Revolutionary Medical Devices, Inc.
% Paul Dryden
Consultant
ProMedic, LLC
131 Bay Point Dr. NE
St. Petersburg, Florida 33704

Re: K173147
Trade/Device Name: SuperNO$_2$VA Et™ Device
Regulation Number: 21 CFR 868.1400
Regulation Name: Carbon Dioxide Gas Analyzer
Regulatory Class: Class II
Product Code: CCK, BSJ
Dated: May 23, 2018
Received: May 24, 2018

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 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,

Todd D. Courtney -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

Form Approved: OMB No. 0910-0120

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Expiration Date: 06/30/2020
See PRA Statement on last page.

Indications for Use

510(k) Number *(if known)*

K173147

Device Name

SuperNO$_2$VA Et™ Device

Indications for Use *(Describe)*

The SuperNO$_2$VA Et™ Device is a nasal mask that creates a seal when positioned over a patient's nose to direct anesthesia gas, air, and / or oxygen to the upper airway during the continuum of anesthesia care.

It has a means for sampling expired gases from the patient's exhaled breath from the oral / nasal areas.

The SuperNO$_2$VA Et™ Device is intended for short-term (<24 hours) use on adult patients (>30 kg.). It is a single patient use, disposable.

The SuperNO$_2$VA Et™ Device is contraindicated for use in long-term ventilation conditions and treatment of sleep apnea.

To be used under clinical supervision with adequate alarms and safety systems for monitoring and treatment of ventilatory failure.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(k) Summary

20-Jun-18

Revolutionary Medical Devices, Inc.
4090 E. Bujia Primera
Tucson, AZ 85718 Tel - (520)-844-3729

Official Contact: David M. Kane – President and CEO

Proprietary or Trade Name: SuperNO_2VA Et™ Device

Common/Usual Name: Nasal anesthesia face mask with gas sampling

Classification Code/Name: CCK – analyzer, gas, carbon-dioxide, gaseous-phase
21CFR 868.1400, Class 2

Device: SuperNO_2VA Et™ Device

Predicate Devices: Primary - K011050 – Oridion Microstream (CapnoLine) - CCK
Secondary – K163277 – RMD – SuperNO_2VA™ Device - BSJ

Reference Devices: Class 510(k) exempt - Medline – Anesthesia Face Mask
K133806 – Monitor Mask – M1

Device Description:
The SuperNO_2VA Et™ Device is a nasal mask with a sampling port for the nasal portion and a sampling "hood" for over the mouth.

The subject device is similar to an anesthesia or oxygen mask with gas sampling port. Instead of covering the full face the SuperNO_2VA Et™ Device design is to allow the clinician to have access to the oral cavity during a procedure but still be able to provide air, oxygen or anesthesia gases to the patient while also sampling expired gases from the nasal or oral areas.

The design incorporates the standard 15 mm male circuit connector, luer fitting for the gas sampling line and a slip-fit port for pressure monitoring or oxygen if the mask is used with a manual resuscitator or hyperinflation bag.

The mask is not considered a long-term use device as it would only be used from pre- to post-operative care. This would be similar to the standard anesthesia mask.

It is not for use in long-term ventilation conditions or the treatment of sleep apnea.

Indications for Use:
The SuperNO_2VA Et™ Device is a nasal mask that creates a seal when positioned over a patient's nose to direct anesthesia gas, air, and / or oxygen to the upper airway during the continuum of anesthesia care.

It has a means for sampling expired gases from the patient's exhaled breath from the oral / nasal areas.

The SuperNO_2VA Et™ Device is intended for short-term (<24 hours) use on adult patients (>30 kg.). It is a single patient use, disposable.

The SuperNO$_2$VA Et™ Device is contraindicated for use in long-term ventilation conditions and treatment of sleep apnea.

To be used under clinical supervision with adequate alarms and safety systems for monitoring and treatment of ventilatory failure.

Patient Population: Adult patients (>30 kg)

Environment of Use: Hospital, Sub-acute

Substantial Equivalence Discussion: Table 1 below compares the key features of the proposed SuperNO$_2$VA Et™ Device mask with the identified primary and secondary predicates and reference devices to demonstrate that the proposed device can be found to be substantially equivalent.

