August 12, 2026

Nihon Kohden Corporation
Charlemagne Chua
Senior Manager, Regulatory Affairs
1-31-4 Nishiochiai, Shinjuku-Ku
Tokyo, 161-8560
Japan

Re: K251641
Trade/Device Name: GF-310R Multigas Unit (GF-310R)
Regulation Number: 21 CFR 868.1400
Regulation Name: Carbon Dioxide Gas Analyzer
Regulatory Class: Class II
Product Code: CCK
Dated: July 11, 2026
Received: July 13, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

for 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

# Indications for Use

| | |
|---|---|
| Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions. | K251641 |

Please provide the device trade name(s).

GF-310R Multigas Unit (GF-310R)

Please provide your Indications for Use below.

The GF-310R Multigas Unit is intended to measure carbon dioxide (CO2), nitrous oxide (N2O), oxygen (O2), 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-310R can measure two anesthetic agents simultaneously.

The GF-310R 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.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

# 510(k) SUMMARY

## Administrative Information

**Sponsor:**
Nihon Kohden Corporation
1-31-4 Nishiochiai, Shinjuku-Ku
Tokyo, Japan 161-8560
FDA Est. Registration: 9611252

**Submitter:**
Nihon Kohden America, LLC
15353 Barranca Parkway
Irvine, CA 92618
FDA Est. Registration: 2080783

**Primary Correspondent /U.S. Agent:**
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Irvine, CA 92618
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Email: charlemgne_chua@nihonkohden.com

## 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)<br>Division of Anesthesia, Respiratory, and Sleep Devices (DHT1C) |
| **Regulation Number:** | 868.1400 |
| **Classification:** | Class II |
| **Decision Type:** | 510(k) |

| | |
|---|---|
| **Proprietary Name:** | GF-310R Multigas Unit |
| **Reason for 510(k) Submission:** | New Device |
| **Previous 510(k) Submissions:** | None |
| **Predicate Device:** | Nihon Kohden GF-210R Multigas Module (K110594) |
| **Submission Date:** | August 12, 2026 |

## 1. PRODUCT DESCRIPTION

The GF-310R Multigas Unit is a device that measures respiration gas concentration. Respiration gas concentration monitoring is mainly used in the operating room to continuously monitor the concentration of oxygen ($O_2$), carbon dioxide ($CO_2$), nitrous oxide ($N_2O$) and volatile anesthetic agents (halothane, enflurane, isoflurane, sevoflurane and desflurane) in the gas inspired by a patient who is being administered anesthetic agents.

The GF-310R unit works by detecting the expiratory and inspiratory phases of respiration from momentary concentrations, calculating the rate of respiration and determining the concentration of each component during inspiration and at exhalation. This monitoring information is displayed on the compatible bedside monitor on the same view screen as other vital signs such as ECG and blood pressure. While the GF-310R is connected to the bedside monitor, error messages from the GF-310R are displayed on the bedside monitor.

The GF-310R Multigas Unit can be connected and used only with compatible Nihon Kohden bedside monitors whose operator's manual specifies that this unit can be used with the monitor.

## 2. INDICATIONS FOR USE / INTENDED USE

The GF-310R Multigas Unit 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-310R can measure any two anesthetic agents simultaneously.

The GF-310R 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. SUBMISSION SCOPE

Nihon Kohden (NK) is requesting market clearance for a new Nihon Kohden device, GF-310R Multigas Unitand accessories. Required Accessories of the GF-310R include the sampling line, water trap, T-piece, exhaust gas tube, connection cable, and power cord. Optional Accessories of the GF-310R include the ground lead (clip type), cart, cart adapter, mount adapter, and GF holder. The GF-310R communicates with compatible Nihon Kohden devices using a connection cable.

## 4. COMPARISON WITH THE PREDICATE DEVICE

### 4.1 Subject Device Information

Table 4 provides the regulation and classification for the subject device GF-310R.

**Table 4 Regulatory Information on GF-310R**

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

### 4.2 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 |
|---|---|---|---|
| K110594 | GF-210R Multi-Gas Module | Nihon Kohden Corp. | October 28, 2011 |

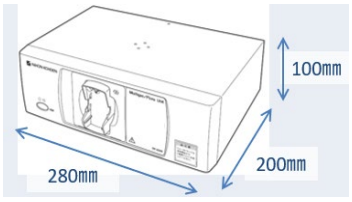
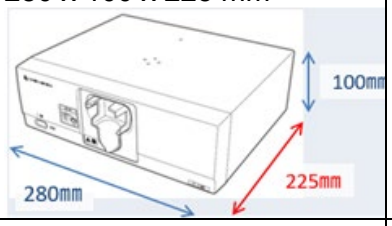
**Table 6 Predicate Device Regulatory Information**

