510(k) Summary

MAY 2 1 2013

Company Name: Nihon Kohden Corporation
90 Icon Street
Foothill Ranch, CA 92610

Device Name: Nihon Kohden TG-970P CO_2 Sensor Kit w/new Airway Adaptor

510(k) Sponsor, Contact: Nihon Kohden America, Inc.
90 Icon Street
Foothill Ranch, CA 92610

Steve Geerdes
Director Quality Assurance and Regulatory Affairs
Phone: (949) 580-1555 Ext. 3325
Fax: (949) 580-1550

Summary Date: **Revised** 05/03/2013

Common Name: Carbon Dioxide (CO_2) Analyzer

Classification Names:

Anesthesiology Device	868.1400	CCK

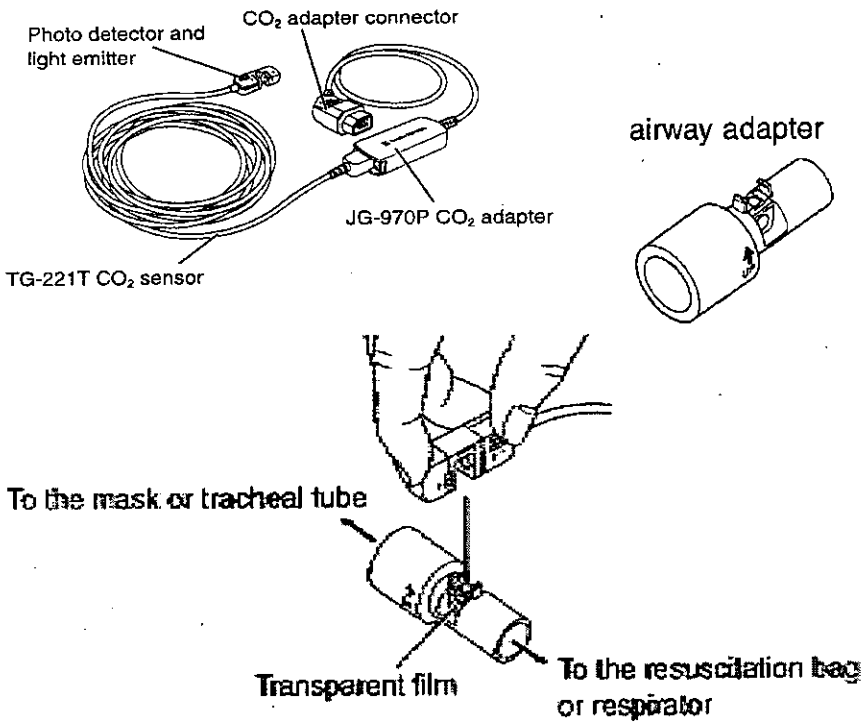
Predicate Device(s):

TG-970P CO_2 Sensor Kit	K083456

1.0 Description of Device

The TG-970P Series CO_2 Sensor Kit is comprised of three main components, a CO_2 Sensor (photo detector and light emitter) with cable and connector, a CO_2 Adapter and an airway adapter. The CO_2 Sensor incorporates an infrared light source, of specified wavelength, and an infrared detector. The photo detector and light emitter end of the CO_2 sensor is connected to an airway adapter. The airway adapter is connected between the patient airway and the respirator. As the patient completes an expiratory breath the sensor measures the CO_2 levels in the expiratory breath and sends that data to the CO_2 adapter. The adapter then reads the data and converts the data so it can be displayed on the patient monitor.

Depending on which airway adapter is used, the TG-970 can be used with patients weighing 2kg or more. The device is not recommended for patients weighing less than 2kg or patients with a respiration rate greater than 150 breaths per minute.



2.0 Intended Use of Device

The Nihon Kohden TG-970P and 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 and is available for use on any patient weighing 2kg or more.

3.0 Technical Characteristics

The Nihon Kohden CO_2 Sensor Kit, model number TG-970P Series, 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.

