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, with the exception of NIBP measurement which is not intended for use on neonates.

Technological Characteristics – Substantial Equivalence Discussion:

The Nihon Kohden Vital Sign Telemeter GZ-140P is substantially equivalent to the predicate devices, Nihon Kohden BSM-6000 Series Bedside Monitor (K080342) and Nihon Kohden Vital Sign Telemeter GZ-120P and GZ-130P. Differences between the devices are minor and do not raise questions regarding safety or efficacy.

These differences include:

- The GZ-140P is substantially equivalent to the GZ-120P/GZ-130P Vital Sign Telemeter other than the additional functions of NIBP measurement and atrial fibrillation detection.

- The GZ-140P has two NIBP measurement modes: Conventional Mode (Deflation Mode) where NIBP measurements are made during deflation of the cuff and iNIBP (Inflation Mode) where NIBP measurements are made during inflation of the cuff. The Conventional Mode (Deflation Mode) is the same as that of the predicate device, BSM-6000 series bedside monitor. The iNIBP (Inflation Mode) measurement uses the same oscillometric method as the Conventional Mode (Deflation Mode) measurement and was validated in the clinical testing (Attachment 015). The similar technology with iNIBP is acquired by Welch Allyn Spot Ultra Vital Signs (K040490), where the blood pressure is measured while the device is inflating a cuff.

- The atrial fibrillation detection algorithm is exactly same as that of Nihon Kohden Afib Detection Program QP-039P (K152305).

Test Summary:

Performance testing for the Nihon Kohden Vital Sign Telemeter GZ-140P includes software verification and validation test, software unit test, integration test, system test, and testing to compliance standards for electrical and electromagnetic safety. Wireless coexistence testing and evaluation was performed following FDA Guidance, “Radio Frequency Wireless Technology in Medical Device”, and the device’s immunity to proximity fields from radio frequency wireless communications equipment was validated. Traceability has been documented between all system specifications to validation test results.

Standards compliance testing includes:

- ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012: 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
- IEC 60601-2-27:2011 Medical electrical equipment - Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment

- IEC 60601-2-49:2011 Medical electrical equipment – Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment
- IEC 80601-2-30:2013 Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
- 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 81060-2:2013 Non-invasive sphygmomanometers – Part 2: Clinical validation of automated measurement type
- ANSI/AAMI EC57:2012 Testing and reporting performance results of cardiac rhythm and ST-segment measurement algorithms
- IEC 62304:2006 Medical device software - Software life-cycle processes
- ISO 10993-5:2009 Biological evaluation of medical devices – Part 5: Tests for In Vitro cytotoxicity
- ISO 10993-10:2010 Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
- ISO 14971:2007 Medical devices – Application of risk management to medical devices

Verification and validation testing includes:

- Software Verification and Validation Test
- Software Unit Test
- Integration Test
- System Test
- Wireless Coexistence Test
- Wireless Design Validation and Verification Test

Conclusion:

The performance of the Nihon Kohden Vital Sign Telemeter GZ-140P is substantially equivalent to the predicate devices, the Nihon Kohden BSM-6000 Series Bedside Monitor (K080342) and the Nihon Kohden Vital Sign Telemeter GZ-120P and GZ-130P (K153707), and raises no safety or effectiveness issues.