May 31, 2018

Orantech Inc.
% Mei Tan
RA Consultant
Chonconn Medical Device Consulting Co. LTD.
22A, Hai Jing Square, No.18 Taizi Road, Nanshan District,
Shenzhen, 51800
China

Re: K171828
Trade/Device Name: ETCO2 Sensor, Model CTM-RP01
Regulation Number: 21 CFR 868.1400
Regulation Name: Carbon Dioxide Gas Analyzer
Regulatory Class: Class II
Product Code: CCK
Dated: April 30, 2018
Received: April 30, 2018

Dear Mei Tan:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Geeta K.
Pamidimukkala -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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)*

K171828

Device Name
EtCO2 Sensor, Model CTM-RP01

Indications for Use *(Describe)*
The intended use of the ETCO2 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.

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.

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510(K) Summary K171828

1. Prepared Date: 2018/5/30

2. Submitter Information

Name	Orantech Inc.
Address	Zone#A,4F,1st Bld,7th Industrial Zone,Yulv Community, GongMing, Guangming New District, Shenzhen,China 518106
Contact person	Mr. Hsin Xiong
Tel	0755-23699939
Fax	0755-23243594
Email	Yunxi.xiong@orantech.cn

3. Submission Correspondent

Name	Chonconn Medical Device Consulting Co.LTD.
Address	22A,HaiJing Square,No.18 Taizi Road,Nanshan District, Shenzhen,Guangdong,P.R.China,
Contact person	Mei(RA consultant)
E-mail	FDA@chonconn.com/Xinmeitan@chonconn.com
Tel	+86-755-33941160

4. Proposed Device Information

Trade Name	$ETCO_2$ Sensor
Model	CTM-RP01
Common name	Carbon Dioxide (CO_2) Analyzer
Regulatory class	II
Production regulation	21 CFR §868.1400
Product code	CCK
Panel	Anesthesiology

5. Predicate Device Information

510(K)No.	Trade Name/model	Submitter
K042601	Capnostat 5 CO_2 sensor	Respironics Novametrix, LLC

6. Device description

The $ETCO_2$ Sensor is comprised of three main components, a sensor with photo detector and light emitter, cable and connector, The CO_2 Sensor incorporates an infrared light source, of specified wavelength, and an infrared detector. The photo

detector and light emitter end of the CO_2 sensor is connected to an airway adapter. The airway adapter is connected between the patient airway and the respirator. As the patient completes an expiratory breath the sensor measures the CO_2 levels in the expiratory breath and sends that data to the compatible CO_2 monitor. The monitor then reads the data and converts the data so it can be displayed on screen.

The $ETCO_2$ sensor are described as follows:

Model	Description	Compatible Monitor
CTM-RP01	Mainstream/ 3.0M	General Meditech INC. Patient Monitor model G3C

7. Intended use & Indications for Use

The intended use of the $ETCO_2$ 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.

8. Comparison to predicate device

The following is provided as a summary of how the technological characteristics of the device compare to the predicate device

Table1 Comparison between CTM-RP01 sensor and Capnostat 5 CO_2 sensor

Comparison item	Subject Device	Predicate Device	Comments
510(K) number	Pending application	K042601	--
Device	CTM-RP01	Capnostat 5 CO_2 sensor	--
Intended use &Indications for Use	The intended use of the $ETCO_2$ 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.	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	Same
Environment of Use	Hospitals, clinics, and other healthcare environments	Hospitals, clinics, and other healthcare environments	Same
Measurement Technique	Non-dispersive infrared (NDIR) Infrared spectroscopy	Non-dispersive infrared (NDIR) Infrared spectroscopy	Same
CO_2 measurement Range	0 to 150 mmHg, 0 to 19.7%	0 to 150 mmHg, 0 to 19.7%	Same
CO_2 Resolution	0.1 mmHg 0 to 69 mmHg 0.25 mmHg 70 to 150 mmHg	0.1 mmHg 0 to 69 mmHg 0.25 mmHg 70 to 150 mmHg	Same

CO_2 Accuracy	0 - 40 mmHg ± 2 mmHg 41 - 70 mmHg ± 5% of reading 71 - 100 mmHg ± 8% of reading 101 - 150 mmHg ± 10% of reading Above 80 breath per minute ± 12% of reading * NOTE: Gas temperature at 25°C	0 - 40 mmHg ± 2 mmHg 41 - 70 mmHg ± 5% of reading 71 - 100 mmHg ± 8% of reading 101 - 150 mmHg ± 10% of reading Above 80 breath per minute ± 12% of reading * NOTE: Gas temperature at 25°C	Same
Respiration Rate Range	0 to 150 breaths per minute (bpm)	0 to 150 breaths per minute (bpm)	Same
Respiration Rate Accuracy	± 1 breaths per minute (bpm)	± 1 breaths per minute (bpm)	Same
Voltage Requirements	5.0 VDC ±5%	5.0 VDC ±5%	Same
Interconnection	Lemo Redel 8-pin plastic	Lemo Redel 8-pin plastic	Same
Temperature and Humidity	Operating: 0 to 40°C, 15 to 85% RH, non-condensing Storage: -10 to 40°C, <90% RH, non-condensing	Operating: 0 to 45°C, 10 to 90% RH, non-condensing Storage: -40 to 70°C, <90% RH, non-condensing	Similar
Water Resistance	IPX2 – Splash-proof (sensor head only)	IPX4 – Splash-proof (sensor head only)	Similar
Compliance	IEC 60601-1(safety) IEC 60601-1-2(EMC) ISO 80601-2-55(Performance)	IEC 60601-1(safety) IEC 60601-1-2(EMC) ISO80601-2-55(Performance)	Same

From the comparison form above, the subject and predicate devices are based on the following same technological elements:

- Same measurement techniques
- Same intended use & indications for Use
- Same CO_2 Resolution & Accuracy
- Same respiration rate range & Accuracy
- Same voltage Requirements
- Both comply to the same FDA recognized standards

The following slightly technological differences exist between the subject and predicate devices:

- Similar temperature and humidity range
- Water Resistance of predicate device is higher than Orantech's

These differences do not raise different questions of safety and effectiveness.

9. Clinical test data

Not applicable.

10. Non-clinical test data

1)Industry Standards for Electrical Safety, EMC and Essential Performance
Testing of the ECO_2 Sensor has been completed to verify compliance with FDA recognized national and international standards for electrical safety and performance for medical devices, and particular requirements applicable to this device including:

- IEC 60601-1:2012 Basic safety and essential performance
- IEC 60601-1-2:2007 and 2014 EMC
- ISO 80601-2-55:2011 Respiratory gas monitors

2) Biocompatibility
The $ETCO_2$ Sensor does not contain any direct or indirect patient contacting components. Patient contacting accessories are previously cleared by FDA. Biocompatibility test is not applicable for subject device.

3) Software Verification
Software verification and validation testing were conducted and documentation was provided as recommended by FDA Software Guidance.

11. Conclusion

The results for testing demonstrate that the $ETCO_2$ Sensor is substantially equivalent to the above listed predicate device.