June 10, 2025

Nihon Kohden Corporation
℅ Charlemagne Chua
Senior Manager, Regulatory Affairs
Nihon Kohden America, LLC
15353 Barranca Parkway
Irvine, California 92618

Re: K243956
Trade/Device Name: TG-980P CO2 Sensor Kit (TG-980P); TG-980P1 CO2 Sensor Kit (TG-980P1)
Regulation Number: 21 CFR 868.1400
Regulation Name: Carbon Dioxide Gas Analyzer
Regulatory Class: Class II
Product Code: CCK
Dated: May 16, 2025
Received: May 16, 2025

Dear Charlemagne Chua:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Bradley Q. Quinn -S

Bradley Quinn
Assistant Director
DHT1C: Division of Anesthesia,
Respiratory, and Sleep Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental Devices
Office of Product Evaluation and Quality
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243956

Device Name

TG-980P CO2 Sensor Kit (TG-980P);
TG-980P1 CO2 Sensor Kit (TG--980P1)

Indications for Use *(Describe)*

The Nihon Kohden TG-980P/TG-980P1 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, ambulatory care, transport, or any other 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.

510(k) SUMMARY

Administrative Information

Sponsor: Nihon Kohden Corporation
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Tokyo, Japan 161-8560
FDA Est. Registration: 9611252

Submitter: Nihon Kohden America, LLC
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Subject Device Information

Submission Type: Traditional 510(k)

Common Device Name: Analyzer, Gas, Carbon-Dioxide, Gaseous-Phase

Regulation Medical Specialty: Anesthesiology

Classification Panel: Anesthesiology

Product Codes: CCK

Premarket Review: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices (OHT1)
Division of Anesthesia, Respiratory, and Sleep Devices (DHT1C)

Regulation Number:	868.1400
Classification:	Class II
Decision Type:	510(k)
Proprietary Name:	TG-980P CO_2 Sensor Kit TG-980P1 CO_2 Sensor Kit
Reason for 510(k) Submission:	New Device
Previous 510(k) Submissions:	None
Predicate Device:	Nihon Kohden TG-970P Series CO_2 Sensor Kit (K083456)
Submission Date:	May 16, 2025

1. PRODUCT DESCRIPTION

The TG-980P and TG-980P1, collectively referred to as TG-980P/TG-980P1, are CO_2 Sensor Kits used to measure the concentration of carbon dioxide (CO_2 or CO2) during patient expiration. The TG-980P/TG-980P1 is intended for use by qualified medical personnel as an aid for determining patient ventilatory status within a hospital, ambulatory care, transport, or any other clinical environment.

The TG-980P/TG-980P1 CO_2 Sensor Kit comprises three main components: a CO_2 sensor, an interface connector, and a sensor cable. It utilizes the mainstream measurement method to sample gas directly from the patient's airway and non-dispersive infrared (NDIR) absorption technology to measure CO_2 concentration during patient expiration. CO_2 gas absorbs infrared light at specific wavelengths, and the amount absorbed is directly related to CO_2 concentration. The CO_2 sensor is equipped with a light source that generates infrared light. The light passes through an attached Nihon Kohden accessory (except the Thermal Airflow Sensor) through which the expired air flows and is converted by photodetectors to voltage, which is used to calculate CO_2 concentration. The calculated digital data is then transmitted and displayed on a connected patient monitor or other device.

The TG-980P/TG-980P1 CO_2 Sensor Kit can be connected via the interface connector and used with Nihon Kohden devices for which the operator's manual specifies compatibility with the TG-980P/TG-980P1.

2. INTENDED USE

The TG-980P/TG-980P1 CO_2 Sensor Kit is intended to be used under the control of a healthcare professional 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, the kits are intended as an indicator of patient carbon dioxide concentration during expiration.

