K110594

OCT 2 8 2011

510(k) Summary

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

Device Name: GF-210R Multi-Gas Module for Nihon Kohden Bedside Monitors

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
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Summary Date: 9/14/2011

Common Name: Gas Analyzer, carbon dioxide, oxygen, nitrous oxide, enflurane, and halothane Gas analyzer

Classification Name:

868.1400	Analyzer, Gas, Carbon dioxide, Gaseous-Phase	CCK

Predicate Device(s):

Nihon Kohden AG-920RA	K#020046
Draeger SC 6802XL w/Scio	K#040188

1.0 Description of Device

The GF-210R Multi-Gas Module is a fully integrated anesthesia gas detection unit that measures Carbon dioxide (CO_2), nitrous oxide (N_2O), oxygen (O_2), and five anesthetic agents and displays the results on a Nihon Kohden bedside monitor.
The GF-210R is an enclosure that contains an OEM Gas Analyzer (Draeger Module # 6871620). There is a sample gas exhaust port that allows the GF-210R to sample gas from a anesthetic or respiration circuit through exhaust gas tube. A multi-link connector allows the GF-210R to comunicate the measured gas value and display the value on a Nihon kohden bedside monitor

1.1 Clinical Application

The GF-210R Multi-Gas Module is used to **mea**sure Carbon dioxide (CO_2), nitrous oxide (N_2O), oxygen (O_2), and any of five anesthetic agents and display the results on a bedside monitor.

This anesthesia gas detection unit samples and measures the concentration of gases administered to and respired by the patient during anesthesia. Infrared ray absorption detection method is used for carbon dioxide (CO_2), nitrous oxide (N_2O), and anesthetic agents (Halothane, Isoflurane, Enflurane, Sevoflurane, and Desflurane). Paramagnetic detection method is used for oxygen (O_2). Gases are monitored on a real time, breath-by-breath basis and the measured inspired and expired gas concentrations are displayed on the Nohon Kohden bedside monitor. The inspired and expired phases are detected from the instantaneous CO_2 concentration and respiration rate is counted from these phases.

The measured data is transferred to and displayed on a Nihon Kohden bedside monitor. User interface for controlling and displaying alarms, setting sampling rates and calibration are provided through the bedside monitor. All measured data (numerics and waveforms) are displayed and recorded through the bedside monitor.

2.0 Intended Use of Device

The Nihon Kohden GR-210R Multi-Gas Module is intended to measure carbon dioxide (CO_2), nitrous oxide (N_2O), oxygen (O_2), and following anesthetic agents (Halothane, Isoflurane, Enflurane, Sevoflurane, and Desflurane) of a patient undergoing anesthesia and display the results on a Nihon Kohden bedside monitor. The GF-210R can measure two anesthetic agents simultaneously.

The system is intended for use by qualified medical personnel within a hospital or clinical environment and is available for use on any patients as determined by the qualified medical personnel.

3.0 Technical Characteristics

The technical characteristics of the GF-210R are equivalent to those of the predicate devices. The following tables summarizes equivalence.

Comparison feature or specification	Predicate device (K#020046) Nihon Kohden AG-920RA	Predicate device (K040188) Draeger SC 6802XL w/Scio	New device Nihon Kohden GF-210R	Comments
<General>				
Host	Nihon Kohden "LifeScope" patient	Infinity Nodular Monitors	Nihon Kohden "LifeScope"	

	monitors	(SC7000, SC8000, SC9000XL)	patient monitors	
Power input	100 to 240 VAC	100-240 V, 50/60 Hz	Same	
Power Consumption	40VA	from specified power supply	70VA	
Operating Temperature	10 to 35 deg C	10 to 40 deg C	10 to 40 deg C	
Dimension	180 x 140 x 220 mm	115 x 190 x 270 mm	280 x 100 x 200 mm	
Weight	3.4 kg	3.457Kg	4.2 kg	
<Multigas measurement>				
OEM manufacturer of gas module	Artema Medical		Draeger Medical	
Measurement Parameters	Fi/ET CO2, N2O, O2, Anesthetic agents (Halothane, Isoflurane, Enflurane, Sevoflurane, Desflurane), Respiration Rate	Fi/ET CO2, N2O, O2, Anesthetic agents (Halothane, Isoflurane, Enflurane, Sevoflurane, Desflurane), Respiration Rate	Same	
Sampling Rate	Selectable : 70 to 200 mL/min Auto : 100 or 200 mL/min	200 mL/min	200 mL/min	
Warm-up time	45 Sec (Startup) 10 min (Full accuracy)	1 min (CO2 Startup) 6 min (Full accuracy)	1 min (CO2 Startup) 6 min (Full accuracy)	
CO2 Measurement				

