May 22, 2020

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

Re: K192488
Trade/Device Name: CO2 Sidestream Module, Capno-S, Capno-S+
Regulation Number: 21 CFR 868.1400
Regulation Name: Carbon Dioxide Gas Analyzer
Regulatory Class: Class II
Product Code: CCK
Dated: September 3, 2019
Received: September 11, 2019

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)*
K192488

Device Name
CO2 Sidestream Module, Capno-S, Capno-S+

Indications for Use *(Describe)*
The CO2 Sidestream Module is designed to provide carbon dioxide monitoring to a host monitoring system during anesthesia / recovery, in the intensive care unit (ICU), and in Respiratory care.
The CO2 Sidestream Module is used for adult patients.

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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Beijing Kingst Commercial & Trade Co., Ltd.

510(k) Summary (21 CFR §807.92)

Submitter Information:

Submitter Name:	Beijing Kingst Commercial & Trade Co., Ltd.
Address:	6th Floor of No.2-7, Beibinhe Road, Xibianmen, Xicheng Dist, Beijing, P.R.C. 100053
Telephone:	+86-10-68158013
Fax:	+86-10-68156857
Contact Person:	Mr. Judong Gao General Manager
Email:	charliemack@irc-us.com

Date of Preparation: May 21, 2020

Subject Devices:

Trade/proprietary name: CO_2 Sidestream Module
Model Capno-S, Capno-S+
Common Name: CO_2 Sidestream Module
Regulation Number: 21CFR868.1400
Regulatory Class: Class II
Classification Code: CCK

Predicate Device:

Trade Name:	Capnograph and Oximeter
510(k) Reference:	K170820
Common Name:	CO_2 Sidestream Module and Oximeter
Regulation Number:	21CFR868.1400
Regulatory Class:	Class II
Manufacturer:	CMI Health Inc.

Trade Name:	LoFlo C5 CO_2 sensor
510(k) Reference:	K053174
Common Name:	CO2 Sidestream Module
Regulation Number:	21CFR868.1400
Regulatory Class:	Class II
Manufacturer:	Respironics Novametrix, LLC

Purpose of Submission

This is a new traditional 510(K) submission of CO_2 Sidestream Module.

Device Description

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

The operation of the CO_2 Sidestream 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. As the sample gas passes through a three-way valve, with the change of temperature and time, the valve leading to the pure air will close for 3-4 seconds to adjust the zero point.

The circuit module retains the atmospheric absolute pressure sensors and control of the pressure sensor. Modules can measure atmospheric pressure, and atmospheric can compensate for 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). Respiration rate is calculated by measuring the time interval between detected breaths.

Indication for use

The CO2 Sidestream Module is designed to provide carbon dioxide monitoring to a host monitoring system during anesthesia/recovery, in the intensive care unit (ICU), and in Respiratory care.

The CO2 Sidestream Module is used for adult patients.

Comparison with the predicate device:

Beijing Kingst Commercial & Trade Co., Ltd. believes that the CO_2 Sidestream Module is substantially equivalent to the CMI Health Inc. Capnograph and Oximeter (K170820) and the Respironics Novametrix LoFlo C5 CO_2 sensor (K053174). The submitted Beijing Kingst Commercial & Trade Co., Ltd. CO2 Sidestream Module, Models Capno-S, and Capno-S+ were components within the predicate CMI Health's Capnograph and Oximeter for that device's FDA clearance. The subject device is also compared to the Respironics Novametrix LoFlo C5 sensor. Beijing Kingst Commercial & Trade Co., Ltd. is submitting the subject device for individual clearance, so that the manufacturer may market the Module separately. The submitted device will be installed in a host monitor, where the host monitor manufacturer will determine fit, form, and function.