3. INDICATIONS FOR USE

The Nihon Kohden TG-980P/TG-980P1 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, ambulatory care, transport, or any other clinical environment**.**

4. SUBMISSION SCOPE

Nihon Kohden (NK) is requesting market clearance for a new Nihon Kohden device, TG-980P/TG-980P1 CO2 Sensor Kit. The TG-980P/TG-980P1 CO2 Sensor Kit used to measure the concentration of carbon dioxide (CO2 or CO2) during patient expiration. The TG-980P/TG-980P1 is intended for use by qualified medical personnel as an aid for determining patient ventilatory status within a hospital, ambulatory care, transport, or any other clinical environment**.** Digital data is then transmitted and displayed on a connected patient monitor or other device.

5. COMPARISON WITH THE PREDICATE DEVICE

5.1 Subject Device Information

Table 4 provides the regulation and classification for the subject device TG-980P/TG-980P1 CO2 Sensor Kit.

Table 4 Regulatory Information on TG-980P/TG-980P1 CO2 Sensor Kit

Regulation	Product Code	Device Classification	Classification
§868.1400	CCK	Analyzer, Gas, Carbon-Dioxide, Gaseous-Phase	Class II (performance standards)

5.2 Predicate Device Information

Table 5 lists the basic information about the predicate device including 510(k) number, device name, 510(k) holder, and clearance date. Regulatory information used for comparison is provided in Table 6.

Table 5 Predicate Device General Information

510(k) Number	Device Name	510(k) Holder	Clearance Date
K083456	TG-970P CO_2 Sensor Kit	Nihon Kohden Corp.	March 2, 2009

Table 6 Predicate Device Regulatory Information

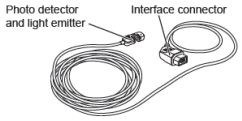
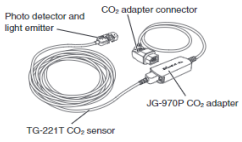
Regulation	Product Code	Device description	Classification
§868.1400	CCK	Analyzer, Gas, Carbon-Dioxide, Gaseous-Phase	Class II (performance standards)

5.3 Comparison Table

Table 7 Comparison Table of TG-980P/TG-980P1 CO2 Sensor Kit and its Predicate

Description	**Subject Device** **TG-980P/TG-980P1**	**Predicate Device** **TG-970P (K083456)**	**Reference Device** **TG-970P (K161860)**	**Comments:**
Trade/ Device Name	Nihon Kohden TG-980P/TG-980P1 CO_2 Sensor Kit	Nihon Kohden TG-970P Series CO_2 Sensor Kit	Nihon Kohden TG-970P Series CO_2 Sensor Kit	**Different** The model numbers differ for product identification.
Regulatory Class	Class II	Class II	Same as Predicate Device	Same
Product Code	CCK (868.1400)	CCK (868.1400)	Same as Predicate Device	Same
Intended Use	The TG-980 Series CO_2 Sensor Kit is intended to be used under the control of a healthcare professional 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, the kits are intended as an indicator of patient carbon dioxide concentration during expiration.	The Nihon Kohden TG-970P Series CO_2 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.	Same as Predicate Device	**Different** Although the wording has changed slightly, the intended use is equivalent in its meaning.

Description	**Subject Device** **TG-980P/TG-980P1**	**Predicate Device** **TG-970P (K083456)**	**Reference Device** **TG-970P (K161860)**	**Comments:**
Indications for Use	The Nihon Kohden TG-980P/980P1 CO_2 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, ambulatory care, transport, or any other clinical environment.	The Nihon Kohden TG-970P Series CO_2 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 Nihon Kohden TG-970P CO_2 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.	**Different** The intended use environments of TG-980P/TG-980P1 were clarified and the emergency environment, such as ambulatory care or transport, was added.
Type of Use	Prescription Device Only	Prescription Device Only	Prescription Device Only	Same
Intended Population	Neonates to adults. All types of genders, races, and languages.	Adult and children patients 7 kg or more	Adults, children, infants and neonates	**Different** from Predicate Same as Reference device