Measurement method	Non-Dispersive Infrared Ray absorption	Non-Dispersive Infrared Ray absorption	Same	
Measuring range	0 to 76 mmHg	0 to 10%	0 to 10 Vol.% (Ref. 0 to 76 mmHg @ambient pressure 760mmHg)	The value using Vol. % is the spec by Draeger. See the value, which is converted to mmHg for reference.
Measuring accuracy	+/- 2 mmHg (0 to 40 mmHg) +/- 3 mmHg (40 to 55 mmHg) +/- 4 mmHg (55 to 76 mmHg)	+/- (0.5 Vol% or ±12% rel)	+/- (0.43 Vol.% + 8 % rel.) (Ref.+/-(3.3 mmHg + 8 % rel.) @ambient pressure 760 mmHg)	The value using Vol. % is the spec by Draeger. See the value, which is converted to mmHg for reference. Essential performance in EMC standard
Rise Time (10 to 90%)	250 ms @ 200mL/min	< 350 ms @ 150mL/min	350 ms	
N2O Measurement				
Measurement method	Non-Dispersive Infrared Ray absorption	Non-Dispersive Infrared Ray absorption	Same	
Measuring range	0 to 100 %	0 to 100 %	Same	
Measuring accuracy	+/- 3 vol.%	+/- (2 Vol.% + 8 % rel.)	+/- (2 Vol.% + 8 % rel.)	
Rise Time (10 to 90%)	250 ms @ 200mL/min	< 500 ms	500 ms	
O2 Measurement				
Measurement method	Paramagnetic	Paramagnetic sensor	Same	
Measuring range	0 to 100 %	0 to 100 %	5 to 100 %	

Measuring accuracy	+/- 2 vol.% (0 to 55 %) +/- 3 vol.% (55 to 100 %)	+/- 3 vol.%	+/- (2.5 Vol.% + 2.5 % rel.)	Essential performance in EMC standard
Rise Time (10 to 90%)	500 ms	< 600 ms @150mL/min	Same	
Anestetic Agent Measurement				
Measurement method	Non-Dispersive Infrared Ray absorption	Non-Dispersive Infrared Ray absorption	Same	
Agent Identification	Auto	Auto	Same	
Mixed Agent Measure.	Primary and Secondary	Primary and Secondary	Same	
Measuring range				
Halothane	0 to 5 %	0 to 8.5 %	0 to 8.5 %	
Isoflurane	0 to 5 %	0 to 8.5 %	0 to 8.5 %	
Enflurane	0 to 5 %	0 to 10 %	0 to 10.0 %	
Sevoflurane	0 to 8 %	0 to 10 %	0 to 10.0 %	
Desflurane	0 to 18 %	0 to 20 %	0 to 20.0 %	
Measuring accuracy	+/- 0.2 vol.% (0 to 5 %) +/- 0.4 vol.% (5 to 10 %) +/- 0.6 vol.% (10 to 15 %) +/- 1.0 vol.% (15 to 18 %)	+/- (0.15 Vol% +15 % rel.)	+/- (0.2 vol% +15.0 % rel.)	Essential performance in EMC standard
Rise Time (10 to 90%)	300 ms (Halothane, Isoflurane, Sevoflurane, Desflurane) @ 200mL/min 500 ms (Enflurane) @ 200mL/min	< 500 ms @ 150mL/min	500 ms	

Respiration Rate Measurement				
Measuring range	4 to 60 counts/min	0 to 90 Counts/min	Same	
Measuring accuracy	1 counts/min	1 Counts/min (0 to 60 counts/min) not specified (>60 counts/min)	Same	
MAC Calculation	available (only when used with BSM-6000)	available	available	

4.0 Data Summary

Testing of the Nihon Kohden System with the MS-120BK was performed in compliance with the Nihon Kohden Corporation design control process. Testing included:

1. Software and hardware verification and validation, and
2. Safety standard compliance

A summary of data supporting the safety of the Nihon Kohden GF-201R was provided.

5.0 Conclusions

The safety and effectiveness of the Nihon Kohden GF-210R was demonstrated by testing in compliance with the Design Control process. The intended use and technology of the Nihon Kohden GF-201R is equivalent to the predicate devices. 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 Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 28 2011

Mr. Steve Geerdes
Director Quality Assurance and Regulatory Affairs
Nihon Kohden Corporation
90 Icon Street
Foothill Ranch, California 92610

Re: K110594
Trade/Device Name: Nihon Kohden GF-210R Multi-Gas Module
Regulation Number: 21 CFR 868.1400
Regulation Name: Carbon Dioxide Gas Analyzer
Regulatory Class: II
Product Code: CCK
Dated: September 14, 2011
Received: September 20, 2011

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
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): _____K110594_____

Device Name: ____ Nihon Kohden GF-210R Multi-Gas Module__

Indications for Use:

The Nihon Kohden GR-210R Multi-Gas Module is intended to measure carbon dioxide (CO_2), nitrous oxide (N_2O), oxygen (O_2), and following anesthetic agents (Halothane, Isoflurane, Enflurane, Sevoflurane, and Desflurane) of a patient undergoing anesthesia and display the results on a Nihon Kohden bedside monitor. The GF-210R can measure two anesthetic agents simultaneously.

The system is intended for use by qualified medical personnel within a hospital or clinical environment and is available for use on any patients as determined by the qualified medical personnel..

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)

L Schultheiss

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

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K110594