The differences noted between the submitted CO2 Sidestream Module and the predicate Capnograph and Oximeter and Respironics Novametrix LoFlo C5 are based on the use. The Capnograph and Oximeter is a complete device that measures CO2 gas and also measures oxygen saturation. The Beijing Kingst Commercial & Trade Co., Ltd. CO2 Sidestream Module only measures CO_2 gas. The display, any alarms, power supply, and physical configuration differences are due to the use in the end product. The subject device is manufactured to be a component of a complete device and not intended to be a stand-alone device and relies on a host device to display information or graphics. Please refer to the following pages for specific difference details.

Comparison Table of Capno-S and Capno-S+

Element of comparison	Capno-S	Capno-S+	Conclusion
Appearance			different
Indications for Use	The CO_2Sidestream Module is designed for monitoring vital physiological signs of the patient. It's intended to be used for non-invasive continuous monitoring of $EtCO_2$, $InsCO_2$, and Respiration Rate. The Module is indicated for inpatients from newborn (neonate) to adult in a hospital environment. It is intended to be used only under the regular supervision of clinical personnel.	The CO_2Sidestream Module is designed for monitoring vital physiological signs of the patient. It's intended to be used for non-invasive continuous monitoring of $EtCO_2$, $InsCO_2$, and Respiration Rate. The Module is indicated for inpatients from newborn (neonate) to adult in a hospital environment. It is intended to be used only under the regular supervision of clinical personnel.	same
Intended patient type	intubated patients and non-intubated patients	intubated patients and non-intubated patients	same
Operation principles	Non-dispersive infrared gas analysis, multi-channel infrared detector, no moving parts	Non-dispersive infrared (NDIR) single beam optics, dual-wavelength, no moving parts	same
Units	mmHg, kPa or Vol%	mmHg, kPa or Vol%	same
EtCO2 Measurement Range	0-150 mmHg 0-19.7% 0-20 kPa	0-150 mmHg 0-19.7% 0-20 kPa	same
$EtCO_2$ 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	same
Respiration Rate measure range	3 - 150 breaths/minute (RPM)	3 - 150 breaths/minute (RPM)	same
Respiration Rate accuracy	±1% of reading or ±1 breaths/min whichever is greater	±1% of reading or ±1 breaths/min whichever is greater	same

Comparison to Predicate Devices

Element of comparison	Subject Device	Predicate Device	Reference Device	Discussion
Company	Beijing Kingst Commercial & Trade Co., Ltd.	Respironics Novametrix, LLC	CMI Health Inc.	N/A
FDA510(K) Number	N/A	K053174	K170820	N/A
Device Name	CO_2 Sidestream Module	LoFlo C5 CO_2 sensor	Capnograph and Oximeter	N/A
Model Number	Capno-S, Capno-S+	LoFlo C5	Capno-H	N/A
CO_2 Module	CapnoCore	LoFlo C5 CO_2 sensor	CapnoCore	N/A
Indications for Use	The CO_2 Sidestream Module is designed to provide carbon dioxide monitoring to a host monitoring system during anesthesia/recovery in the intensive care unit (ICU) and in Respiratory care. The CO_2 Sidestream Module is used for adult patients.	The intended use of the LoFlo C5 CO_2 sensor is to provide carbon dioxide monitoring to a host monitoring system during anesthesia/recovery in the intensive care unit (ICU) and Emergency Medicine/Transport or Respiratory care.	The Capnograph and Oximeter are designed for monitoring the vital physiological signs of the patient. It is used for non-invasive continuous monitoring of oxygen saturation (SpO_2), Pulse Rate, $EtCO_2$, $InsCO_2$, and Respiration Rate. The Capnograph and Oximeter are adaptable to adult usage in a hospital environment. It is intended to be used only under regular supervision of clinical personnel	Identical to the predicate device. The indications for the use of the subject device are the same as the predicate device, LoFlo C5 CO2 sensor, and add the limit to the adult patient population only. The subject CO_2 Sidestream Module is the same as the CO2 sidestream module used in the Reference Device, and they are the same manufacturer -Beijing Kingst. The Reference device has an additional SpO2 module for additional function, but the subject device has no SpO2 module and function.
Power Supply	DC	DC	Battery or AC	Identical All Comply with IEC requirement
The type of protection against electric shock	Class II	Class II	Class I and internally powered per IEC 60601-1.	Identical All Comply with IEC requirement
The degree of protection against electric shock	Type BF	Type BF	Type BF	Identical
Display	No display	No display	LED and LCD display	Identical Module's measurement data can be displayed on the primary device.