Description	**Subject Device** **TG-980P/TG-980P1**	**Predicate Device** **TG-970P (K083456)**	**Reference Device** **TG-970P (K161860)**	**Comments:**
Patient Contact	Intubated/ Non-intubated	Intubated	Intubated/ Non-intubated	**Different** from Predicate Same as Reference device
Configuration	CO_2 sensor Connector Sensor Cable	CO_2 sensor Connector Sensor cable CO_2 adapter	Same as Predicate Device	**Different**
Dimension	CO_2 sensor: 37×8.3×13.7 mm ±10%  	CO_2 Sensor: 37 x 8.3 x 13.7 mm ±10% CO2 Adapter: 77.3 x 30 x 15.8 mm ± 10%  	Same as Predicate Device	**Different** The size of the CO_2 sensor of TG-980P/TG-980P1 is equivalent to Predicate.
Weight	65 g±10 g (with cable and connector) (Sensor part: 4 g ±2 g)	120 g ± 10% (with cable and connector) (Sensor part: 4 g ±1 g)	Same as Predicate Device	**Different** Weight is slightly lower for a lightweight product. The weight tolerance of sensor part was adjusted. .

Description	**Subject Device** **TG-980P/TG-980P1**	**Predicate Device** **TG-970P (K083456)**	**Reference Device** **TG-970P (K161860)**	**Comments:**
Principle of operation				
Sampling method	Mainstream infrared absorption	Mainstream infrared absorption	Same as Predicate Device	Same
Measurement principle	Single-wave spectroscopic method (Non-dispersive infrared gas analyzing method (NDIR))	Single-wave spectroscopic method (Non-dispersive infrared gas analyzing method (NDIR))	Same as Predicate Device	Same
CO2 measurement method	Quantitative method	Quantitative method	Same as Predicate Device	Same
Calibration	YES	YES	Same as Predicate Device	Same
CO_2 Measurement				
$EtCO_2$ determination	YES	YES	Same as Predicate Device	Same
No Breath detect	YES	YES	Same as Predicate Device	Same
No Breath detect limit	CO_2 < 5 mmHg for ≥ 20 msec	CO_2 < 5 mmHg for ≥ 20 msec	Same as Predicate Device	Same
Response ($EtCO_2$ Response/ Rise time)	60 msec	120 msec	Same as Predicate Device	**Different** TG-980P/TG-980P1 response is faster than TG-970P. This function does not affect the monitoring function.

Description	**Subject Device** **TG-980P/TG-980P1**	**Predicate Device** **TG-970P (K083456)**	**Reference Device** **TG-970P (K161860)**	**Comments:**
CO_2 partial pressure measuring range	0 to 20 kPa (0 to 150 mmHg)	0 to 20 kPa (0 to 150 mmHg)	Same as Predicate Device	Same
CO_2 partial pressure measuring accuracy	±0.27 kPa (0 ≤ CO_2 ≤ 5.33 kPa) (±2 mmHg (0 ≤ CO2 ≤ 40 mmHg)) ±5% of gas level (5.33 < CO_2 ≤ 9.33 kPa (40 < CO_2 ≤ 70 mmHg)) ±7% of gas level (9.33 < CO_2 ≤ 13.3 kPa (70 < CO_2 ≤ 100 mmHg)) ±10% of gas level (13.3 < CO_2 ≤ 20 kPa (100 < CO_2 ≤ 150 mmHg)) (noncondensing)	±0.27 kPa (0 ≤ CO_2 ≤ 5.33 kPa) (±2 mmHg (0 ≤ CO2 ≤ 40 mmHg)) ±5% of gas level (5.33 < CO_2 ≤ 9.33 kPa (40 < CO_2 ≤ 70 mmHg)) ±7% of gas level (9.33 < CO_2 ≤ 13.3 kPa (70 < CO_2 ≤ 100 mmHg)) ±10% of gas level (13.3 < CO_2 ≤ 20 kPa (100 < CO_2 ≤ 150 mmHg)) (noncondensing)	Same as Predicate Device	Same
Respiration Rate Measurement				
Respiration Rate* measuring range	0 to 150 breaths/min	0 to 150 breaths/min	0 to 150 breaths/min	Same *Value determination from 510(k) Cleared host devices.
Respiration Rate* measuring accuracy	±1 breath/min	±1 breath/min	±1 breath/min	Same *Value determination from 510(k) Cleared host devices.
Operation/Storage				
Power	Auxiliary device attachment provides power	Auxiliary device attachment provides power	Auxiliary device attachment provides power	Same

