O-Two Medical Technologies Inc.
David Zhang
QA Manager
45A Armthorpe Road
Brampton, Ontario L6T 5M4

Re: K173205
Trade/Device Name: Equinox Advantage Nitrous Oxide/Oxygen Analgesic Gas Mixing and Delivery System
Regulation Number: 21 CFR 868.5330
Regulation Name: Breathing Gas Mixer
Regulatory Class: Class II
Product Code: BZR
Dated: July 30, 2018
Received: August 1, 2018

Dear David Zhang:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 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

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)*
K173205

Device Name
Equinox® Advantage Nitrous Oxide/Oxygen Analgesic Gas Mixing and Delivery System

Indications for Use *(Describe)*
The Equinox® Advantage Nitrous Oxide/Oxygen Analgesic Gas Mixing and Delivery System is indicated for administering an adjustable mixture of Nitrous Oxide analgesic gas and Oxygen, on demand, to a conscious, spontaneously breathing patient.

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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510 (k) Summary

Submitter's Name & Address: O-Two Medical Technologies
45A Armthorpe Road
Brampton, Ontario, L6T 5M4
Canada
Tel: 905-792-6896

Official Contact: David Zhang

Date of Revision: 2018-08-17

Proprietary or Trade Name: Equinox® Advantage Nitrous Oxide/Oxygen Analgesic Gas Mixing and Delivery System

Common/Usual Name: Mixer, Breathing Gases, Anesthesia Inhalation

Classification Name: Breathing Gas Mixer
(21 CFR 868.5330, product code: BZR)

Device Class: Class II

Classification Panel: Anesthesiology

Predicate Devices: Equinox® Relieve
- Manufactured by O-Two Medical Technologies Inc.
- 510(k) number K113687

Device Description:

Equinox® Advantage Nitrous Oxide/Oxygen Analgesic Gas Mixing and Delivery System is a portable pneumatically powered device intended to administer an adjustable mixture of Nitrous Oxide analgesic gas and Oxygen mixture to provide pain relief, on demand, to a conscious, spontaneously breathing, patient.

The device provides two input connectors for connection with nitrous oxide and oxygen cylinders through pressure regulators. The device has a control knob for turning ON or OFF the device. When it is turned ON, the output of N_2O/O_2 gas mixture will only be administered by an inspiratory effort by the patient.

A selection knob is used to select desired N_2O/O_2 gas mixture. The adjustable range is from 25% O_2 (N_2O 75%) to 100% O_2 (N_2O 0%), with the minimum of 25% oxygen output to eliminate the possibility of delivering a hypoxic mixture.
The Oxygen Enrichment Function is designed to provide 30 L/min of 100% oxygen in order to flush any residual gas from the patient circuit following the completion of the patient treatment.

The built-in pneumatically powered alarm system will generate both visual and audible alarms should either nitrous oxide or oxygen input fall below 40 PSI, and the device will be automatically shut off should oxygen input falls below 35 PSI.

The main accessories for the proposed device are a disposable Patient Circuit and a Mouth Piece or a universal Face Mask.

Indications for Use:

The Equinox® Advantage Nitrous Oxide/Oxygen Analgesic Gas Mixing and Delivery System is indicated for administering an adjustable mixture of Nitrous Oxide analgesic gas and Oxygen, on demand, to a conscious, spontaneously breathing patient.

Patient Population:

Conscious, spontaneous breathing patients requiring pain relief.

Contraindications:

- Hypersensitivity to the medication
- Head injuries with impaired consciousness
- Maxillofacial injuries
- Artificial, traumatic or spontaneous pneumothorax
- Air embolism
- Middle ear occlusion, ear infection
- Decompression sickness
- Abdominal distension / intestinal obstruction

NOTE: Nitrous Oxide/Oxygen (N_2O/O_2) mixtures must never be used in any condition where air is trapped in the body and expansion (up to 3x original size) would be dangerous. For example, it will exacerbate pneumothorax and increase pressure from any intracranial air. Air in any other cavities such as the sinuses, middle ear and gut may also expand.

Environment of Use:

Pre-hospital (ambulance) use and in-hospital use (ER, Labor and Delivery etc.)

