January 4, 2018

Respirion, Inc.
% Paul Dryden
Consultant
ProMedic, LLC
24301 Woodsage Dr.
Bonita Springs, Florida 34134

Re: K171235
Trade/Device Name: OmniCap
Regulation Number: 21 CFR 868.1400
Regulation Name: Carbon Dioxide Gas Analyzer
Regulatory Class: Class II
Product Code: CCK
Dated: December 6, 2017
Received: December 8, 2017

Dear Paul Dryden:

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,

Michael J. Ryan -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)*

K171235

Device Name

OmniCap™

Indications for Use *(Describe)*

The use of the OmniCap™ capnometer is indicated to provide measurement and monitoring of carbon dioxide concentration of the expired breath and respiration rate of adult patients. It is an adjunct in patient assessment, to be used in conjunction with other methods to determine clinical signs and symptoms by or on the order of a qualified healthcare provider.

Environment of Use: Hospitals, Sub-acute care facilities and intra-hospital transport.

Type of Use *(Select one or both, as applicable)*

XX 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
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27-Dec-17

Official Contact: Ed Fadel, CEO
Respirion, Inc.
212 Jewell Drive
Chapel Hill, NC 27516
Tel: 919-280-2534

Proprietary or Trade Name: OmniCap

Common/Usual Name: analyzer, gas, carbon-dioxide, gaseous-phase

Classification Name: analyzer, gas, carbon-dioxide, gaseous-phase
CCK, Class II, 21CFR 868.1400

Predicate Device: Oridion Microcap / Nellcor N-85 - K981114

Reference Device: Maxtec Flocap - K133540

Device Description:
The OmniCap system incorporates three parts:

- OmniCap monitor
- Sensor cartridge with a colorimetric litmus media
- AC power adapter

The OmniCap monitor houses the electronics including the color sensor, a LED light source, a miniature vacuum pump, internal sample gas tubing, a rechargeable nickel metal hydride battery pack, and the user interface.

The OmniCap Sensor cartridge is a colorimetric litmus media sealed in a plastic cartridge with clear windows on each side.

The AC power adapter is IEC 60601-1 compliant. The AC power adapter converts supplied AC power to DC power to facilitate charging the battery.

The OmniCap unit can operate with or without the AC adapter connected and powered.

Indications for Use:
The use of the OmniCap™ capnometer is indicated to provide measurement and monitoring of carbon dioxide concentration of the expired breath and respiration rate of adult patients. It is an adjunct in patient assessment, to be used in conjunction with other methods to determine clinical signs and symptoms by or on the order of a qualified healthcare provider.

Environment of Use: Hospitals, Sub-acute care facilities and intra-hospital transport.

Contraindications:
We have listed the following contraindications:

- This product is not intended for use with anesthesia agents.
- Do not use OmniCap in an MR environment.

- Do not use in the presence of flammable anesthetics or gases.
- Do not use OmniCap during defibrillation.

Device Comparison

Substantial Equivalence Discussion

We have identified the primary predicate as the Oridion Microcap / Nellcor N-85, K981114, for its performance characteristics and intended use for measurement and monitoring of end-tidal carbon dioxide and respiration rate.

There is a difference in the technology of measuring the CO_2 in the expired gas between the predicate and the subject device. Namely the OmniCap uses colorimetric litmus media which has been treated with chemical and a color sensor to detect carbon dioxide by color change of the media, while the Nellcor N-85 uses an infrared absorption (IR) technique to determine the level of carbon dioxide.

FDA has cleared CO_2 detector, indicators, and measurement devices which utilize colormetric technology. We have identified the reference device Maxtec FloCap, K133540, for the similar technology and intended use. In the case of the reference device, the user must visually determine and read the color change to determine the CO_2 level whereas the subject device, OmniCap, has a color sensor which detects the color change of the media and presents the change as a $\%CO_2$.

We believe that the technological characteristics are testable with acceptable methods.

Table 1 outlines the characteristics to support the primary predicate and reference device rationale for substantial equivalence.