Description	**Subject Device** **TG-980P/TG-980P1**	**Predicate Device** **TG-970P (K083456)**	**Reference Device** **TG-970P (K161860)**	**Comments:**
Total system response time	≤ 0.5 seconds	≤ 0.5 seconds	Same as Predicate Device	Same
Data communication interval (Data sampling rate)	TG-980P: 25 msec (40 Hz) TG-980P1:16 msec (62.5 Hz)	25 msec (40 Hz)	Same as Predicate Device	Same for TG-980P **Different** for TG-980P1 TG-980P1 communication interval (16 msec) is shorter than the Predicate (25 msec).
Warm-up time	TG-980P: About 10 seconds TG-980P1: About 5 seconds	10 seconds	Same as Predicate Device	Same for TG-980P **Different** for TG-980P1 TG-980P1 has a shorter Warm-up time but this does not affect the CO_2 measurement on a host device.
Operation environment	Temperature: 0 to 40°C Humidity: 15 to 95% (non-condensing) Atmosphere pressure: 70 to 106 kPa	Temperature:0 to 40°C Humidity: 30 to 85%RH (non-condensing) Atmosphere pressure: 70 to 106 kPa	Same as Predicate Device	**Different** for humidity TG-980P/TG-980P1 series has a wider range in upper and lower limits of humidity. operation environment and the equivalency was demonstrated.

Description	**Subject Device** **TG-980P/TG-980P1**	**Predicate Device** **TG-970P (K083456)**	**Reference Device** **TG-970P (K161860)**	**Comments:**
Storage environment	Temperature: -25 to 65°C Humidity:10 to 95% (non-condensing) Atmosphere pressure: 70 to 106 kPa	Temperature: -20 to 65°C Humidity:10 to 95%RH (non-condensing) Atmosphere pressure: 70 to 106 kPa	Same as Predicate Device	**Different** in temperature TG-980P/TG-980P1 has a wider range in upper and lower limits of temperature for storage environments.

6. PERFORMANCE

6.1 Summary of Non-Clinical Performance Testing

Nihon Kohden conducted non-clinical bench testing for the finished TG-980P/TG-980P1 CO_2 Sensor Kit as part of the design verification and validation activities. The TG-980P/TG-980P1 CO_2 Sensor Kit was evaluated for reprocessing & shelf-life, biocompatibility, software & firmware, cybersecurity & interoperability, electromagnetic compatibility & electrical, mechanical, wireless & thermal safety, system connection, and usability performance, as well as compatibility with the Nihon Kohden bedside monitors. The same test methods and specifications were used as for the predicate device, establishing equivalency of the TG-980P/TG-980P1 CO_2 Sensor Kit to the predicate. These tests were performed according to the international and FDA-recognized consensus standards listed in Table 8.

Table 8 Applied Standards and Guidance List for the TG-980P/TG-980P1 CO2 Sensor Kit

No.	Recognized Consensus (Rec) Standard Number	Description
1	19-49	IEC 60601-1 Edition 3.2 2020-08, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
2	19-46	ANSI AAMI ES60601-1:2005/ (R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/ (R)2012 (Cons. Text) (Incl. AMD2:2021), Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD) (Including Amendment 2 (2021))
3	1-140	ISO 80601-2-55 Second edition 2018-02, Medical electrical equipment - Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors
4	19-36	IEC 60601-1-2 Edition 4.1 2020-09, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests Identical adoption : ANSI AAMI IEC 60601-1-2:2014 (Including AMD 1:2021)
5	19-39	IEC 60601-1-12 Edition 1.1 2020-07, Medical electrical equipment - Part 1-12: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment Identical adoption: ANSI AAMI IEC 60601-1-12:2016 (Including AMD 1:2021)

