



August 28, 2025

Prior Care Science Technology LTD
John Liu
RA Manager
Area F2 ,2F, Building 1, Bao'an Avenue Industrial Zone,
Yabian Xueziwei, Yabian Community, Shajing Subdictrict, Bao'
Shenzhen, GD 518101
China

Re: K250148
Trade/Device Name: Medical Gas Analyzer (AG200)
Regulation Number: 21 CFR 868.1400
Regulation Name: Carbon Dioxide Gas Analyzer
Regulatory Class: Class II
Product Code: CCK, CBR, CBS, CBQ, NHQ, NHP, NHO
Dated: July 23, 2025
Received: July 23, 2025

Dear John Liu:

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

Indications for Use

Submission Number (if known)

K250148

Device Name

Medical Gas Analyzer (AG200)

Indications for Use (Describe)

The Medical Gas Analyzer is intended to be connected to other medical devices for monitoring of the breathing gases CO₂, N₂O and the anesthetic agents Halothane, Enflurane, Isoflurane, Sevoflurane and Desflurane.

It is intended to be connected to a patient breathing circuit for monitoring of inspired/expired gases during anesthesia, recovery and respiratory care. It may be used in the operating suite, intensive care unit and patient room for adult, pediatric and infant patients. The CO₂ may also be used in the emergency medical services environment and road ambulances.

Note: The Medical Gas Analyzer shall only be connected to medical devices approved by Prior-care.

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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510(k) Summary

This summary of 510(k) information is submitted as required by requirements of 21 CFR 807.92.

1. Submitter's Identification

Applicant: Prior Care Science Technology LTD
Address: Area F2 ,2F, Building 1, Bao'an Avenue Industrial Zone,
Yabian Xueziwei, Yabian Community, Shajing Subdistrict, Bao'an
District, Shenzhen City, Guangdong Province, China

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General Manager
Tel: +86-13787119781
E-mail: jacky@prior-care.com
Prepared by: Mr. John Liu
E-mail: john0086@aliyun.com
Company: Prior Care Science Technology LTD

Date prepared: July. 18, 2025

2. Subject device information

Device: Multigas Monitor
Device Trade Name: Medical Gas Analyzer
Model: AG200
Regulation Name: Carbon dioxide gas analyzer
Regulatory Class: II
Product Code: CCK
Regulation Number: 21 CFR 868.1400
Review Panel: Anesthesiology

3. Predicate device information

- Predicate device

510(k) Number: K123043

Trade/ Device Name: IRMA-Infrared Mainstream Gas Analyzer

Manufacturer: PHASEIN AB/ Masimo Sweden AB

Regulation Name: Carbon dioxide gas analyzer

Regulatory Class: II

Product Code: CCK

Regulation Number: 21 CFR 868.1400

Review Panel: Anesthesiology

- Reference device

510(k) Number: K042601

Trade/ Device Name: CAPNOSTAT 5 CO₂ sensor

Manufacturer: Respironics Novamatrix, LLC

Regulation Name: Carbon dioxide gas analyzer

Regulatory Class: II

Product Code: CCK

Regulation Number: 21 CFR 868.1400

Review Panel: Anesthesiology

4. Device description

The Medical Gas Analyzer is a mainstream respiratory gas analyzer based on infrared gas spectrometry. It is intended to be connected to another medical host device for display of respiratory parameters. It is connected to the patient breathing circuit via the Airway Adapter. This premarket submission adds the C50 Multi-parameter Patient Monitor as a host backboard display to AG200. The C50 Multi-parameter Patient Monitor produced by Shenzhen Comen Medical Instruments Co., Ltd., which has obtained FDA's 510K clearance (K191106).

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The concentrations of CO₂, N₂O, Halothane, Enflurane, Isoflurane, Sevoflurane and Desflurane can be determined together with derived parameters such as waveform data and inspired / expired concentrations of all gases.

The mainstream probe airway adapter is inserted between the endotracheal tube and the breathing circuit, and the gas measurements are obtained through the windows in the sides of the adapter. Running on a standard low voltage DC 5V, the mainstream probe is designed with portability in mind and has low power consumption.

The mainstream gas analyzers are characterized by the following features:

- Low system integration complexity

- Low power consumption

- Fast startup time

- Low weight < 30g

- Visual status indicator

5. Indication for use/ Intended Use

The Medical Gas Analyzer is intended to be connected to other medical devices for monitoring of the breathing gases CO₂, N₂O and the anesthetic agents Halothane, Enflurane, Isoflurane, Sevoflurane and Desflurane.