Table 1 Rationale for Predicate and Reference vs. Subject Device

Feature	Primary Predicate	Reference	Subject device
	Oridion MicroCap / Nellcor N-85 (K981114)	Maxtec FloCap (K133540)	OmniCap
Classification	CCK CFR 868.1400 analyzer, gas, carbon-dioxide, gaseous-phase		
Indications for Use	The use of the Microcap capnography monitor is indicated whenever a professionally trained health care providers determine that a patient requires the continuous, non-invasive measurement and monitoring of carbon dioxide concentration of the expired and inspired breath and respiration rate	The FLOCAP is to provide a semi-quantitative visualization of the C02 in the patient airway. It is an adjunct in patient assessment, to be used in conjunction with other methods to determine clinical signs and symptoms by or on the order of a physician. The FLOCAP has a visual indicator to visually detect the end of exhalation. For use up to 24 hours. For patients greater than 15 kg (33 lbs.) Environment of use - hospital, sub-acute, pre-hospital, transport	The use of the OmniCap™ capnometer is indicated to provide measurement and monitoring of carbon dioxide concentration of the expired breath and respiration rate of adult patients. It is an adjunct in patient assessment, to be used in conjunction with other methods to determine clinical signs and symptoms by or on the order of a qualified healthcare provider. Environment of Use: Hospitals, Sub-acute care facilities and intra-hospital transport.
Patients	Adult, pediatric, and infant/neonatal patients	Patients >15 kg (33 lbs.)	Adult
Environment of Use	Hospitals Mobile use	Hospitals Sub-acute Pre-hospital Transport	Hospitals Sub-acute care facilities Intra-hospital transport
Technology for CO_2 measurement	Infrared Presents values	Colormetric User reads the color change	Colormetric Sensor for reading color change Presents values
Duration of technology	Unlimited	Up to 24 hours	8 hours then sensor cartridge replaced

Table of Comparison and Differences

Table 2 presents a technical comparison of the OmniCap and the predicate and reference devices to establish substantial equivalence.

Table 2 - Device Comparison

Feature	**Subject device** **OmniCap™**	**Predicate** **Oridion MicroCap / Nellcor N-85** **(K981114)**	**Reference** **Maxtec FloCap** **(K133540)**
Monitoring	Continuous	Continuous	Quantitative indicator
Duration of Use	8 hours / cartridge	Unlimited	< 24 hours per device
Patient Population	Adults	Adult, pediatric, and infant/neonatal patients	For patients greater than 15 kg (33 lbs.)
Environment of Use	Hospitals Sub-acute care facilities Intra-hospital transport	Hospitals Sub-acute care facilities (not stated) Mobile use	Hospital Sub-acute care facilities Pre-hospital transport
Technology to detect CO_2 concentration	Colormetric media changes color and sensor detects color change and reports a value	Infrared	Colormetric media changes color and user uses guide to determine the % CO_2
How CO_2 are displayed?	mmHg Value as a number	mmHg Value as a number Waveform	% CO_2 Color interpreted by the user
Respiratory Rate	Displayed value	Displayed value	Not displayed
Method of drawing sample	Pump pulls a vacuum to sample	Pump pulls a vacuum to sample	Patient inhales / exhales through the device
Patient interface	Nasal cannula	Nasal cannula Face mask Gas sampling line	Connected to a device through which patient exhales, e.g., endotracheal tube or mask

Feature	**Subject device** **OmniCap**	**Predicate** **Oridion MicroCap / Nellcor N-85** **(K981114)**	**Reference** **Maxtec FloCap** **(K133540)**
Specifications			
CO_2 range	12 – 76 mmHg	0 – 99 mmHg	0 – 5%
Accuracy of CO_2	+/- 3.268 mm Hg or + 8% of reading Applicable parts of ISO 80601-2-55	+/- 2 mmHg between 0 – 38 mmHg +/- 5% of reading between 39 – 99 mmHg Meets ISO 80601-2-55	No accuracy stated ISO 80601-2-55 not applicable
Respiratory Rate (RR)	5 to 40 bpm	0 -150 bpm	Does not measure rate
Accuracy of RR	+/- 1 bpm between 5 to 40 Meets ISO 80601-2-55	0-70 bpm: ±1 bpm 71-120 bpm: ±2 bpm 121-150 bpm: ±3 bpm	Not applicable
Time to Steady state	2 minutes	1 minute	After 6 breathes
Flow rate	285 mL/min	50 mL/min	None
Shelf-life of Disposable	6 months	N/A	2 years
Alarms			
$EtCO_2$ value	Low High	Low High	None
Respiratory Rate	Low High	Low High	None
Low battery alarm	Yes	Yes	None
Technical Specifications			
Power	AC Rechargeable Battery	AC Rechargeable Battery	None
Dimensions	5.8”H x 4.8”W x 1.3”D	8.1”H x 3.5”W x 2.1”D	3.3”W x 3.3”W x x1.3”D
Weight	320 grams	850 grams	23 grams
Biocompatibility	No materials in the gas pathway Gas sampling accessories supplied by user	No materials in the gas pathway Gas sampling accessories supplied by user	Externally communicating Tissue Limited duration of use
Performance Testing	Shelf-life Effects of Aging Accuracy and repeatability of RR and CO_2		
Standards	ANSI/AAMI/ES 60601-1 IEC 60601-1-2 IEC 60601-1-8	ANSI/AAMI/ES 60601-1 IEC 60601-1-2 IEC 60601-1-8	Not applicable, not electrically powered