Indications for Use – SuperNO$_2$VA Et™ Device combines indications for use from the predicates, namely expired gas sampling – oral and nasal, with the secondary predicate SuperNO$_2$VA, K163277, which provides a seal to delivery of gases.
Discussion – The proposed indications are a combination of the predicate and reference devices and there are no differences in the indications which raise new concerns of safety and effectiveness when compared to the predicates.

Technology and construction – SuperNO$_2$VA Et™ Device is a nasal mask with a means, a "hood" to also sample expired exhaled from the mouth.

Like the predicate and reference devices they all sample exhaled gases via a port which is a conduit for the samples gases to be delivered to the monitor.
Discussion – The difference is the combination of a nasal mask and the "hood" over the mouth. The predicate uses nasal cannula and an additional sampling means for the mouth. However, the comparison performance testing has demonstrated equivalence.

The difference of delivering gases is similar to the secondary predicate SuperNO$_2$VA, K163277, which provides a seal to delivery of gases. Delivery of gases under pressure to only the nasal area only is consistent with the secondary predicate and thus does not raise different concerns of safety or effectiveness than the predicates.

Environment of Use – The environment of use is similar to the predicates and reference devices.
Discussion – The subject device does not include the pre-hospital setting.

Table 1 – Comparison to Predicate and Reference Devices

Feature	Proposed SuperNO₂VA Et™ Device	Primary Predicate K011050 Oridion - Capnostream Oral / Nasal Cannula	Secondary Predicate K163277 RMD SuperNO₂VA Mask	Reference Exempt Medline Anesthesia mask	Reference K133806 Monitor Mask – M1
Product Classification	CCK 868.1400 BSJ 868.5550 (Secondary)	CCK 868.1400	BSJ 868.5550	BSJ 868.5550	CCK 868.1400
Indications for Use	The SuperNO₂VA Et™ Device is a nasal mask that creates a seal when positioned over a patient's nose to direct anesthesia gas, air, and / or oxygen to the upper airway during the continuum of anesthesia care. It has a means for sampling expired gases from the patient's exhaled breath from the oral / nasal areas. To be used under clinical supervision with adequate alarms and safety systems for monitoring and treatment of ventilatory failure. The SuperNO₂VA Et™ Device is intended for short-term (<24 hours) use on adult patients (>30 kg.). It is a single patient use, disposable. The SuperNO₂VA Et™ Device is contraindicated for use in long-term ventilation conditions and treatment of sleep apnea.	Is used whenever the physician needs to measure the CO_2 in a patient's breathing in a non-intubated patient. Intended to conduct a sample of the patient's breathing from the patient to the gas measurement device for measuring the percentage of CO_2 in the patient's exhalation.	The SuperNO₂VA™ Device is a mask that creates a seal when positioned over a patient's nose and mouth, or nose only, to direct anesthesia gas, air, and / or oxygen to the upper airway during the continuum of anesthesia care. To be used under clinical supervision with adequate alarms and safety systems for monitoring and treatment of ventilatory failure. The SuperNO₂VA™ Device is intended for short-term (<24 hours) use on adult patients (>30 kg.) It is a single patient use, disposable. The SuperNO₂VA™ Device is contraindicated for use in long-term ventilation conditions and treatment of sleep apnea.	Positioned over a patient's nose or mouth to direct anesthetic gases to the upper airway. Port for expired gas sampling	The M1 Capnagraphy Mask is a single-use device intended for delivering supplemental oxygen and monitoring exhaled carbon dioxide in non-intubated spontaneously breathing patients. Standard oxygen tubing and two female luer ports for gas sample line attachment are Included.

