DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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September 2, 2016

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

Re: K153707
Trade/Device Name: Nihon Kohden Vital Sign Telemeter, GZ-120P / GZ-130P0
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, DRG
Dated: August 12, 2016
Received: August 15, 2016

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 yours,

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)*
K153707

Device Name
Nihon Kohden Vital Sign Telemeter GZ-120P, GZ-130P

Indications for Use *(Describe)*
The Nihon Kohden Vital Sign Telemeters GZ-120P and GZ-130P are 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. Both GZ-120P and GZ-130P transmit electrocardiogram (ECG) and respiration data, and GZ-130P transmits blood oxygen saturation (SpO2) in addition. 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 devices can be configured for use as a temporary simple monitor to display the patient's vital signs on the device screens and generate alarms without transmitting the data to other Nihon Kohden monitor.
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.

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510(k) Summary

Nihon Kohden Vital Sign Telemeter GZ-120P/GZ-130P

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:	September 01, 2016
Device name:	Nihon Kohden Vital Sign Telemeter GZ-120P/GZ-130P
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 ZS-940PA Transmitter (K043517)

Description:

The Nihon Kohden Vital Sign Telemeter GZ-120P/GZ-130P is mainly used as a telemetry system within a medical facility. The device transmits patient's vital signs (ECG, SpO_2*, respiration, pulse waveform) 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 for use as a temporary simple monitor.

*SpO_2 is for GZ-130P only.

Indications for Use:

The Nihon Kohden Vital Sign Telemeters GZ-120P and GZ-130P are 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. Both GZ-120P and GZ-130P

transmit electrocardiogram (ECG) and respiration data, and GZ-130P transmits blood oxygen saturation (SpO_2) in addition. 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 devices can be configured for use as a temporary simple monitor to display the patient's vital signs on the device screens and generate alarms without transmitting the data to other Nihon Kohden monitor.

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 Vital Sign Telemeter GZ-120P/GZ-130P is substantially equivalent to the predicate devices, Nihon Kohden BSM-6000 Series Bedside Monitor (K080342) and Nihon Kohden ZS-940PA Transmitter (K043517). Differences between the devices are minor and do not raise questions regarding safety or efficacy.

These differences include:

- The GZ-120P/GZ-130P provides less number of physiological parameters and less maximum traces than its predicates. It is because the device is smaller in size with a smaller screen when compared to the predicates. Its specifications of parameter measurements, ECG analysis and alarming function are equivalent to the predicate device, BSM-6000, one of Nihon Kohden's high-end patient monitoring device.

- The GZ-120P/GZ-130P has limited memory when compared to the predicate, BSM-6000 Bedside Monitor. This is because GZ-120P/GZ-130P is intended to transmit acquired data which are then saved at the central monitor. The other predicate, ZS-940PA is a telemeter and does not have any memory storage.

- The GZ-120P/GZ-130P uses radiofrequency wireless technology for its communication with central patient monitoring network to help portability of the device. The communication method is in compliance with the FCC rule and the associated risks are properly managed for successful validation of functional performance of the device.

- The water resistance specification of GZ-120P/GZ-130P is better than that of the predicates, and the improved function is evaluated by safety standard.

Test Summary:
Performance testing for the Nihon Kohden Vital Sign Telemeter GZ-120P/GZ-130P 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 IEC 60601-1-2

(Edition 4, 2014), 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:

1. ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)
2. IEC 60601-1-2:2007: Electromagnetic compatibility
3. IEC 60601-1-2:2014: Electromagnetic compatibility, enclosure port immunity to radiated RF EM fields and proximity fields from RF wireless communications equipment only.
4. IEC 60601-1-8: 2006 + Am1: 2012: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
5. IEC 60601-2-27: 2011: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment

Verification and validation testing includes:

1. Software Verification and Validation Test
2. Software Unit Test
3. Integration Test
4. System Test

Conclusion:

The performance of the Nihon Kohden Vital Sign Telemeter GZ-120P/GZ-130P is substantially equivalent to the predicate devices, the Nihon Kohden BSM-6000 Series Bedside Monitor and the Nihon Kohden ZS-940PA Transmitter, and raises no safety or effectiveness issues.