Substantial Equivalence Discussion and Rationale

In **Table 2** we have compared the OmniCap to the predicate and reference devices for equivalence of:

Indications – The indications are for measuring and monitoring exhaled CO_2 and respiratory rate in adult patients by qualified healthcare providers.
Discussion – The indications are similar to the predicate - Oridion MicroCap / Nellcor N-85 (K981114) but the predicate also includes SpO_2 monitoring which is not included in the subject device. The measurement of expired CO_2 can be and is a standalone physiological parameter. The predicate is a multi-parameter patient monitor. The subject device as an end-tidal CO_2 monitor only does not affect the intended diagnostic use of measuring and monitoring end-tidal CO_2.

Patient Population – The population for the subject device is for adults only.
Discussion – The population of the predicate - Oridion MicroCap / Nellcor N-85 (K981114) includes neonates to adults. This difference which is included in the labeling does not affect substantial equivalence for the intended use.

Environment of Use – The subject device does not include pre-hospital while the predicate and reference devices include a larger range of environments of use.
Discussion – This difference does not affect substantial equivalence.

Design and Technology – The OmniCap is using a combination of technologies, colormetric for detecting the amount of CO_2 present and a sensor to detect the color change and convert it to a numerical value.
Discussion – The reference device – Maxtec FloCap (K133540) uses colormetric CO_2 detection but does not quantify it except in a range which the user ten confirms. While the predicate - Oridion MicroCap / Nellcor N-85 (K981114) uses infrared to detect, measure and display a numerical value of CO_2 detected and respiratory rate. While the technologies of the OmniCap are a combination of both, we have confirmed that the accuracy of the OmniCap meets the performance requirements of ISO 80601-2-55 like the predicate. These differences have been evaluated and do not raise new concerns of safety and effectiveness.

Performance Specifications – The performance of the OmniCap complies with the applicable requirement specifications of the FDA recognized standard ISO 80601-2-55.
Discussion – Both the subject device and the predicate - Nellcor N-85 (K981114) meet the performance requirements of ISO 80601-2-55. We note that the reference device – Maxtec FloCap (K133540) does not meet ISO 80601-2-55. Differences noted are: range of measured $EtCO_2$, range of measured respiratory rate, response time and sampling flow rate. These differences in performance are disclosed to the user and while narrower in scope, the intended use and compliance with ISO 80601-2-55 is non-specific. We have demonstrated that the differences do not raise concerns of safety and effectiveness that can be addressed in labeling.

Compliance with standards – The subject device has been tested to a number of standards, ISO 80601-2-55, ES 60601-1, and IEC 60601-1-2 and complies with the applicable requirements.
Discussion – The predicate – Oridion MicroCap / Nellcor N-85 (K981114) also complies with these standards. These do not raise concerns of safety and effectiveness.

Performance Testing – Non-clinical

Bench -
We have performed bench tests and found that the met all requirements specifications and standards requirements and was found to be equivalent in comparison to the predicate. Testing includes the following:

- ANSI/AAMI/ES 60601-1
- IEC 60601-1-2
- ISO 80601-2-55

In addition and as part of the above standard we performed testing for:

- Comparative performance to the predicate – IR technology
  - Tested as various concentrations of $CO_2$and respiration rate
- Accuracy and repeatability of measured $CO_2$the sensor cartridges
- Respiration rate accuracy and repeatability
- Shelf-life and Effects of Aging
- Useful Life

The results demonstrate that the device performs as intended and can be found to be substantially equivalent to the predicate and reference devices.

Biocompatibility and Materials –
There are no patient contacting materials.

Differences and Substantial Equivalence Conclusion

The OmniCap is substantially equivalent to the predicate in: indications for use, patient population, environment of use, technology characteristics, materials, specifications / performance and compliance with international standards. The differences do not raise different questions of safety or effectiveness when compared to the predicate and reference devices for the proposed indications for use.