Feature	Proposed SuperNO$_2$VA Et™ Device	Primary Predicate K011050 Oridion - Capnostream Oral / Nasal Cannula	Secondary Predicate K163277 RMD SuperNO$_2$VA Mask	Reference Exempt Medline Anesthesia mask	Reference K133806 Monitor Mask – M1
Patient Population	Adult Patients > 30 kg	All patients	Adult Patients > 30 kg	All patients	All patients
Environment of Use	Hospital Sub-acute	Hospital Sub-acute Pre-hospital	Hospital Sub-acute	Hospital Sub-acute Pre-hospital	Hospital Sub-acute Pre-hospital
Duration of Use	Single patient use, Disposable < 24 hours	Single patient use, disposable	Single patient use, Disposable < 24 hours	Single patient use, disposable	Single patient use, disposable
Technological Characteristics					
Where expired gas sampled	Nasal Oral	Nasal Oral	No sampling	No sampling	Nasal Oral
Where is gas delivered	Nasal	Nasal	Nasal Oral	Nasal Oral	Nasal Oral
Technology for directing gases under pressure	Seal at nasal area	No seal	Seal at both nasal and oral	Seal at both nasal and oral	No seal
Technology for sampling expired gases	Luer port in nasal mask Open hood for oral portion	Open sampling in nasal area Open hood for oral portion	No sampling port	Luer port in mask	Luer port in mask
Provides a seal for delivery of gas	Yes Nasal only	No	Yes Nasal and Oral	Yes Nasal and Oral	No
Oxygen or pressure monitoring port	Yes	No	Yes	No	Yes
Method of sampling expired gases	At nasal portion via a port At oral via a hood	At nasal via a cannula At oral via a hood	Does not sample	At oral and nasal via a port	At oral and nasal via a port
Patient connector	15 mm connector for delivered gas source	No patient connector	15 mm connector for connecting delivered gases	15 / 22 mm connector for delivered gas source	Oxygen tubing connector for delivered gas source

Feature	**Proposed SuperNO$_2$VA Et™ Device**	**Primary Predicate K011050 Oridion - Capnostream Oral / Nasal Cannula**	**Secondary Predicate K163277 RMD SuperNO$_2$VA Mask**	**Reference Exempt Medline Anesthesia mask**	**Reference K133806 Monitor Mask – M1**
Performance Comparison					
Internal volume	Nasal mask only Medium – 53 ml Large – 87 ml	Not applicable	Nasal mask only Medium – 53 ml Large – 87 ml	Full mask ~ 158 ml	Not applicable
Pressure to maintain a seal for gas delivery	Up to 30 cmH$_2$O	Not applicable	Up to 30 cmH$_2$O	Not specified	Not applicable
Resistance to flow	0.46 cmH$_2$O @ 50 lpm 1.8 cmH$_2$O @ 100 lpm	Not applicable	0.46 cmH$_2$O @ 50 lpm 1.8 cmH$_2$O @ 100 lpm	30 lpm – 0.13 cmH$_2$O 60 lpm – 0.25 cmH$_2$O 90 lpm – 0.51 cmH$_2$O	Not tested
Leak rate under pressure	0.8 Lpm @ 20 cmH$_2$O	Not applicable	0.8 Lpm @ 20 cmH$_2$O	Not tested	Not tested
Biocompatibility	ISO 10993-1 Externally communicating Tissue Surface Contact Skin / Mucosal Limited duration (< 24 hours)	ISO 10993-1 Externally communicating Tissue Surface Contact Skin / Mucosal Prolonged duration	ISO 10993-1 Externally communicating Tissue Surface Contact Skin / Mucosal Limited duration (< 24 hours)	ISO 10993-1 Externally communicating Tissue Surface Contact Skin / Mucosal Limited duration	ISO 10993-1 Externally communicating Tissue Surface Contact Skin / Mucosal Prolonged duration
Performance testing	Internal volume Resistance to flow through the connector Leakage under simulated seal conditions with a mannequin face Connector – 15 mm testing – pre- and post-aging Drop Environmental – Operating / Storage conditions	EtCO$_2$ performance	Internal volume Resistance to flow through the connector Leakage under simulated seal conditions with a mannequin face Connector – 15 mm testing – pre- and post-aging Drop Environmental – Operating / Storage conditions	Resistance to flow through the connector Leakage under simulated seal conditions with a mannequin face Connector – 15 mm testing	EtCO$_2$ performance

