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

Nihon Kohden Corporation
Thomas Bento
Sr. Vice President, Quality and Regulatory Affairs
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Irvine, California 92618

February 24, 2017

Re: K161860
Trade/Device Name: TG-970P CO2 Sensor Kit
Regulation Number: 21 CFR 868.1400
Regulation Name: Carbon Dioxide Gas Analyzer
Regulatory Class: Class II
Product Code: CCK
Dated: January 23, 2017
Received: January 24, 2017

Dear Thomas 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,

Susan Runner DDS, MA

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 TG-970P CO2 Sensor Kit

Indications for Use *(Describe)*
The Nihon Kohden TG-970P CO2 sensor kit is intended for medical purposes to measure the concentration of carbon dioxide in a gas mixture to aid in determining the patient's ventilatory status. Along with other methods indicated by the physician for medical diagnosis, this device is intended as an indicator of patient carbon dioxide concentration during expiration.

The device is intended for use by qualified medical personnel within a hospital or clinical environment.

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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Traditional 510(k) Summary

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Date Prepared: February 22, 2017

Device Name: Nihon Kohden TG-970P CO_2 Sensor Kit

Common Name: Carbon Dioxide (CO_2) Gas Analyzer

Classification:

The device has been classified as Class II per the Division of Anesthesiology Devices.

Carbon Dioxide (CO2) Gas Analyzer	868.1400	CCK

Predicate Device(s): Nihon Kohden TG-970P CO_2 Sensor Kit (K122214)

1.0 Description of Device

The TG-970P CO2 Sensor Kit measures the partial pressure of the expired CO2 of the patient by measuring the amount of absorbed CO2 infrared light, using a CO2 feature which absorbs infrared light. It is comprised of three main components; a CO2 Sensor (photo detector and light emitter) with cable and connector, a CO2 adapter and an airway adapter (YG-211T, YG-213T and YG-214T) or mask (YG-232T and YG-242T).

The CO2 Sensor incorporates an infrared light source, of specified wavelength, and an infrared detector. It detects the infrared light from the light emitter which passes through the expired air in the airway adapter and calculates the partial pressure of the expired CO2. The photo detector and light emitter end of the CO2 Sensor is connected to the airway adapter or mask. The airway adapter is then connected between the patient airway and the respirator. The CO2 adapter processes the electrical signal of the detected infrared light into digital data which is sent to the instrument.

2.0 Indications For Use

The Nihon Kohden TG-970P CO2 sensor kit is intended for medical purposes to measure the concentration of carbon dioxide in a gas mixture to aid in determining the patient's ventilatory status. Along with other methods indicated by the physician for medical diagnosis, this device is intended as an indicator of patient carbon dioxide concentration during expiration.

The device is intended for use by qualified medical personnel within a hospital or clinical environment.

3.0 Technical Characteristics

The Nihon Kohden CO_2 Sensor Kit, model number TG-970P, is intended for medical purposes to measure the concentration of carbon dioxide in a gas mixture to aid in determining the patient's ventilatory (end tidal CO_2) status. The device measuring technique is through absorption of infrared radiation.

4.0 Substantial Equivalence

The technology, performance and materials of the Nihon Kohden TG-970P CO2 Sensor Kit, with airway adapters YG-213T and YG-214T, is substantially equivalent to the predicate device, the Nihon Kohden TG-970P CO2 Sensor Kit with airway adapter YG-213T (K122214). Differences between the devices are minor and are described below.

4.1 The new airway adapter YG-214T/TW is being added and is considered substantially equivalent to YG-213T/TW. The difference between the YG-213T/TW and YG-214T/TW is that the YG-214T/TW does not have an inner connection tube, which allows it to be connected to other types of respirators that have an existing inner connection tube. There is no change to the materials. It was assessed through design verification/validation testing that this modification does not impact the intended use of the device.

4.2 The dead space calculation for airway adapter YG-213T/TW has been updated to better simulate the clinical setting. The connection between the adapter and the endotracheal tube overlap in the respiration circuit and the actual dead space volume is decreased by the connecting parts. Bench testing was conducted to confirm the calculation. This change does not impact the intended use of the device.

4.3 The device durability of the airway adapter was improved by changing the outer shape where the user holds the device for connecting and disconnecting. The thickness of this area has increased. Bench testing was conducted to evaluate this change and this modification does not impact the intended use of the device.

4.4 The intended use of the TG-970P has not changed as a result of the above described modifications. The neonate/infant airway adapters, YG-213T/TW and YG-214T/TW, may be used for intubated neonates and infants, using an endotracheal tube size of ≤ 4.0 mm. It has been shown that the minimal dead space in the YG-213T/TW and YG-214T/TW airway adapters allows monitoring at low tidal volumes

which helps identify the intended patient population, as described in the literature review letter and bench testing. The proposed labeling for YG-213T/TW and YG-214T/TW would remove the current patient weight requirement of 2-7kg and recommend the intended population based on the endotracheal tube size and dead space volume of the airway adapters. The physician should determine the total dead space of the capnography setup with all other connected equipment to determine the appropriate airway adaptor based on the individual patients tidal volume and weight. Warnings and Caution statements are provided in the Operators Manual on p. 3.

5.0 Performance Testing

The following tests were identified and performed based on the modifications made to the device.

- Clinical evaluation for prototype of a new neonatal airway adapter with no inner tube, applied to patient mouth
- Confirmation of CO_2 waveform with YG-213T on the bench test
- Design change evaluation for YG-213T shape
- YG-214T bench test for CO2 waveform
- Airway adapter for neonate and infant YG-214T, 214-TW dead space volume
- Evaluation of reducing mechanical burden on the sensor part due to YG-214T shape change
- YG-214T/214-TW device detailed design specification conformity evaluation
- YG-211T/YG-213T/YG-214T Biocompatibility evaluation

6.0 Conclusions

The TG-970P CO_2 Sensor Kit was previously cleared in K122214 and the airway adapter (YG-213T/TW) cleared with the TG-970P is capable of accurately measuring CO_2 in the patient's airway during expiration. The technology of the photo detector and light emitter of the TG-970P has not changed. An additional accessory, airway adapter YG-214T/TW, has been shown to be equivalent to the predicate, YG-213T/TW.

The intended population for the YG-213T and YG-214T airway adapters is for neonates and infants. Removal of the patient weight from the labeling is supported by literature and similar products. Furthermore, a recommended endotracheal tube size has been added to the labeling. Additionally, the dead space has been updated for YG-213T, which also further identifies the intended patient population. The device durability was also improved by changing the outer shape where the user holds the device for connecting and disconnecting. Based on a literature review and verification/validation testing in compliance with the Design Control requirements, these airway adapters are shown to be equivalent in safety and effectiveness to the predicate device.

The technology, performance and materials of the Nihon Kohden TG-970P CO2 Sensor Kit, with airway adapters YG-213T and YG-214T, is substantially equivalent to the predicate device, the Nihon Kohden TG-970P CO2 Sensor Kit with airway adapter YG-213T (K122214).