

K113687

Non-Confidential Summary of Safety and Effectiveness

O-Two Medical Technologies
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Canada
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Official Contact: David Zhang

Application Date: 8-Dec-11

Proprietary or Trade Name: Equinox Relieve®

Common/Usual Name: Nitrous Oxide/Oxygen Analgesic Gas Mixing and Delivery System

Classification Name: Breathing Gas Mixer (21 CFR 868.5330, product code: BZR) and Ventilator, emergency, powered (21 CFR 868.5925, product code: BTL)

Device Class: Class II

Classification Panel: Anesthesiology

Predicate Devices:

- Nitronox®
 - Manufactured by Matrix Medica Inc.
 - 510(k) number K883833
- CAREvent ALS⁺
 - Manufactured by O-Two Medical Technologies Inc.
 - 510(k) number K991195

Device Description:

The proposed **Equinox Relieve® Nitrous Oxide/Oxygen Analgesic Gas Mixing and Delivery System** is a portable pneumatically powered device designed to provide a 50/50% nitrous oxide and oxygen mixture.

The device provides two input connectors for connection with nitrous oxide and oxygen cylinders through pressure regulators. The device has only one control for turning ON or OFF the device. When it is turned ON, the output of N₂O/O₂ gas mixture will only be activated by an

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inspiratory effort by the patient. The out put of N₂O/O₂ gas mixture is pre-set at 50/50%. Neither the patient nor medical personnel are able to adjust, eliminating the risk of delivering a hypoxic mixture.

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

The device is also equipped with a secondary “fail safe” circuit that will activate an alarm and shut off the device should internal malfunction occur in the mixer or any internal hoses rupture or kink.

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

Indications for Use:

The Equinox Relieve[®] Nitrous Oxide/Oxygen Analgesic Gas Mixing and Delivery System is indicated for delivering a 50%/ 50% mixture of nitrous oxide and oxygen, on demand, to a conscious, spontaneously breathing patient.

Patient Population:

Spontaneous breathing patients requiring relief from moderate to severe pain due to trauma, childbirth etc.

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 (N₂O/O₂) 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:

Characteristic	Proposed Equinox Relieve®	Predicate K883833 Nitronox®	Predicate K991195 CAREvent ALS+
Intended Use	Provide 50/50% N ₂ O/O ₂ mixture, on demand, to a conscious, spontaneously breathing patient for the relief of pain	Provide 50/50% N ₂ O/O ₂ mixture, on demand, to a conscious, spontaneously breathing patient for the relief of pain	Provide ventilatory support to non-breathing patient as well as “Demand Breathe” to spontaneously breathing patient
Environments of use	Pre-hospital use and in-hospital environment	Emergency settings	Pre-hospital and in-hospital environment
Patient population	Spontaneous breathing patients requiring pain relief	Spontaneous breathing patients requiring pain relief	- Non-breathing patients requiring ventilatory support; - Spontaneous breathing patients
Operating principles	Pneumatic, demand flow system	Pneumatic, demand flow system	Pneumatic, time/volume cycled, demand flow system
Input gas	O ₂ and N ₂ O	O ₂ and N ₂ O	O ₂
Input pressure	50 to 70 PSI	40 – 65 PSI, preferably 50 -55 PSI	45 to 70 PSI
Built-in Mixer	Yes	Yes	N/A
Output mixture concentration	Preset 50/50% (V/V) N ₂ O /O ₂	Preset 50/50% (V/V) N ₂ O/O ₂	O ₂ only
Displays	Low input visual alarms for both gases (O ₂ and N ₂ O)	O ₂ and N ₂ O Mixture pressure gauge	- Airway pressure gauge; - Low input visual alarm
Safety features	<ul style="list-style-type: none"> - Preset 50/50% N₂O /O₂; - Activated only by patient inspiratory effort; - CGA connection to prevent misconnection of gas supply - Audible & visual alarms - Oxygen Fail Safe: Shut off mixer output if O₂ pressure drops - Input Gas Fail Safe: Shut off the device if supply of either N₂O or O₂ dropped below 35 PSI 	<ul style="list-style-type: none"> - Preset 50/50% N₂O /O₂; - Activated only by patient inspiratory effort; - CGA connection to prevent misconnection of gas supply - Audible alarm; - Oxygen Fail Safe: Shut off mixer output if O₂ pressure drops 	<ul style="list-style-type: none"> - Demand valve activated only by patient inspiratory effort; - CGA connection to prevent misconnection of gas supply; - Audible & visual alarm - Air way Pressure-relief
Alarms	<ul style="list-style-type: none"> - Audible/Visual (Red indicator) alarms if N₂O input is below 40 PSI; - Audible/Visual (Green indicator) alarms if O₂ input is below 40 PSI - Audible alarm if device is shut off due to low O₂ output 	<ul style="list-style-type: none"> - Audible alarm triggered if N₂O supply is depleted 	<ul style="list-style-type: none"> - Audible/Visual (Green) alarms if O₂ supply is below 40 PSI; - Maximum Pressure-relief Audible alarm

Patient support mode	Demand valve	Demand valve	IMV, Demand valve
Demand Valve function	Built-in	Realized by extended handheld supply valve	Built-in
Peak Flow on Demand (L/min)	120 minimum	140	120 minimum
Materials in gas pathway	Compatible with O ₂ & N ₂ O	Unknown	Compatible with O ₂
Accessories	- Universal PVC Face Mask; - Disposable patient circuit with 30 mm Scavenging port; - Oxygen supply hose; - Nitrous Oxide supply hose	- Adult PVC Face Mask; - Supply Valve & Supply Valve Hose; - Oxygen supply hose; - Nitrous Oxide Cylinder	- Universal PVC Face Mask; - Disposable patient circuit with 30 mm Scavenging port; - Oxygen supply hose

Differences Between Other Legally Marketed Predicate Devices:

The proposed device is viewed as substantially equivalent to the predicate devices, K883833 and K991195.

There are no significant differences that affect the safety or effectiveness of the intended device as compared to the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Mr. David Zhang
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APR 30 2012

Re: K113687

Trade/Device Name: Equinox Relieve[®] Nitrous Oxide/Oxygen Analgesic Gas Mixing
and Delivery System

Regulation Number: 21 CFR 868.5330

Regulation Name: Breathing Gas Mixer

Regulatory Class: II

Product Code: BZR

Dated: March 22, 2012

Received: April 2, 2012

Dear Mr. 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. 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.

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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 go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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 yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

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510(k) Number: K113687 (To be assigned)

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Indications for Use:

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Prescription Use X
(21 CFR 801 Subpart C)

AND/OR

Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Robert J. Povinani, Jr.
Conurrence of CDRH, Office of Device Evaluation (ODE)
(Division Sign-Off) Lex Sheth
Division of Anesthesiology, General Hospital
infection Control, Dental Devices

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