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

## 4.3 Comparison Table

**Table 7 Comparison Table of GF-310R Multigas Unit and its Predicate**

| Criteria | Predicate Device Nihon Kohden GF-210R K110594 | Subject Device Nihon Kohden GF-310R | Remarks |
|---|---|---|---|
| **Regulation Items** | | | |
| **Device Name** | Nihon Kohden GF-210R Multigas Module | Nihon Kohden GF-310R Multigas Unit | N/A |
| | | | |
| **Classification Panel** | Anesthesiology | Anesthesiology | Same |
| **Common Device Name** | Analyzer, Gas, Carbon-Dioxide, Gaseous-Phase | Analyzer, Gas, Carbon-Dioxide, Gaseous-Phase | Same |
| **Regulatory Class** | Class II (performance standards) | Class II (performance standards) | Same |
| **Regulatory Number** | 21CFR 868.1400 – Carbon Dioxide Gas Analyzer | 21CFR 868.1400 – Carbon Dioxide Gas Analyzer | Same |
| **Product Code** | CCK - Analyzer, Gas, Carbon-Dioxide, Gaseous-Phase | CCK - Analyzer, Gas, Carbon-Dioxide, Gaseous-Phase | Same |
| **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.<br>The GF-210R can measure two anesthetic agents simultaneously.<br>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. | The GF-310R Multigas Unit 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.<br>The GF-310R can measure two anesthetic agents simultaneously.<br>The GF-310R 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. | Same |

| Criteria | Predicate Device<br>Nihon Kohden GF-210R<br>K110594 | Subject Device<br>Nihon Kohden GF-310R | Remarks |
|---|---|---|---|
| | | | |
| **General** | | | |
| **Appearance** |  |  | **Change:** The photo is for reference use only. |
| **Host Monitoring Core Units** | Nihon Kohden "Life Scope" Patient Monitors: BSM-3000, BSM-6000, BSM-9101, CSM-1900 | Nihon Kohden Life Scope® Bedside Monitors: CSM-1901, G5 Series, G7 Series, BSM-3000 series, and BSM-6000 series | **Change:** A host monitor is required for both GF-210R and GF-310R to work. Each of the host monitors are indicated to monitor $CO_2$ and are not considered a significant difference. |
| **Power input** | 100-240 V, 50/60 Hz<br>US cord | 100-240 V, 50/60 Hz<br>US cord | Same |
| **Power Consumption** | 70VA | 70VA | Same |
| **Operating Temperature** | 10 to 40°C | 10 to 40°C | Same |
| **Operating Humidity** | 30 to 85% | 30 to 85% | Same |
| | 280 x 100 x 200 mm<br>  | 280 x 100 x 225 mm<br>  | **Change:** The dimensions are different and not considered a significant different. |
| | 4.2 kg | 3.9 Kg | **Change:** The weight is different and not considered a |

| Criteria | Predicate Device<br>Nihon Kohden GF-210R<br>K110594 | | Subject Device<br>Nihon Kohden GF-310R | | Remarks |
|---|---|---|---|---|---|
| | | | | | significant difference |
| **Multigas Measurement** | | | | | |
| **Measurement Parameters** | Fi/ET $CO_2$, $N_2O$, $O_2$, Anesthetic agents (Halothane, Isoflurane, Enflurane, Sevoflurane, Desflurane), Respiration Rate | | Fi/ET $CO_2$, $N_2O$, $O_2$, Anesthetic agents (Halothane, Isoflurane, Enflurane, Sevoflurane, Desflurane), Respiration Rate | | Same |
| **MAC Calculation** | Available | | Available | | Same |
| **Sampling Rate** | 200 mL/min | | 200 mL/min | | Same |
| **Warm-up Time** | 1 min ($CO_2$ Startup)<br>6 min (Full accuracy) | | 1 min ($CO_2$ Startup)<br>6 min (Full accuracy) | | Same |
| **Anesthetic 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 |
| **Volatile Anesthetic Agent Measurement** | | | | | |
| **Measuring Range** | Halothane<br>Isoflurane | 0 to 8.5% | Halothane<br>Isoflurane | 0 to 8.5% | Same |
| | Enflurane<br>Sevoflurane | 0 to 10.0% | Enflurane<br>Sevoflurane | 0 to 10.0% | Same |
| | Desflurane | 0 to 20.0% | Desflurane | 0 to 20.0% | Same |
| **Measuring Accuracy** | +/- (0.2 vol% +15.0% rel.) | | +/- (0.2 vol% +15.0% rel.) | | Same |
| **Rise Time (10 to 90%)** | < 500 ms | | < 500 ms (Enflurane, Isoflurane, Sevoflurane, Desflurane)<br><br>< 550 ms (Halothane) | | **Change**: Halothane rise time slightly increased but there is no significant impact on monitoring function |
| **Respiration Rate Measurement** | | | | | |

| Criteria | Predicate Device<br>Nihon Kohden GF-210R<br>K110594 | Subject Device<br>Nihon Kohden GF-310R | Remarks |
|---|---|---|---|
| **Measuring Range** | 4 to 60 counts/min | 4 to 60 counts/min | Same |
| **Measuring Accuracy** | 1 counts/min | 1 counts/min | Same |