No.	Recognized Consensus (Rec) Standard Number	Description
6	2-258	ISO 10993-1 Fifth edition 2018-08, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process Identical adoption: ANSI AAMI ISO 10993-1: 2018
7	5-125	ISO 14971 Third Edition 2019-12, Medical devices - Application of risk management to medical devices Identical adoption: ANSI AAMI ISO 14971:2019
8	5-129	IEC 62366-1 Edition 1.1 2020-06, Medical devices - Part 1: Application of usability engineering to medical devices Identical adoption: ANSI AAMI IEC 62366-1: 2015 + AMD1: 2020
9	5-132	IEC 60601-1-6 Edition 3.2 2020-07, Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
10	13-79	IEC 62304 Edition 1.1 2015-06, Medical device software - Software life cycle processes Identical adoption : ANSI AAMI IEC 62304:2006/A1:2016
11	14-579	ISO 17664-2 First edition 2021-02, Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 2: Non-critical medical devices.

7. SUBSTANTIAL EQUIVALENCE DISCUSSION

The comparison of the TG-980P/TG-980P1 CO_2 Sensor Kit to its predicate device (TG-970P CO_2 Sensor Kit / K033456) and the discussion of the key aspects are presented in the following sections.

7.1 Discussion for Intended Use

The TG-980P/TG-980P1 CO_2 Sensor Kit has the same Intended Use as the predicate device.

7.2 Discussion for Indications for Use

The TG-980P/TG-980P1 CO2 Sensor Kit has the same Indications for Use as the predicate device.

7.3 Discussion for Technological Characteristics

The TG-980P/TG-980P1 CO2 Sensor has the same Technological Characteristics as the predicate device.

7.4 Discussion for Design Characteristics

The predicate device, reference device and TG-980P/TG-980P1 CO2 Sensor Kit have very similar design characteristics. There were changes to the physical dimensions. The dimensional changes and design changes do not impact the safety and effectiveness of the TG-980P/ TG-980P1 CO2 Sensor Kit when compared to the predicate device.

7.4.1 When compared to the predicate and reference devices, the overall size of the TG-980P/TG-980P1 CO2 Sensor Kit is smaller, and the device configuration has changed. This is due to the removal of the CO2 adapter from the subject device.

7.4.2 When compared to the predicate and reference devices, the overall weight of the TG-980P/TG-980P1 CO2 Sensor Kit is lighter. This is a design improvement to make the subject device more lightweight.

7.5 Discussion for Compatible Device

The predicate device, reference device and TG-980P/TG-980P1 CO2 Sensor Kit require the devices to be connected to a Nihon Kohden host device to display the measured data. The differences do not impact the safety and effectiveness of the TG-980P/TG-980P1 CO2 Sensor Kit when compared to the predicate device.

7.6 Discussion for Performance Specifications

The predicate device, reference device and TG-980P/TG-980P1 CO2 Sensor Kit have similar CO2 measurement specifications. The predicate and reference devices have a slower response time when EtCO2 is measured. The difference does not impact the safety and effectiveness of the TG-980P/TG-980P1 CO2 Sensor Kit when compared to the predicate device.

8. CONCLUSION

The results of the substantial equivalence assessment, taken together with non-clinical bench testing, electrical safety and EMC, and electromagnetic compatibility, software verification, and validation demonstrate that the TG-980P/TG-980P1 CO2 Sensor Kit does not raise concerns regarding its safety and effectiveness when compared to its predicate device and operates in accordance with claimed indications for use. Nihon Kohden believes that the TG-980P/ TG-980P1 CO2 Sensor Kit is substantially equivalent to the TG-970P predicate and reference devices.