It is intended to be connected to a patient breathing circuit for monitoring of inspired/expired gases during anesthesia, recovery and respiratory care. It may be used in the operating suite, intensive care unit and patient room for adult, pediatric and infant patients. The CO₂ may also be used in the emergency medical services environment and road ambulances.

Note: The Medical Gas Analyzer shall only be connected to medical devices approved by Prior-care.

6. Substantial Equivalence Comparison

Characteristics	Subject device	Predicate device (K123043)	Reference device (K042601)	Remark
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Medical Gas Analyzer Traditional 510k Submission

Device name	Medical Gas Analyzer	Infrared Mainstream Gas Analyzer	CAPNOSTAT 5 CO ₂ sensor	NA
Model	AG200	IMRA AX+	CAPNOSTAT 5	NA
Manufacturer	Prior Care Science Technology LTD	PHASEIN AB/ Masimo Sweden AB	Respironics Novamatrix, LLC	NA
Regulation number	21 CFR868.1400	21 CFR868.1400	21 CFR868.1400	Substantially Equivalent.
Product code	CCK	CCK	CCK	Substantially Equivalent.
Prescription or OTC	Prescription Use	Prescription Use	Prescription Use	Substantially Equivalent.
Indication for use/ Intended use	The Medical Gas Analyzer is intended to be connected to other medical devices for monitoring of the breathing gases CO₂, N₂O and the anesthetic agents Halothane, Enflurane, Isoflurane, Sevoflurane and Desflurane. It is intended to be connected to a patient breathing circuit for monitoring of inspired/expired gases during anesthesia, recovery and respiratory care. It may be used in the operating suite, intensive care unit	The IRMA mainstream gas analyzer is intended to be connected to other medical devices for monitoring of breath rate and the breathing gases CO₂, N₂O and the anesthetic agents Halothane, Enflurane, Isoflurane, Sevoflurane and Desflurane. It is intended to be connected to a patient breathing circuit for monitoring of inspired/expired gases during anesthesia, recovery and respiratory	The intended use of the Capnostat 5 CO₂ sensor is to provide carbon dioxide monitoring to a host monitoring system during anesthesia/ recovery, in the intensive care unit (ICU), and in Emergency Medicine/ Transport or Respiratory care.	Compared with Predicate device: Breath rate monitoring capability is not incorporated in the subject device. (Different Note 01) Compared with Reference device: The reference device is exclusively equipped for CO₂ monitoring, employed solely to verify the

Medical Gas Analyzer Traditional 510k Submission

	and patient room for adult, pediatric and infant patients. The CO ₂ may also be used in the emergency medical services environment and road ambulances. Note: The Medical Gas Analyzer shall only be connected to medical devices approved by Prior-care.	care. It may be used in the operating suite, intensive care unit and patient room for adult, pediatric and infant patients. IRMA CO ₂ may also be used in the emergency medical services environment and road ambulances. Note: An IRMA mainstream gas analyzer shall only be connected to medical devices approved by PHASEIN.		equivalence in "Prevent the impact of water vapor condensation" and "Warm-up time".
Intended patient population	Adult, pediatric and infant patients	Adult, pediatric and infant patients	Adult, pediatric and infant patients	Substantially Equivalent.
Principle of operation	Infrared gas spectrometry, no moving parts	Infrared gas spectrometry, no moving parts	Infrared absorption, no moving parts	Substantially Equivalent.
Energy source	Power by the matching backboard device; 4.5 - 5.5 VDC, max 1.5W	Power by the matching backboard device; 4.5 - 5.5 VDC, max 1.4W	Power by the matching backboard device	Substantially Equivalent.
Type of protection	Class II	Class II	Class II	Substantially Equivalent.
Degree of protection of	Defibrillation proof BF-Applied Part	Defibrillation proof BF-Applied Part	Not specified	Compared with Predicate device:

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Electrical Shock				Substantially Equivalent. Compared with Reference device: The reference device is exclusively equipped for CO₂ monitoring, employed solely to verify the equivalence in "Prevent the impact of water vapor condensation" and "Warm-up time".
Protection against harm from liquid ingress	IP44	IP44	Not specified	Compared with Predicate device: Substantially Equivalent. Compared with Reference device: The reference device is exclusively equipped for CO₂ monitoring,