Element of comparison	Subject Device	Predicate Device	Reference Device	Discussion
Intended patient population	Adult	From newborn (neonate) to adult	The whole device claim for Adult *SpO_2 Measurement available for Adult* *CO_2 Measurement available for Adult and Neonatal*	The target population for CO_2 Measurement is smaller than the predicate device.
CO_2 measurement method	Infrared absorption method	Infrared absorption method	Infrared absorption method	Infrared absorption method
CO_2 measure mode	Sidestream	Sidestream	Sidestream	Sidestream
Measuring parameters	$EtCO_2$ and Respiration Rate	$EtCO_2$ and Respiration Rate	$EtCO_2$ and Respiration Rate	$EtCO_2$ and Respiration Rate
Units	mmHg, kPa or Vol%	mmHg, kPa or Vol%	mmHg, kPa or Vol%	mmHg, kPa or Vol%
$EtCO_2$ measure range	0-150 mmHg 0-19.7% 0-20 kPa	0-150 mmHg 0-19.7% 0-20 kPa	0~150 mmHg 0-19.7% 0-20 kPa	0~150 mmHg 0-19.7% 0-20 kPa
CO2 Accuracy	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	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	2 - 150 breaths per minute	3 - 150 breaths/minute	2 RPM of the respiration rate will be abnormal. So, it doesn't matter whether the minimum range is 2 or 3. It is complying with ISO80601-2-55
Respiration Rate accuracy	±1% of reading or ±1 breaths/min whichever is greater	±1 breath per minute	±1% of reading or ±1 breaths/min whichever is greater	±1% of reading or ±1 breaths/min whichever is greater
Flow Rate	50±10 mL/min	50±10 mL/min	50–250 mL/min	50–250 mL/min
NO CO_2 DETECTED Alarm Delay	N/A	N/A	15~39s off	Compare with predicate device: Identical Compare with the reference device: The Module itself has no alarm function.
Alarm of $EtCO_2$	N/A	N/A	High and lower alarms. The limits are adjustable.	Compare with predicate device: Identical Compare with the reference device: The Module itself has no alarm function.
Alarm of RR	N/A	N/A	High and lower alarms. The limits are adjustable.	Compare with predicate device: Identical Compare with the reference device: The Module itself has no alarm function.
Operation principles	Non-dispersive infrared gas analysis, multi-channel infrared detector, no moving parts.	Non-dispersive infrared (NDIR) single beam optics, dual-wavelength, no moving parts	Non-dispersive infrared gas analysis, multi-channel infrared detector, no moving parts.	Non-dispersive infrared gas analysis, multi-channel infrared detector, no moving parts.
Materials	the upper case: ABS the lower case: ABS	the upper case: ABS the lower case: ABS	the upper case: ABS battery cover: ABS the lower case: ABS SpO_2 Module: K063641	Identical. All comply with ISO10993-1 Biocompatibility requirement.

Safety and Performance Data:

To establish substantial equivalence to the identified predicate devices, tests were completed as defined below to the subject devices, CO2 Sidestream Module. The results of the testing demonstrate that the device complies with the requirements of the applicable standard, and the device is substantially equivalent to the predicate device.

