May 21, 2020

Beijing Kingst Commercial & Trade Co.,Ltd.
℅ Charlie Mack
Principal Engineer
Irc
2950 E Lindrick Drive
Chandler, Arizona 85249

Re: K192446
Trade/Device Name: CO2 Mainstream Module
Regulation Number: 21 CFR 868.1400
Regulation Name: Carbon Dioxide Gas Analyzer
Regulatory Class: Class II
Product Code: CCK
Dated: March 21, 2020
Received: April 14, 2020

Dear Charlie Mack:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192446

Device Name
CO2 Mainstream Module, Capno-M, Capno-M+

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.

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Beijing Kingst Commercial & Trade Co., Ltd.

510(k) Summary (21 CFR §807.92)

K192446

Submitter Information:

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Email:	charliemack@irc-us.com

Date of Preparation: May 18, 2020

Subject Devices :

Trade/proprietary name : CO_2 Mainstream Module
Common Name: Model Capno-M, Capno-M+ Carbon Dioxide Gas Analyzer
Classification: CCK

Regulatory Class: Class II

Regulation Number: 21CFR868.1400

Predicate Device :

Trade Name: CAPNOSTAT 5
510(k) Reference: K042601
Common Name: Carbon Dioxide Gas Analyzer
Regulation Number: 21CFR868.1400
Regulatory Class: Class II
Manufacturer: Respironics Novametrix, Inc.

Purpose of Submission

This is a new traditional 510(K) submission of a Carbon Dioxide Gas Analyzer.

Device Description

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 CO2 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, ETCO2 measurement range, accuracy, respiration rate range, and respiration rate accuracy are the same for both devices.

Indication for use

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.

Comparison with the predicate device:

Beijing Kingst Commercial & Trade Co., Ltd. believes that the Beijing Kingst Commercial & Trade Co., Ltd. CO_2 Mainstream Module is substantially equivalent to the Respironics Novametrix, Inc. CAPNOSTAT 5 Carbon Dioxide Gas Analyzer (K042601).

There are differences in the CO_2 response time and the respiration rate measurement range. The response time difference is 10 ms. This does not affect the accuracy or usage. The measurement range difference is at the lowest part of the scale. The predicate devices' range is 2-150 breaths per minute, where the submitted device range is 3-150 breaths per minute. The difference at the lower end of the range does not pose any risks or hazards to patients. They have the same intended use. The minor differences in technological characteristics do not raise issues of safety and effectiveness. The subject device is identical to the predicate device. Please refer to the following pages for specific difference details.

Comparison to Predicate Devices

Element of comparison	**Subject Device**	**Predicate Device**	**Discussion**
Company	Beijing Kingst Commercial & Trade Co., Ltd.	RESPIRONICS NOVAMETRIX, INC.	N/A
FDA510(K) Number	Pending	K042601	N/A
Device Name	CO_2 Mainstream Module	CAPNOSTAT 5 $EtCO_2$ SENSOR (Mainstream)	N/A
Model Number	Capno-M, Capno-M+	CAPNOSTAT 5	N/A
Indications for Use	The CO2 Mainstream Module is intended 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.	The intended use of the Capnostat 5 CO_2 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.	IFU is the same for both devices.
The type of protection against electric shock	Class II	Class II	No difference in insulation methodology.
The degree of protection against electric shock	Type BF	Type BF	No difference in protection against electric shock.
Waveform Display	No display	No display	Neither device has a display.
Intended patient population	from newborn (neonate) to adult	from newborn (neonate) to adult	Same patient population.

Element of comparison	Subject Device	Predicate Device	Discussion
CO_2 module	CO_2 Mainstream Module	CAPNOSTAT 5 EtCO2 (Main-stream) Module(K042601)	N/A
CO_2 measurement method	Infrared absorption method	Infrared absorption method	No difference in the measurement method
CO_2 measure mode	Mainstream	Mainstream	Same measure mode
Performance Standards	Complies with ISO80601-2-55	Unknown	N/A
Measuring parameters	$EtCO_2$ and Respiration Rate	$EtCO_2$ and Respiration Rate	Matching measuring parameters
CO_2 Response Time	<70 ms	Mainstream: <60 ms (rise time)	The 10 ms difference in response time will not influence the usage effect. It complies with ISO80601-2-55
Units	mmHg, kPa or Vol%	mmHg, kPa or Vol%	The same unit of measurement
$EtCO_2$ Measurement Range	0-150 mmHg 0-19.7% 0-20 kPa	0 - 150 mmHg 0 - 20% 0 - 20 kPa	It complies with ISO80601-2-55

Element of comparison	Subject Device	Predicate Device	Discussion
$EtCO_2$ 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 (At respiration rates > 80 breaths per minute, all ranges are ±12% of actual.)	It complies with ISO80601-2-55
Respiration Rate measure range	3 - 150 breaths/minute (RPM)	2~150 breaths/minute (RPM)	2 RPM of the respiration rate will be abnormal. Respiration at the minimum is not critical, and the device complies with ISO80601-2-55
Respiration Rate accuracy	±1% of reading or ±1 breaths/min whichever is greater	±1 breath per minute	Both devices have the same accuracy.
Operation principles	Non-dispersive infrared gas analysis, a multi-channel infrared detector, no moving parts	Non-dispersive infrared (NDIR) single beam optics, dual-wavelength, no moving parts	The measurement technology principle is the same. Both devices adopt NDIR (non-dispersive infrared gas) technology.

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).

Safety and Performance Data :

To establish substantial equivalence to the identified predicate devices, tests were completed as defined below to the subject devices, Carbon Dioxide Gas Analyzer. The results of the testing demonstrate that the device complies with the requirements of the applicable standards, and the device is substantially equivalent to the predicate device.

Non-Clinical Study:

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 CO2 range and accuracy, and Respiration rate range and accuracy in accordance to ISO 80601-2-55 Second edition 2018-02 Medical electrical equipment - Part2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors*

Biocompatibility

- *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*

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Clinical Study:

- *No clinical studies were performed.*

Sterility Information:

- *This device is not delivered sterile and is not sterile during operation.*

Package and Shelf Life:

- *The CO_2 Mainstream module (Capno-M, Capno-M+) is not subject to shelf life, as the device does not contain any sterile or degradable elements.*

Conclusion:

The subject device has the same intended use as the predicate device, and the technological differences are addressed by performance testing, and do not raise different questions of safety and effectiveness.

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification, the subject device, CO_2 Mainstream Module, models Capno-M and Capno-M+ is substantially equivalent to predicate device

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