Feature	**Proposed SuperNO$_2$VA Et™ Device**	**Primary Predicate K011050 Oridion - Capnostream Oral / Nasal Cannula**	**Secondary Predicate K163277 RMD SuperNO$_2$VA Mask**	**Reference Exempt Medline / Ventlab Anesthesia mask**	**Reference K133806 Monitor Mask – M1**
Dead space	Nasal mask only Medium – 53 ml Large – 87 ml	- - N/A	Nasal mask only Medium – 53 ml Large – 87 ml	Large - 158 ml (Nasal and Oral) Medium -	- - N/A
Pressure / Leak	Can maintain pressure of > 20 cmH$_2$O with 10 lbs. force Leakage < 2 Lpm		Can maintain pressure of > 20 cmH$_2$O with 10 lbs. force Leakage < 2 Lpm	Can maintain pressure of > 20 cmH$_2$O with 10 lbs. force Leakage ave. 2.6 Lpm	
Pressure Drop Acceptance < 5 cmH$_2$O @60 Lpm	30 lpm – 0.13 cmH$_2$O 60 lpm – 0.38 cmH$_2$O 90 lpm – 1.15 cmH$_2$O	- - N/A	30 lpm – 0.13 cmH$_2$O 60 lpm – 0.38 cmH$_2$O 90 lpm – 1.15 cmH$_2$O	30 lpm – 0.13 cmH$_2$O 60 lpm – 0.25 cmH$_2$O 90 lpm – 0.51 cmH$_2$O	- - N/A

Table 2 – Comparative O_2 / CO_2 Performance Nasal and Oral Sampling

Feature	Proposed SuperNO₂VA Et™ Nasal Sampling	K011050 Oridion - Capnostream Nasal Sampling	Proposed SuperNO₂VA Et™ Oral Sampling	K011050 Oridion - Capnostream Oral Sampling
Adult				
BPR = 12 **TV (ml) = 500 ml** **CO_2% - 1%** **O_2 Flow rate – 1 and 5 lpm**	$EtCO_2$ @ 1% and **1** Lpm Ave. – 1.00% $EtCO_2$ @ 1% and **5** Lpm Ave. – 4.93%	$EtCO_2$ @ 1% and **1** Lpm Ave. - 0.93% $EtCO_2$ @ 1% and **5** Lpm Ave. - 0.88%	$EtCO_2$ @ 1% and **1** Lpm Ave. – 0.98% $EtCO_2$ @ 1% and **5** Lpm Ave. – 4.95	$EtCO_2$ @ 1% and **1** Lpm Ave. – 0.86% $EtCO_2$ @ 1% and **5** Lpm Ave. – 4.19%
BPR = 12 **TV (ml) = 500 ml** **CO_2% - 5%** **O_2 Flow rate – 1 and 5 lpm**	$EtCO_2$ @ 5% and **1** Lpm Ave. - 0.94% $EtCO_2$ @ 5% and **5** Lpm Ave. – 4.92%	$EtCO_2$ @ 5% and **1** Lpm Ave. - 4.22% $EtCO_2$ @ 5% and **5** Lpm Ave. - 4.07%	$EtCO_2$ @ 5% and **1** Lpm Ave. - 0.90% $EtCO_2$ @ 5% and **5** Lpm Ave. – 4.46%	$EtCO_2$ @ 5% and **1** Lpm Ave. - 0.79% $EtCO_2$ @ 5% and **5** Lpm Ave. – 3.59%
Pediatric				
BPR = 20 **TV (ml) = 300 ml** **CO_2% - 1%** **O_2 Flow rate – 1 and 5 lpm**	$EtCO_2$ @ 1% and **1** Lpm Ave. 0.91% $EtCO_2$ @ 1% and **5** Lpm Ave. – 4.62%	$EtCO_2$ @ 1% and **1** Lpm Ave. - 0.82% $EtCO_2$ @ 1% and **5** Lpm Ave. - 4.02%	$EtCO_2$ @ 1% and **1** Lpm Ave. 0.87% $EtCO_2$ @ 1% and **5** Lpm Ave. – 4.67%	$EtCO_2$ @ 1% and **1** Lpm Ave. - 0.77% $EtCO_2$ @ 1% and **5** Lpm Ave. – 4.01%
BPR = 20 **TV (ml) = 300 ml** **CO_2% - 5%** **O_2 Flow rate – 1 and 5 lpm**	$EtCO_2$ @ 5% and **1** Lpm Ave. – 0.88% $EtCO_2$ @ 5% and **5** Lpm Ave. – 4.60%	$EtCO_2$ @ 5% and **1** Lpm Ave. -0.81 $EtCO_2$ @ 5% and **5** Lpm Ave - 3.96%	$EtCO_2$ @ 5% and **1** Lpm Ave. – 0.91% $EtCO_2$ @ 5% and **5** Lpm Ave. – 4.06%	$EtCO_2$ @ 5% and **1** Lpm Ave. – 0.72% $EtCO_2$ @ 5% and **5** Lpm Ave. – 3.35%
Note: Testing of the Secondary Predicate for $EtCO_2$ is not applicable as the device does not have this feature				