Medical Gas Analyzer Traditional 510k Submission

				employed solely to verify the equivalence in "Prevent the impact of water vapor condensation" and "Warm-up time".
Operating mode	Continuous	Continuous	Continuous	Substantially Equivalent.
Display type	No display, displayed by the matching backboard device	No display, displayed by the matching backboard device	No display, displayed by the matching backboard device	Substantially Equivalent.
Monitoring gas	The breathing gases CO ₂ , N ₂ O and the anesthetic agents Halothane, Enflurane, Isoflurane, Sevoflurane and Desflurane	The breath rate and breathing gases CO ₂ , N ₂ O and the anesthetic agents Halothane, Enflurane, Isoflurane, Sevoflurane and Desflurane	Respiration rate and breathing gases CO ₂	Compared with Predicate device: Breath rate monitoring capability is not incorporated in the subject device. (Different Note 01) Compared with Reference device: The reference device is exclusively equipped for CO ₂ monitoring, employed solely to

Medical Gas Analyzer Traditional 510k Submission

				verify the equivalence in "Prevent the impact of water vapor condensation" and "Warm-up time".
Measurement method	Infrared absorption method	Infrared absorption method	Infrared absorption method	Substantially Equivalent.
Measure mode	Mainstream	Mainstream	Mainstream	Substantially Equivalent.
Airway adapters	Disposable adult/pediatric: - Adds less than 6 ml deadspace Disposable infant: - Adds less than 1 ml deadspace	Disposable adult/pediatric: - Adds less than 6 ml deadspace Disposable infant: - Adds less than 1 ml deadspace	Disposable adult/pediatric: - Adds less than 5 ml deadspace Disposable infant: - Adds less than 1 ml deadspace	Substantially Equivalent.
Respiration rate	/	0 to 150 $\pm$ 1breaths/min. The respiration rate is displayed after three breaths and the average value is updated every breath	Range: 2 - 150 breaths per minute Accuracy: $\pm$ 1breaths/min	Compared with Predicate device: Breath rate monitoring capability is not incorporated in the subject device. (Different Note 01) Compared with Reference device: The reference

Medical Gas Analyzer Traditional 510k Submission

				device is exclusively equipped for CO ₂ monitoring, employed solely to verify the equivalence in "Prevent the impact of water vapor condensation" and "Warm-up time".
Fi and Et	CO₂, N₂O, Agents (HAL, ISO, ENF, SEV, DES) Fi and Et are displayed after one breath and have a continually updated breath average. The following methods are used to calculate end-tidal(Et) values: - CO₂: The highest concentration of CO₂ during one breathing cycle - N₂O and anesthetic agents: The momentary gas concentration at the time point where ETCO₂ is detected. Et-values for anaesthetic	Measured gas: CO₂, N₂O, primary and secondary agents (HAL, ISO, ENF, SEV, DES) Fi and Et are displayed after one breath and have a continuously updated breath average. The following method is used to calculate end-tidal (Et) values: - CO₂: The highest concentration of CO₂ during one breathing cycle with a weight function applied to favor values closer to the end of the cycle.	Not specified	Compared with Predicate device: Substantially Equivalent. Compared with Reference device: The reference device is exclusively equipped for CO₂ monitoring, employed solely to verify the equivalence in "Prevent the impact of water vapor condensation" and

Medical Gas Analyzer Traditional 510k Submission

	agents and N₂O will typically decrease below nominal value when respiration rate exceeds 80 bpm. EtCO₂ will be within specification for all respiration rates up to 150 bpm.	- N₂O primary and secondary agents (HAL, ISO, ENF, SEV, DES): The momentary gas concentration at the time point where EtCO₂ is detected. Et-values for anaesthetic agents and N₂O will typically decrease below nominal value when respiratory rate exceeds 80 bpm. EtCO₂ will be within specification for all respiratory rates up to 150 bpm.		"Warm-up time".
Accuracy (for dry single gases at 22±5°C and 1013±40hPa.)	CO₂: range 0 to 15 vol%, ±(0.2 vol% + 2% of reading)	CO₂: range 0 to 15 vol%, ±(0.2 vol% + 2% of reading)	0 - 40 mmHg, ±2 mmHg 41 - 70 mmHg, ±5% of actual 71 - 100 mmHg, ±8% of actual 101 - 150 mmHg, ±10% of reading (At respiration rates > 80 breaths per minute, all ranges are ±12% of actual.)	Compared with Predicate device: Substantially Equivalent. Compared with Reference device: Different Note 02