Technical Comparison

	Modified Device	**Predicate Device**	**Comments**
Product	**TG-970P with YG-213T airway adapter**	**TG-970P with YG-211T airway adapter (K#083456)**	
Intended Use	To measure the	Same	

	Modified Device	**Predicate Device**	**Comments**
Product	**TG-970P with YG-213T airway adapter**	**TG-970P with YG-211T airway adapter (K#083456)**	
	concentration of carbon dioxide in a gas mixture to aid in determining the patient's ventilatory status		
Use frequency	Single Patient Use	Same	
Shelf life	36 months	Same	
Population	YG-213T: For patients 2kg to 7kg.	For patients more than approx. 7kg.	Technology & materials are substantially equivalent to the predicate device. Validation/verification testing confirms that the accuracy of the measured gas is substantially equivalent to the predicate device. No new questions of safety or effectiveness were raised
Dead space	1mL	4mL	The change in dead space is due to smaller airway adapter. Validation/verification testing confirms that the smaller dead space does not affect the accuracy of the measured gas and is substantially equivalent to the predicate device. No new questions of safety or effectiveness were raised
Function	Airway adapter with windows which infrared light of the CO_2 sensor kit can pass through is connected to respiratory circuit.	Same	
Specifications			
Transmissivity	More than approx 45% (at 4.27um±0.02um)	Same	

	Modified Device	**Predicate Device**	**Comments**
Product	**TG-970P with YG-213T airway adapter**	**TG-970P with YG-211T airway adapter (K#083456)**	
Optical length	6mm±0.2mm	Same	
Ratio of antifogging performance : fog	Ratio of fog: less than 5%(at 15℃to35℃ 20% to 80RH 10 minutes later)	Same	
Ratio of antifogging performance : Wet	Ratio of Wet: less than +/-8% (at 15℃ to 35℃, 20% to 80RH 10 minutes later)	Same	

Environment			
Facility	Hospitals, Clinics, Physician office	Same Same Same	
Operating environment	10 to 40 degree C 30 to 85%RH, non condensing	Same	
Storage environment	-20 to 65 degree C 10 to 95%RH	Same	
Chemical resistance	This product cannot be cleaned or disinfected.	Same	
Sterilization	No	No	
Continuation use time	72 hours	24 hours	Validation/verification testing confirms that the accuracy of the measured gas is not changed with longer continuous use time. No new questions of safety or effectiveness were raised

4.0 Data Summary

Testing of the Nihon Kohden TG-970P with new YG-213T Neonatal/Infant Airway Adapter was performed in compliance with Nihon Kohden Corporation design control process. Testing included:

The device is in compliance with the following voluntary industrial standards:

Medical Electrical Equipment

IEC 60601-1	Part1: General requirements for safety 1998-12
IEC 60601-1, Amendment 1	Part 1: General Requirements for safety, Amendment 1, 1991-11
IEC 60601-1, Amendment 2	Part 1: General Requirements for safety, Amendment 2, 1995-03
ISO 10993-1	Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing, 2003-08
ISO 14971	Medical Devices - Application of Risk Management to Medical Devices, 2007

5.0 Conclusions

TG-970P CO_2 Sensor Kit was previously cleared in K083456 and the airway adaptor cleared with the TG-970P (YG-211T) is capable of accurately measuring CO_2 in the patient's airway during expiration on patients 7kg or larger. A new airway adapter (YG-213T) is being added to the TG-970P. This will allow the TG-970P to accurately measure CO_2 in the patient's airway during expiration on patients 2kg or larger.
The technology of the photo detector and light emitter of the TG-970P has not changed. The only change is the new YG-213T airway adapter which has under gone verification and validation testing.
Based on the comparison information in the technical comparison chart above and confirmed by verification/validation testing in compliance with the Design Control requirements. The intended use, technology and materials of the YG-213T Airway Adapter was shown to be equivalent in safety and effectiveness to the predicate devices YG-211T and YG-211TW which are accessories of the TG-970P CO2 Sensor Kit K083456 (TG-970P). No new questions of safety or effectiveness are raised.

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

May 21, 2013

Mr. Steve Geerdes
Director of Regulatory Affairs and Quality Assurance
Nihon Kohden Corporation
90 Icon Street
FOOTHILL RANCH CA 92610

Re: K122214
Trade/Device Name: Nihon Kohden TG-970P
Regulation Number: 21 CFR 868.1400
Regulation Name: Carbon Dioxide Gas Analyzer
Regulatory Class: II
Product Code: CCK
Dated: May 8, 2013
Received: May 9, 2013

Dear Mr. Geerdes:

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Kwame O. Ulmer -S for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): ____K122214_____

Device Name: ____ Nihon Kohden TG-970P__

Indications for Use:

The Nihon Kohden TG-970P and 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 and is available for use on any patient weighing 2kg or more.

Prescription Use ____X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use_____(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off
Office of In Device Evaluation
510(k)_____

Lester W. Schultheis Jr
2013.05.21 13:40:16 -04'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices
510(k) Number: K122214