Non-Clinical Study:

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:

- *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*

Test	Test Method	Test Result	Test Report No.
EtCO2	See test report	Range: 0-150mmHg Accuracy: 0 - 40 mmHg: ± 2 mm Hg; 41- 70 mmHg: ± 5% of reading; 71 - 100 mmHg: ± 8% of reading; 101 -150 mmHg: ± 10% of reading	JJX-FDA-A/0-06-04
Inspired Dioxide Carbon (InsCO2)			JJX-FDA-A/0-06-06
Respiration Rate		Range: 3bpm～150bpm Accuracy: ±1% of reading or ±1 breaths/min whichever is greater	JJX-FDA-A/0-06-07

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 10993-11: 2017 Biological evaluation of medical Devices – Part 11: Tests for systemic toxicity*
- *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*

Device	Category and Contact	Duration	Test Conducted
Capno-S, Capno-S+	Surface Device →Skin	A – Limited≤(24 h)	In Vitro Cytotoxicity (ISO10993-5) Irritation (ISO10993-10) Delayed-Type Hypersensitivity (ISO10993-10)
Accessories (nasal tubes for adult and infant, filters, L- and T-Connectors, sampling line, etc.)	external communicating devices →Tissue contact (contacting the patient's inhaled and exhaled gases)	A – Limited≤(24 h)	In Vitro Cytotoxicity (ISO10993-5) Irritation (ISO10993-10) Delayed-Type Hypersensitivity (ISO10993-10) Acute systemic toxicity(ISO10993-11) Material mediated pyrogenicity ISO10993-11)

Test	Test Method	Test Result	Test Report No.
In Vitro Cytotoxicity Test	**ISO10993-5 MTT method extracts MEM with 10% FBS Extract**	**Viability%: 87.9% No toxicity.**	**SDWH-M201602887-1**
Skin Sensitization Test	**ISO10993-10 Guinea Pig Maximization Test 0.9% Sodium Chloride Injection Extract**	**Skin sensitization rate: 0% No evidence of skin sensitization.**	**SDWH-M201602887-2**
Skin Sensitization Test	**ISO10993-10 Guinea Pig Maximization Test Sesame Oil Extract**	**Skin sensitization rate: 0% No evidence of skin sensitization.**	**SDWH-M201602887-3**
Skin Irritation Test	**ISO10993-10 0.9% Sodium Chloride Injection Extract**	**Primary irritation index: 0 Negligible.**	**SDWH-M201602887-4**
Skin Irritation Test	**ISO10993-10 Sesame Oil Extract**	**Primary irritation index: 0 Negligible.**	**SDWH-M201602887-5**
Test for emissions of particulate	**ISO18562-2**	**Particulate Matter: 3.2×10^{-3} μg/m^3(Particle size ≤2.5 μm) 3.2×10^{-3} μg/m^3(Particle size ≤10 μm) Qualified**	**SDWH-M201901183-2(E)**
Tests for emissions of volatile organic compounds (VOCs)	**ISO18562-3**	**Each VOC < 360 μg/d Qualified**	**SDWH-M201901183-1(E)**
Tests for leachable substances in condensate	**ISO18562-4**	**Organic impurities(acetophenone): <0.03 μg/d Metal ions (Ba): 4.83 μg/d Metal ions(others): <0.8 μg/ d Qualified**	**SDWH-M201901183-3(E)**
Acute Systemic Toxicity	**ISO 10993-11 Intravenous 0.9% Sodium Chloride Extract**	**All animals appeared clinical normal throughout the study. Qualified**	**SDWH-M201901183-4(E)**
Acute Systemic Toxicity	**ISO 10993-11 Intraperitoneal Sesame Oil Extract**	**All animals appeared clinical normal throughout the study. Qualified**	**SDWH-M201901183-5(E)**
Pyrogen Test	**ISO 10993-11 0.9% Sodium Chloride Injection Extract Rabbit**	**No rabbit shows an individual rise in temperature of 0.5°C or more.**	**SDWH-M201901183-6(E)**

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

Conclusion:
The differences between subject device and predicate devices do not raise issues of safety and effectiveness based on the indication for use, technological characteristics, and performance testing. The subject device complies with the same applicable standards as the predicate device.

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 Sidestream Module, models Capno-S and Capno-S+ is safe and effective and substantially equivalent to predicate devices as described herein.

END