Comparative table - Intended use:

Characteristic	Proposed Equinox® Advantage	Predicate K113687 Equinox® Relieve	Substantial Equivalence
Intended Use	Administer an adjustable mixture of N_2O/O_2, on demand, to a conscious, spontaneously breathing patient	Administer 50/50% N_2O/O_2 mixture, on demand, to a conscious, spontaneously breathing patient	Equivalent
Environments of use	Pre-hospital use and in-hospital environment	Pre-hospital use and in-hospital environment	Yes
Patient population	Conscious, spontaneous breathing patients requiring pain relief	Conscious, spontaneous breathing patients requiring pain relief	Yes
Contra-Indications	• Hypersensitivity to the medication • Head injuries with impaired consciousness • Maxillofacial injuries • Artificial, traumatic or spontaneous pneumothorax • Air embolism • Middle ear occlusion, ear infection • Decompression sickness • Abdominal distension / intestinal obstruction	• Hypersensitivity to the medication • Head injuries with impaired consciousness • Maxillofacial injuries • Artificial, traumatic or spontaneous pneumothorax • Air embolism • Middle ear occlusion, ear infection • Decompression sickness • Abdominal distension / intestinal obstruction	Yes

Comparative table - Operating principle:

Characteristic	Proposed Equinox® Advantage	Predicate K113687 Equinox® Relieve	Substantial Equivalence
Gas input and regulating	50- 70 PSI Oxygen and Nitrous Oxide regulated by internal regulators	50- 70 PSI Oxygen and Nitrous Oxide stabilized by internal regulators	Yes
Gas mixing	Oxygen and Nitrous Oxide are equalized and mixed at variable ratios	Oxygen and Nitrous Oxide are equalized and mixed at 1:1 ratio	Similar- (mixing ratio is adjustable)
Gas delivery	Gas mixture delivery is proportional to patient's demand.	Gas mixture delivery is proportional to patient's demand.	Yes
Monitoring and alarms	The input pressure from each gas input is measured by pressure sensors and Audible/Visual alarms activated should: - N_2O input is below 40 PSI; - O_2 input is below 40 PSI	The input pressure from each gas input is measured by pressure sensors and Audible/Visual alarms activated should: - N_2O input is below 40 PSI; - O_2 input is below 40 PSI	Yes
Safety features	1. In the event of O_2 supply failure, the protection circuit will shut off the device;	1. In the event of O_2 supply failure, the protection circuit will shut off the device;	Yes
	2. In the event of N_2O supply failure, Oxygen will be supplied as per ISO 11195:1995 Sec.12.4	2. In the event of N2O supply failure, the protection circuit will shut off the device	Similar- (Modification made as per ISO 11195 Sec.12.4)

Comparative table- Materials

Materials	Proposed Equinox® Advantage	Predicate K113687 Equinox® Relieve	Substantial Equivalence
Metal parts	Brass-Nickel plated, Anodized Aluminum, Stainless Steel	Brass-Nickel plated, Anodized Aluminum, Stainless Steel	Yes
Plastic parts	ABS, PC / ABS blends, Polycarbonate, Silicone, Polypropylene, PVC	ABS, PC / ABS blends, Polycarbonate, Silicone, Polypropylene, PVC	Yes
Tubing	Polyurethane	Polyurethane	Yes

Comparative table- Safety features

Characteristic	Proposed Equinox® Advantage	Predicate K113687 Equinox® Relieve	Substantial Equivalence
Safety features	- CGA gas specific connection to prevent misconnection of gas supply;	- CGA gas specific connection to prevent misconnection of gas supply;	Yes
	- Activated only by patient inspiratory effort;	- Activated only by patient inspiratory effort;	Yes
	- Audible & visual alarms;	- Audible & visual alarms;	Yes
	- Input Gas Fail Safe: Shut off the device if supply of O_2 dropped below 35 PSI	- Input Gas Fail Safe: Shut off the device if supply of either N_2O or O_2 dropped below 35 PSI	Similar- (Modification made as per ISO 11195 Sec.12.4)

Comparative table- Technological characteristics/specifications of performance

Characteristic	Proposed Equinox® Advantage	Predicate K113687 Equinox® Relieve	Substantial Equivalence
Input gas	O_2 and N_2O	O_2 and N_2O	Yes
Input pressure	50 to 70 PSI	50 to 70 PSI	Yes
Output mixture concentration	Adjustable Oxygen: 25%-100%	Preset 50/50% *(V/V)* O_2 / N_2O	Equivaqlent- (mixing ratio is adjustable)
Oxygen Enrichment	30 l/min oxygen	Not available	New feature
Alarms	Low input audible and visual alarms for both gases if either or both inputs dropped below 40 PSI	Low input audible and visual alarms for both gases if either or both inputs dropped below 40 PSI	Yes