Table 3 – Comparative O_2 / CO_2 Performance under Positive Pressure

Feature	**Proposed SuperNO₂VA Et™ Both Nasal / Oral Sampling**	**Reference - Exempt Medline Anesthesia mask Both Nasal / Oral Sampling**
Adult		
BPR = 12 TV (ml) = 500 ml CO_2% - 1% Pressure – 20 cmH_2O	$EtCO_2$ @ 1% Ave. - 0.98%	$EtCO_2$ @ 1% Ave. - 0.97%
BPR = 12 TV (ml) = 500 ml CO_2% - 5% Pressure – 20 cmH_2O	$EtCO_2$ @ 5% Ave. - 4.96%	$EtCO_2$ @ 5% Ave. - 4.90%
Pediatric		
BPR = 20 TV (ml) = 300 ml CO_2% - 1% Pressure – 20 cmH_2O	$EtCO_2$ @ 1% Ave. – 1.00%	$EtCO_2$ @ 1% Ave. – 0.95%
BPR = 20 TV (ml) = 300 ml CO_2% - 5% Pressure – 20 cmH_2O	$EtCO_2$ @ 5% Ave. - 5.00%	$EtCO_2$ @ 5% Ave. - 4.62%

Note: Testing of the Secondary Predicate for $EtCO_2$ is not applicable as the device does not have this feature

Non-Clinical Testing Summary –

Bench Testing
We performed testing which evaluated the design. These tests included:

- Dead space / volume
- Pressure drop
- Pressure and leakage
- O_2 / CO_2 performance at various simulated settings including positive pressure, oral / nasal sampling only
- Age and shelf-life
- Drop testing

Biocompatibility
SuperNO₂VA™ based upon ISO 10993-1 is considered:

Surface Contact
Mucosal membrane
Limited Duration (< 24 hours)
And
Externally Communicating
Tissue
Limited Duration (< 24 hours)

Testing would include:

- Cytotoxicity
- Sensitization
- Irritation

Discussion of Differences –
The differences are:

- The subject device provides a means to delivered gases under pressure only to the nasal area and sample expired gases. The secondary predicate, SuperNO_2VA, K163277 delivers gases under pressure to also, but does not sample expired gases under pressure. Therefore, the reference device, Medline mask which is a full-face mask and delivers gases under pressure and also samples expired gases was compared and comparative testing demonstrated that performance was substantially equivalent.
- Technology of sampling expired gases is a combination of 2 devices.
    - In the sealed nasal mask portion this is similar to the reference full face mask, Medline.
    - Via the oral hood is similar to the primary predicate, Oridion – K011050 which samples both via an oral hood and via nasal cannula.
    - Comparative testing demonstrated that the performance of measuring expired gases was substantially equivalent.

Substantial Equivalence Conclusion –
Based upon the presented information the sponsor has demonstrated through performance testing, design and features, and non-clinical testing that the proposed devices and predicates have been found to substantially equivalent and there are no different safety or effectiveness concerns raised.