# 5. PERFORMANCE

## 5.1 Summary of Non-Clinical Performance Testing

Nihon Kohden conducted non-clinical bench testing for the finished GF-310R as part of the design verification and validation activities. The GF-310R was evaluated for gas monitoring measurement, risk management and mitigation, 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 GF-310R 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 GF-310R**

| Recognition Number | Description |
|---|---|
| **Standard** | |
| 5-125 | ISO 14971:2019 Medical devices - Application of risk management to medical devices |
| 13-79 | IEC 62304:2006/A1:2015 Medical device software -Software life cycle processes |
| 19-46 | ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010 /(R)2012 Medical electrical equipment—Part 1: General requirements for basic safety and essential performance |
| 19-49 | IEC 60601-1: 2005 + A1: 2012 + A2: 2020<br>Medical electrical equipment—Part 1: General requirements for basic safety and essential performance |
| 19-36 | IEC 60601-1-2:2014 + A1: 2020 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests |
| 5-129 | ANSI/AAMI/IEC 62366-1:2015 + A1: 2020, Medical devices –Part 1: Application of usability engineering to medical devices. |
| 1-140 | ISO 80601-2-55:2018 Medical Electrical Equipment - Part 2-55: Particular Requirements for the Basic Safety & Essential Performance of Respiratory Gas Monitors |
| 2-258 | ISO 10993-1: 2018 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process |
| - | ISO 18562 series (2017) Biocompatibility evaluation of breathing gas pathways in healthcare applications |
| **Guidance** | |
| “General Principles of Software Validation” issued January 11, 2002 | |
| “Content of Premarket Submissions for Software Contained in Medical Devices” issued May 11, 2005 | |
| “Content of Premarket Submissions for Device Software Functions” Issued June 14, 2023 | |
| “Content of Premarket Submissions for Management of Cybersecurity in Medical Devices” issued October 2, 2014 | |

| Recognition Number | Description |
|---|---|
| “Cybersecurity in Medical devices: Quality System Considerations and Contents of Premarket Submissions” issued September 27, 2023 | |
| “Postmarket Management of Cybersecurity in Medical Devices” issued December 28, 2016 | |
| “Off-The-Shelf Software Use in Medical Devices” issued August 11, 2023. | |
| “Electromagnetic Compatibility (EMC) of Medical Devices” issued June 6, 2022. | |
| “Applying Human Factors and Usability Engineering to Medical Devices” issued February 3, 2016 | |

## 6. SUBSTANTIAL EQUIVALENCE DISCUSSION

The comparison of the GF-310R Multigas Unit to its predicate device (GF-210R Multigas Unit/ K110594) and the discussion of the key aspects are presented in the following sections.

### 6.1 Discussion for Intended Use / Indications for Use

The GF-310R has the same Indications for Use as the predicate device.

### 6.2 Discussion for Technological Characteristics

The GF-310R has the same Technological Characteristics as the predicate device.

### 6.3 Discussion for Design Characteristics

The GF-310R Multigas Unit has very similar design characteristics as the predicate device. There were changes to the physical dimensions, design of the water trap and software changes (in zero calibration timing and time intervals for gas measurement). The water trap for the predicate device GF-210R is developed by Drager, but the water trap for the subject device GF-310R is developed by Nihon Kohden. The shape is different, but the function is the same. The dimensional changes and design changes do not impact the safety and effectiveness of the GF-310R Multigas Unit when compared to the predicate device.

### 6.4 Discussion for Compatible Devices

The GF-310R Multigas Unit and predicate device are both required to be connected to a Nihon Kohden bedside monitor to display the measured data. While there are other Nihon Kohden bedside monitors that are referenced with the GF-310R, the beside monitors provide the same functionality. There is no impact to safety and effectiveness of the GF-310R Multigas Unit when compared to the predicate device.

### 6.5 Discussion for Performance Specifications

The GF-310R Multigas Unit and predicate device have similar performance specifications in measuring the gases ($CO_2$, $N_2O$ and $O_2$) and anesthetic agents (halothane, enflurane, isoflurane, sevoflurane and desflurane). Both the predicate device and GF-310R can measure two anesthetic agents simultaneously. The differences do not raise additional risks that may impact the safety and effectiveness of the GF-310R.

## 7. CONCLUSION

The results of the substantial equivalence assessment, taken together with non-clinical bench testing, electrical safety, and electromagnetic compatibility, software verification, and validation demonstrate that the GF-310R does not raise concerns regarding its safety and effectiveness compared to its predicate device and operates in accordance with claimed indications for use.