March 4, 2021

Unimed Medical Supplies, Inc.
Linbin Ye
RA Manager
Bld#8, Nangang 3rd Industrial Park Tangtou, Shiyan
Shenzhen, Guangdong 518108
China

Re: K210019
Trade/Device Name: Unimed CO2 Mainstream Module Model Capno-M, Unimed CO2 Mainstream Module Model Capno-M+
Regulation Number: 21 CFR 868.1400
Regulation Name: Carbon Dioxide Gas Analyzer
Regulatory Class: Class II
Product Code: CCK
Dated: December 25, 2020
Received: January 4, 2021

Dear Linbin Ye:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Todd Courtney
Assistant Director
DHT1C: Division of ENT, Sleep Disordered Breathing, Respiratory and Anesthesia 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210019

Device Name
Unimed CO2 Mainstream Module

Indications for Use *(Describe)*
The CO2 Mainstream Module is intended to provide carbon dioxide monitoring to a host monitoring system during anesthesia/recovery in Emergency Medicine/Transport or Respiratory 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

K210019

Submitter:	Name: Unimed Medical Supplies, Inc. Address: Bld#8, Nangang 3rd Industrial Park Tangtou, Shiyan, 518108, Shenzhen, PEOPLE'S REPUBLIC OF CHINA
Contact Person:	Name: Mr. Linbin Ye Title: RA Manager Phone Number: +86 755 2669 5137 Email Address: yelb@unimed.cn
Date Prepared:	December 25, 2020
Device Trade Name:	Unimed CO_2 Mainstream Module
Device Common Name:	CO_2 Mainstream Module
Classification Names: **Regulation Number:** **Product Code:**	Analyzer, Gas, Carbon-Dioxide, Gaseous-Phase 21 CFR 868.1400 CCK
Predicate Device : **510(k) Number:** **Device Name:** **Manufacturer:**	 K192446 CO_2 Mainstream Module Beijing Kingst Commercial & Trade Co.,Ltd.

Description of Devices:

The CO_2 Mainstream module is a non-dispersive infrared gas analyzer with an auto-zero adjustment system and gain control.

The operation of the CO_2 Mainstream module is based on CO_2 energy absorption rates. CO_2 molecules absorb infrared light energy of specific wavelengths, with the amount of energy absorbed being directly related to the CO_2 concentration. When an IR light beam is passed through a gas sample containing CO_2, the electronic signal from the infrared sensor (which measures the remaining light energy), can be obtained. This signal is then compared to the energy of the IR source, and calibrated to reflect CO_2 concentration in the sample accurately. Calibration is performed using the infrared sensor's response to a known concentration of CO_2 stored in the module's memory.

The circuit module retains the atmospheric absolute pressure sensors and control of the pressure sensor. Modules can measure atmospheric pressure, and atmospheric can compensate the calculation for the concentrations of carbon dioxide, which improves the design accuracy.

The module then determines CO_2 concentration in the breathing gases by measuring the amount of light absorbed by these gases. EtCO_2 displays a numerical value in millimeters of mercury (mmHg), percent (%), or kilopascals (kPa). In addition, a CO_2 waveform (Capnogram) may be displayed, which is a valuable clinical tool that can be used to assess patient airway integrity and proper endotracheal tube placement. Respiration rate is calculated by measuring the time interval

between detected breaths.

The differences between the Capno M and M+ are only with the intended patient type. The Capno M is intended for use on intubated patients, where the Capno M+ is intended for use with intubated and non-intubated patients. The operating principles, unit of measurement, $ETCO_2$ measurement range, accuracy, respiration rate range, and respiration rate accuracy are the same for both devices.

Intended Use:

The CO_2 Mainstream Module is intended to provide carbon dioxide monitoring to a host monitoring systemduring anesthesia/recovery in Emergency Medicine/Transport or Respiratory care.

Comparison to predicate device:

The subject and predicate devices are exactly the same, and there is no any difference between them.

Table 1 Substantial Equivalence Table

Description	Subject Device	Predicate Device (K192446)
Indications for use	The CO_2 Mainstream Module is intended to provide carbon dioxide monitoring to a host monitoring systemduring anesthesia/recovery in Emergency Medicine/Transport or Respiratory care.	The CO_2 Mainstream Module is intended to provide carbon dioxide monitoring to a host monitoring systemduring anesthesia/recovery in Emergency Medicine/Transport or Respiratory care.
Prescription/over-the-counter use	Prescription	Prescription
The type of protection against electric shock	Class II	Class II
The degree of protection against electric shock	Type BF	Type BF
Waveform Display	No display	No display
Intended patient population	From newborn (neonate) to adult	From newborn (neonate) to adult
CO2 measurement method	Infrared absorption method	Infrared absorption method
CO2 measure mode	Mainstream	Mainstream
Measuring	$EtCO_2$ and Respiration Rate	$EtCO_2$ and Respiration Rate

parameters		
CO2 Response Time	<70 ms	<70 ms
Units	mmHg, kPa or Vol%	mmHg, kPa or Vol%
EtCO2 Measurement Range	0-150 mmHg 0-19.7% 0-20 kPa	0-150 mmHg 0-19.7% 0-20 kPa
EtCO2 Accuracy (at 760 mmHg, ambient temperature of 25°C)	0~40 mmHg ±2 mmHg 41~70 mmHg ±5% of reading 71~100 mmHg ±8% of reading 101~150mmHg ±10% of reading	0~40 mmHg ±2 mmHg 41~70 mmHg ±5% of reading 71~100 mmHg ±8% of reading 101~150mmHg ±10% of reading
Respiration Rate measure range	3 - 150 breaths/minute (RPM)	3 - 150 breaths/minute (RPM)
Respiration Rate accuracy	±1% of reading or ±1 breaths/min whichever is greater	±1% of reading or ±1 breaths/min whichever is greater
Operation principles	Non-dispersive infrared gas analysis, a multi-channel infrared detector, no moving parts	Non-dispersive infrared gas analysis, a multi-channel infrared detector, no moving parts
Performance Standards	Complies with ISO 80601-2-55	Complies with ISO 80601-2-55

Non-clinical test data:

Electrical Safety and EMC:

- ✓ ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601- 1:2005, MOD)
- ✓ IEC 60601-1-2: 2014 Medical devices part 1-2: General requirements for basic safety and essential performance – Collateral standards: electromagnetic compatibility – Test and requirements

Performance Data:

- ✓ Bench testing for Inspired CO_2 range and accuracy, and Respiration rate range and accuracy in accordance to 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

Biocompatibility:

The subject device is classified as an external communicating device in contact with tissue (indirect via the gas pathway) for limited contact duration (<24 h).

- ✓ ISO 10993-5: 2009 Biological evaluation of medical devices – Part 5 Tests for In Vitro Cytotoxicity
- ✓ ISO 10993-10: 2010 Biological evaluation of medical Devices – Part 10: Tests for Irritation and Delayed-Type Hypersensitivity
- ✓ 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

- ✓ ISO 18562-2 First edition 2017-03 Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 2: Tests for emissions of particulate matter
- ✓ 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
- ✓ ISO 18562-4 First edition 2017-03 Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 4: Tests for leachables in condensate

Clinical test data:

Not applicable, the determination of substantial equivalence is not based on Clinical Performance data.

Conclusions:

Based on the comparison, analysis, and the submitted performance data, we believe that the Unimed CO_2 Mainstream Module are as safe, as effective, and performs as well as the predicate device. The subject device and the predicate device are identical with the same intended use and technological characteristics, and are substantially equivalent.