DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

October 13, 2017

Revolutionary Medical Devices, Inc.
% Paul Dryden
Consultant
Promedic, LLC
24301 Woodsage Dr.
Bonita Springs, Florida 34134

Re: K163277
Trade/Device Name: SuperNO_2VA™ Device
Regulation Number: 21 CFR 868.5550
Regulation Name: Anesthetic Gas Mask
Regulatory Class: Class I
Product Code: BSJ
Dated: September 8, 2017
Received: September 11, 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Tara A. Ryan -S

for
Tina Kiang, PhD
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 on last page.

510(k) Number *(if known)*

K163277

Device Name

SuperNO$_2$VA™ Device

Indications for Use *(Describe)*

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

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
K163277
October 12, 2017

Revolutionary Medical Devices, Inc.
6363 N Swan Rd.
Tucson AZ 85718 Tel - (520)-820-3749

Official Contact: Cassie Vollmer, Director of RA/QA

Proprietary or Trade Name: SuperNO_2VA™ Device

Common/Usual Name: Patient interface Nasal and Nasal / Oral mask

Classification Code/Name: BSJ – Anesthesia face mask
21CFR 868.5550, Class 1

Device: SuperNO_2VA™ Device

Predicate Device: K953107 – Medical Marketing Concepts – Anesthesia / Respiratory Face Mask

Device Description:
The SuperNO_2VA™ is a 2-piece construction with a nasal and an oral portion. When assembled together the oral portion is connected to the nasal portion. The nasal portion (chamber) contains 2 one way (duck bill) valves which are normally closed until the oral chamber is connected. Then gas passes through each portion to the patient. If one desires to remove the oral chamber during a procedure which requires oral access, then gas can still be provided via the nasal portion. Depending upon the equipment and the clinician's desire one can provide non-invasive positive pressure ventilation as well.

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

The SuperNO_2VA™ Device is contraindicated for use in long-term ventilation conditions and treatment of sleep apnea.

Patient Population: Adult patients (>30 kg)

Environment of Use: Hospital and Out-patient surgery settings

510(k) Summary
K163277
October 12, 2017

Feature	**Predicate** **K953107** **Anesthesia mask**	**Proposed** **SuperNO$_2$VA™**
Product Classification	BSJ – anesthetic face mask 21 CFR 868.5550	BSJ – anesthetic face mask 21 CFR 868.5550
Indications for Use	An Anesthesia / Respiratory face mask that is positioned over a patient's nose or mouth to direct anesthetic gases, air, and oxygen to the upper airway.	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.
Patient Population	All age patients	Adults > 30 kg
Environment of Use	Hospital Sub-acute	Hospital Sub-acute
Duration of Use	Single patient use, disposable	Single patient use, disposable
Equipment	Anesthesia gas machine Manual resuscitators Not intended to be used with CPAP or bi-level equipment	Anesthesia gas machine Manual resuscitators Not intended to be used with long-term ventilations conditions and with CPAP equipment intended for long-term use.
Anatomical seal	Nasal and Oral	Nasal and Oral Nasal Only
Components	Single part Non-vented connector Headstrap	2 parts – nasal and oral chamber Non-vented connector Headstrap
Other feature		Can be separated to be nasal only Contains duck-bill valves which seal when the oral chamber is removed
Oxygen or pressure port	Yes	Yes
Monitoring of airway / circuit pressures	Yes	Yes
Sizes	Multiple - more than 2	2

510(k) Summary
K163277
October 12, 2017

Feature	**Predicate** **K953107** **Anesthesia mask**	**Proposed** **SuperNO$_2$VA™**
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 Limited duration (< 24 hours)
Materials	Shell – Flexible PVC Cushion – PVC	Shell - polypropylene Seal – PVC
Provided sterile	No	No
Performance testing	Not available	Comparative - Internal Volume Comparative – Pressure Drop Testing Comparative - Pressure and Leak Rate Test Comparative – Strap and Anchor Connector Testing (unaged and aged) Drop Test Age / Shelf-life
Internal Volume	~ 150 ml - medium	Medium – Nasal - 53 ml Full mask – 84 ml Large – Nasal - 87 ml Full mask – 137 ml
Therapy Pressure Range	This mask does not have a defined pressure limitation	The device does not provide therapy but the maximum pressure range is recommended to be 30 cmH_2O in order to maintain a seal.
Connectors and Resistance at connector Per ISO 17501 acceptance is a reported value.	15 mm and 22 mm < 1 cmH_2O @ 60 lpm	15 mm 0.46 cmH_2O @ 50 lpm 1.8 cmH_2O @ 100 lpm Note subject device will not be used with CPAP / bi-level equipment.
Operating / Storage Conditions	No stated conditions are available	-28 to + 60^oC 15 to 85% RH

The above table compares the key features of the proposed SuperNO$_2$VA™ mask with the identified predicate device to demonstrate that the proposed device can be found to be substantially equivalent.

Indications for Use – SuperNO$_2$VA™ indications for use of the predicate that is Class 1 exempt. The subject device is an accessory that can be used with anesthesia gas machine, manual resuscitators, or Hyperinflation bags. It is intended to deliver anesthesia gases, air, or oxygen to the patient's upper airway. In order to do so, the mask must provide a positive seal so that the clinician can deliver the gases to the patient. The delivery of these gases is under positive pressure.

Discussion – The proposed indications are an expansion of the anesthesia face mask predicate. The expanded indications for use the anesthesia face mask is within the current practice and use of the device. The proposed device is contraindicated for use in long-term ventilation and with CPAP / bi-level equipment for long-term use.

Technology and construction – SuperNO$_2$VA™ is a 2-part mask with a nasal and oral chamber but each must provide a proper seal for the device to be effective for the intended use. Like the predicate devices it incorporates a rigid shell with a soft sealing surface which contacts the patient's

face. They contain a standard fitting to connect to a circuit. The subject device is connected to devices which operate as significantly lower flow rates and the equipment has one-way valves and flow which prevent rebreathing.
Discussion – The difference of a 2-part configuration is that it allows the proposed device to represent 2 separate configurations, nasal and full face. Whether they are a full face mask or a nasal only mask the SuperNO_2VA™ can serve as either one. The use of connecting channels to allow for gas to pass to the oral chamber yet is sealed off when the oral chamber is removed has been evaluated for its effectiveness of the seal.

Environment of Use – The environment of use is similar to the predicate device.
Discussion – An Anesthesia / Respiratory face mask can and is used in the hospital and sub-acute settings where the equipment to which it is attached may be used.

Discussion of Overall Differences –

We have identified differences which have been tested and compared to the predicate devices and they do not raise new risk concerns for the proposed indications for use.

Non-Clinical Testing Summary –

We performed testing which evaluated the comparative performance and some tests specific to the subject device. These tests included:

- Internal volume / Dead space
- Resistance through the connector
- Age and shelf-life
- Seal of duck-bill valves (only the subject device)
- Drop testing
- Biocompatibility testing

Differences –
Since the proposed device is limited in the equipment to which it would be used, namely, anesthesia gas machines with appropriate alarms and safety features; manual resuscitators, and Hyperinflation bags, which do not include an exhalation port.

Anesthesia gas machines provide one-way flow with directional valves and the flow rates have built-in pressure relieve features. This same one-way directional flow is in the manual resuscitators and Hyperinflation bags.

Biocompatibility
SuperNO_2VA™ 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

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 device and predicate have been found to substantially equivalent and there are no new concerns raised.