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	N ₂ O: range 0 to 100 vol%, ±(2 vol% + 2% of reading)	N ₂ O: range 0 to 100 vol%, ±(2 vol% + 2% of reading)	The reference device does not support N ₂ O, HAL, ISO, ENF, SEV, or DES monitoring.	Compared with Predicate device: Substantially Equivalent.
	HAL, ISO, ENF: range 0 to 8 vol%, ±(0.15 vol% + 5% of reading)	HAL, ISO, ENF: range 0 to 8 vol%, ±(0.15 vol% + 5% of reading)		Compared with Reference device: The reference device is exclusively equipped for CO ₂ monitoring, employed solely to verify the equivalence in "Prevent the impact of water vapor condensation" and "Warm-up time".
	SEV: range 0 to 10 vol%, ±(0.15 vol% + 5% of reading)	SEV: range 0 to 10 vol%, ±(0.15 vol% + 5% of reading)		
	DES: range 0 to 22 vol%, ±(0.15 vol% + 5% of reading)	DES: range 0 to 22 vol%, ±(0.15 vol% + 5% of reading)		
Accuracy (all conditions)	CO ₂ : ±(0.3 vol% + 4% of reading)	CO ₂ : ±(0.3 vol% + 4% of reading)	Not specified	Compared with Predicate device: Substantially Equivalent.
	N ₂ O: ±(2 vol% + 5% of reading)	N ₂ O: ±(2 vol% + 5% of reading)	The reference device does not support N ₂ O, HAL, ISO, ENF, SEV, or DES monitoring.	Compared with Reference device: The reference device is exclusively
	Agents: ±(0.2 vol% + 10% of reading)	Agents: ±(0.2 vol% + 10% of reading)		

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				equipped for CO ₂ monitoring, employed solely to verify the equivalence in "Prevent the impact of water vapor condensation" and "Warm-up time".
Anaesthetic agents threshold	0.2 vol%	0.15 vol%. When an agent is identified, concentrations will be reported even below 0.15% as long as apnea is not detected; 0.2 vol% + 10% of total agent concentration	The reference device does not support N ₂ O, HAL, ISO, ENF, SEV, or DES monitoring.	Compared with Predicate device: Different Note 03 Compared with Reference device: The reference device is exclusively equipped for CO ₂ monitoring, employed solely to verify the equivalence in "Prevent the impact of water vapor condensation" and "Warm-up time".
Anaesthetic agents identification	Manual selection	Automatic identification	The reference device does not support N ₂ O, HAL,	Compared with Predicate device:

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			ISO, ENF, SEV, or DES monitoring.	Different Note 04 Compared with Reference device: The reference device is exclusively equipped for CO ₂ monitoring, employed solely to verify the equivalence in "Prevent the impact of water vapor condensation" and "Warm-up time".
Prevent the impact of water vapor condensation	Heater-based	Optional HME (Heat Moisture Exchanger)	Heater-based	Compared with Predicate device: Different Note 05 Compared with Reference device: Substantially Equivalent.
Warm-up time	10-180 seconds	< 20 seconds (agent identification enabled and full accuracy)	Full specifications within 2 minutes at an ambient temperature of 25° C	Different Note 06
Data update frequency	20Hz	20Hz	Not specified	Compared with Predicate device:

Medical Gas Analyzer Traditional 510k Submission

				Substantially Equivalent. Compared with Reference device: The reference device is exclusively equipped for CO₂ monitoring, employed solely to verify the equivalence in "Prevent the impact of water vapor condensation" and "Warm-up time".
Total system response time	<1 second	<1 second	Not specified	Compared with Predicate device: Substantially Equivalent. Compared with Reference device: The reference device is exclusively equipped for CO₂ monitoring,

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				employed solely to verify the equivalence in "Prevent the impact of water vapor condensation" and "Warm-up time".
Performance	Complied with ISO 80601-2-55	Complied with ISO 80601-2-55	Complied with ISO 80601-2-55	Substantially Equivalent.

Note 01:

The subject device does not support breath rate monitoring, and the predicate device supports breath rate monitoring. The CO₂, N₂O and the anesthetic agents of subject device have been verified by the bench test, and the subject device complies with ISO 80601-2-55. The difference does not raise any safety and effectiveness issues based on tests in this submission.

Note 02:

The subject device exhibits different CO₂ range and accuracy compared to the reference device. These parameters, however, are identical to those of the predicate device. The CO₂ range and accuracy of subject device have been verified by the bench test, and the subject device complies with ISO 80601-2-55. The difference does not raise any safety and effectiveness issues based on tests in this submission.