Safety features	- Activated only by patient inspiratory effort; - CGA connection to prevent misconnection of gas supply; - Audible & visual alarms; - Power Fail Safe: Shut off the device if supply of O_2 drops below 35 PSI	- Activated only by patient inspiratory effort; - CGA connection to prevent misconnection of gas supply; - Audible & visual alarms; - Power Fail Safe: Shut off the device if supply of O_2 drops below 35 PSI - Power Fail Safe: Shut off the device if supply of N_2O drops below 35 PSI	Similar- (Modification made as per ISO 11195 Sec.12.4)
Patient support mode	Demand valve	Demand valve	Yes
Peak Flow on Demand (L/min)	120 minimum	120 minimum	Yes
Accessories	- Disposable patient circuit with 30 mm Scavenging port and Universal PVC Face Mask; - Oxygen supply hose; - Nitrous Oxide supply hose	- Disposable patient circuit with 30 mm Scavenging port and Universal PVC Face Mask; - Oxygen supply hose; - Nitrous Oxide supply hose	Yes

Substantially equivalence to the predicate devices:

The proposed device (Equinox® Advantage) is equivalent to the predicate device in Intended use, Patient populations, Environment of use and Contra-indications.

It not only incorporates parts which are identical to the Equinox® Relieve/K113687, but also use the same materials as the Equinox® Relieve/K113687.

Furthermore, Equinox® Advantage uses the identical operating principle as the Equinox® Relieve.

Safety features and range of performance specifications of the Equinox® Advantage are also found equivalent to those on the Equinox® Relieve/K113687.

The proposed Equinox® Advantage is substantially equivalent to the predicate Equinox® Relieve/ K113687 with the following minor modifications:

	Modification made	Equinox Relieve (K113687)	The proposed Equinox Advantage	Standard compliance

Mixing system	Gas mixing ratio	Fixed (Oxygen 50%)	Modified to adjustable mixing ratio (Oxygen 25% - 100%)	ISO 11195:1995 Sec.3.1
Delivery system	Oxygen enrichment	Not available	Oxygen enrichment (30 L/min) added	ISO 80601-2-13:2011 Sec. 201. 101.8
Safety/ Warning system	Output failure shutoff	When O_2 output pressure is much lower than N_2O, Shut Off Sensor will shut off the device to prevent delivering a hypoxic mixture.	"Output failure shutoff" function removed to enable adjustable mixing ratio. Minimum 25% oxygen setting prevents delivering a hypoxic mixture.	ISO 11195:1995 Sec.11.1
	Power failure shutoff- Nitrous oxide	If the Nitrous Oxide input pressure drops to 35 PSI, the Demand Valve and the Mixer will be shut off.	"Nitrous oxide failure shutoff" function removed. When Nitrous Oxide input drops to 35 PSI, with low pressure N_2O alarm on, the proposed device continues to operate with higher oxygen output. If there is no N_2O input, the device will deliver 100% oxygen.	ISO 11195:1995 Sec.12.4

As all the modifications made, meet the requirements of the current technical standards with safety measures also in place to prevent from introducing new potential risks, there is not any significant differences that raise different questions of safety or effectiveness of the intended device as compared to the predicate devices.

Summary of Performance Testing:

A comparative performance testing was performed on Equinox® Advantage and Equinox® Relieve. The result of the test demonstrates substantial equivalence of the proposed to the predicate.

The summary of the test results follows:

- Both mixers delivered equivalent Inspiratory Resistance, Expiratory Resistance, volume-time, pressure-time and flow- time wave forms under the same ventilation mode;
- Both mixers showed equivalent "Low Oxygen supply" and "Low Nitrous Oxide supply" alarm characteristics;
- Both mixers showed equivalent "Oxygen Failure Shutoff" characteristic;
- When Equinox® Advantage is set at 50% Oxygen mixing ratio, both units delivered equivalent Oxygen concentration and Nitrous Oxide concentration.

We have also performed bench testing as per ISO 11195 and other applicable standards with respect to Electrical Safety & Essential performance of the proposed device and its accessory.

Conclusion:

The results of the above comparative performance testing as well as bench testing demonstrate that the proposed Equinox® Advantage is as safe, as effective and performs as well as the legally marketed predicate devices - Equinox® Relieve (K113687).