Note 03:

The anaesthetic agents threshold of the subject device is different from the predicate device. But the anaesthetic agents threshold of the subject device has been verified by the bench test, and the subject device complies with ISO 80601-2-55. The difference does not raise any safety and effectiveness issues based on tests in this submission.

Note 04:

The predicate device incorporates automated anesthetic gas identification, whereas the subject device requires manual selection of the anesthetic agent by qualified clinicians via key operation. Software validation testing confirmed the efficacy of the gas selection function on the subject device. Manual selection by clinicians demonstrated higher reliability compared to automated gas identification. The difference does not raise any safety and effectiveness issues based on tests in this submission.

Note 05:

Both the subject device and the reference device (K042601) don't incorporate an HME (Heat and Moisture Exchanger). Both the subject device and the reference device (K042601) utilize a heater for preventing the impact of water vapor condensation. The predicate device offers HME as an optional feature. The reference device has a commercial distribution history of over 15 years in the market, which substantiates that the use of a heater is effective in preventing the impact of water vapor condensation. Consequently, the difference in "preventing the impact of water vapor condensation" between the subject device and predicate device are not clinically significant with regard to safety or effectiveness.

Note 06:

Neither the subject device nor the reference device incorporates an HME (Heat and Moisture Exchanger), whereas the predicate device offers HME as an optional feature. As with the reference device, the subject device exhibits an extended warm-up duration relative to the predicate device. The warm-up time of the subject device (range: 10-180 seconds) corresponds to its operational performance within the specified operating temperature range of 10°C to 40°C, demonstrating minor variations compared to the reference device. And the warm-up time of the subject device has been verified by the bench test. The software system level test report in this submission under defined conditions demonstrated a nominal surface heating

temperature of 38°C ($\pm 2^\circ\text{C}$ accuracy) for the subject device, with a maximum recorded value of 43.6°C at an ambient temperature of 40° C. The airway adapter has a relatively short profile. Since the gas is in a continuous flow state within the breathing circuit, the surface temperature of the airway adapter has a minimal effect on the temperature of the gas itself. And the surface heating temperature is safe for patients, clinicians and subject device. The difference in warm-up time does not raise any safety and effectiveness issues.

Based on the aforementioned substantial equivalence comparison table, the subject device is as same as predicate device. The Breath rate (refer to Note 01), CO₂ range and accuracy (refer to Note 02), Anaesthetic agents threshold (refer to Note 03), Anaesthetic agents identification (refer to Note 04), Prevent the impact of water vapor condensation (refer to Note 05), Warm-up time (refer to Note 06) are different which had been validated. However, the differences would not raise any safety and effectiveness issue based on tests in this submission. Thus, the subject device is substantially equivalent to the predicate device which is legally marketed in US.

7. Brief discussions of the non-clinical tests

The following tests were conducted to demonstrate substantial equivalence to the predicate device:

Test Standard	Description	Result
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)]	Pass
IEC 60601-1-2 Edition 4.1 2020-09	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential	Pass

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CONSOLIDATED VERSION	performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests	
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	Pass
ISO 10993-1 Fifth edition 2018-08	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	Pass
ISO 10993-5 Third edition 2009-06-01	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity	Pass
ISO 10993-10 Fourth edition 2021-11	Biological evaluation of medical devices - Part 10: Tests for skin sensitization	Pass
ISO 10993-23 First edition 2021-01	Biological evaluation of medical devices - Part 23: Tests for irritation	Pass
ISO 18562-1 First edition 2017-03	Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 1: Evaluation and testing within a risk management process	Pass
ISO 18562-2 First edition 2017-03	Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 2: Tests for emissions of particulate matter	Pass
ISO 18562-3 First edition 2017-03	Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 3: Tests for emissions of volatile organic compounds	Pass
ISO 18562-4 First edition 2017-03	Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 4:	Pass

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	Tests for leachables in condensate	
ISO 14971 Third edition 2019-12	Medical devices - Application of risk management to medical devices	Pass

It is concluded that the subject devices are in compliance with the requirements of the aforementioned tests.

8. Brief discussions of the clinical tests

Not applicable, the subject device does not require clinical test data to support substantial equivalence.

9. Software information

The software documentation level of the Medical Gas Analyzer should be of the Basic Documentation. According to FDA Guidance document “Content of Premarket Submissions for Device Software Functions”, the software validation documentation summarizes the required information for a Basic Documentation level.

10. Conclusions

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification, Prior Care Science Technology LTD concludes that the subject device is as safe and as effective, and thus substantially equivalent, to the predicate device, IMRA AX+ Infrared Mainstream Gas Analyzer (K123043).