April 22, 2021

Parker Hannifin
% Dave Yungvirt
CEO
Third Party Review Group, LLC
25 Independence Blvd
Warren, New Jersey 07059

Re: K202480
Trade/Device Name: Nitronox Plus
Regulation Number: 21 CFR 868.5330
Regulation Name: Breathing gas mixer
Regulatory Class: Class II
Product Code: BZR
Dated: August 26, 2020
Received: August 28, 2020

Dear Dave Yungvirt:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Todd Courtney
Assistant Director
DHT1C: Division of ENT, Sleep Disordered Breathing, Respiratory and Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K202480

Device Name
Nitronox Plus

Indications for Use *(Describe)*
The Nitronox Plus is intended to provide a mixture of N2O/O2, on demand, to a conscious, spontaneously breathing patient. The Nitronox Plus is designed for use with adult and pediatric patients and is not intended to be used with infants or neonates.

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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5. 510(k) Summary

Parker Hannifin
Nitronox Plus
(per 21CFR 807.92)

5.1. Submitter/510(k) Holder

Parker Hannifin Corporation
Precision Fluidics Division
245 Township Line Road
Hatfield, Pennsylvania 19440
Phone: 215-723-4000

Contact: Andrew Ellinger,
Product Development Engineer
Contact Phone: 215-660-8175
Contact Email: andrew.ellinger@parker.com

Date Prepared: May 1, 2020

5.2. Device Name

Proprietary Name:	Nitronox Plus
Common Name:	Breathing gas mixer
Classification Name:	Mixer, breathing gases, anesthesia inhalation
Classification Regulation:	21 CFR 868.5330
Classification Panel:	Anesthesiology
Product Code:	BZR
Device Class:	Class II

5.3. Predicate Device

Nitronox Pre-Set 50/50 Nitrous Oxide/Oxygen Gas Mixer (K760766)

5.4. Device Description

The Nitronox Plus is a portable "on demand" analgesia system used to deliver a mixture of nitrous oxide and oxygen gases to a conscious, spontaneously breathing patient. The device is designed for use with adult and pediatric patients and is not intended to be used with infants or neonates. It is only for use in a healthcare setting by healthcare professionals. The Nitronox Plus is available in three models which differ only in adjustability and maximum ratio of nitrous oxide that can be delivered. The Nitronox Plus features a 0-70% N_2O adjustable model, 0-50% N_2O adjustable model, and 50% N_2O/50% O_2 fixed model.

The Nitronox Plus is a pneumatic system. Oxygen and nitrous oxide are supplied to the device through flexible hoses. Inlet gas is regulated and equalized through the use of an oxygen piloted dual diaphragm regulator. The inlet pressure of both gases and the mixed gas pressure are displayed on the front panel of the device through the use of pressure gauges. The device is designed to function with a medical breathing circuit and face mask or mouthpiece accessory.

Delivery of mixed gas starts with a patient's demand; upon inhalation through a face mask or mouthpiece, a demand valve opens and supplies mixed gas to the patient through the connected Medical Breathing Circuit. In adjustable models, the healthcare professional is able to set the desired concentration through the use of a control knob on the front panel. Mixed gas is supplied through the breathing circuit until inhalation ceases.

The Nitronox Plus contains several safety features. Pneumatically powered alarms for both gas inlets alert the user when either gas supply begins to deplete. The device will also maintain delivery of the set concentration with depleting oxygen pressure. Once the oxygen pressure drops below a certain threshold, the device will allow ambient air to be delivered through an Emergency Air Intake valve. The device also features a key lock to control the nitrous oxide gas supply, allowing healthcare professionals to prevent unauthorized use of the device.

5.5. Indications for Use

The Nitronox Plus is intended to provide a mixture of N_2O/O_2, on demand, to a conscious, spontaneously breathing patient. The Nitronox Plus is designed for use with adult and pediatric patients and is not intended to be used with infants or neonates.

The Indications for Use statement for the Nitronox Plus is not identical to the predicate device; however, the differences do not alter the intended therapeutic use of the device. Modifications made to enhance gas delivery functionality do not significantly change the key functional technology and operational characteristics of the device, nor do they affect the safety and effectiveness of the device relative to the predicate. Both the subject and predicate devices are intended to deliver mixtures of N_2O/O_2, on demand, to a conscious, spontaneously breathing patient.

5.6. Summary of Technological Characteristics Compared to the Predicate Device

The Nitronox Plus (subject device) is a redesigned version of the Nitronox HD originally cleared by FDA under submission K760766 (predicate device). The key technological characteristics of the Nitronox Plus are based on well-established technology that uses springs, diaphragms, valves, orifices, and other pneumatic mechanisms to regulate the pressure and flow of gases. The subject device is similar to the predicate device regarding:

- Force-balancing system consisting of diaphragms, springs, and poppet valves
- Gas mixing through tapered valve stems and orifices
- Pneumatic "whistle" alarms
- Bourdon tube gauges
- Demand valve to only deliver gas upon patient inhalation

The major technological differences between the subject device and predicate device include:

- Adjustable mixture ratio
- Low inlet pressure alarms
- Emergency air intake valve
- Key lock feature

A summary comparison of the subject and predicate devices is provided below:

Side-by-Side Comparison of the Subject and Predicate Devices

Characteristic	Subject: Nitronox Plus	Predicate: Nitronox (K760766)	Comparison
Intended Use	Provide a mixture of N_2O/O_2, on demand, to a conscious, spontaneously breathing patient. The Nitronox Plus is designed for use with adult and pediatric patients and is not intended to be used with infants or neonates.	Provide 50/50% N_2O/O_2 mixture, on demand, to a conscious, spontaneously breathing patient.	Similar
Target Population	Adult and pediatric patients. Not intended to be used with infants or neonates	Spontaneous breathing patients requiring pain relief.	Similar
Prescription or Over-the-Counter Use	Prescription Use	Prescription Use	Same
Anatomical Site	Gas is to be inhaled through the mouth and nose region.	Gas is to be inhaled through the mouth and nose region.	Same
Where used	To be used by healthcare professionals in a healthcare setting.	Dentistry, Emergency Departments, Ambulances, Obstetrics, Physiotherapy, Nursing, Specialist Procedures, and Podiatry.	Similar
Operating principle	Pneumatic, demand flow system.	Pneumatic, demand flow system.	Same
Energy used	Compressed oxygen/nitrous oxide gas.	Compressed oxygen/nitrous oxide gas.	Same
Energy delivered	Low pressure mixed gas.	Low pressure mixed gas.	Same
Gas input pressure	45-60 psi.	45-60 psi.	Same
Gas regulation mechanism	Oxygen Piloted Regulator with dual diaphragms.	Oxygen Piloted Regulator with dual diaphragms.	Same
Gas delivery	Proportional to patient's demand.	Proportional to patient's demand.	Same
Gas mixing	Oxygen and nitrous oxide are equalized and mixed at variable ratios.	Oxygen and nitrous oxide are equalized and mixed at a fixed 50% ratio.	Different
Alarms	Audible alarm sounds when: - N_2O input is below 35 psi; - O_2 input is below 35 psi.	Audible alarm is triggered if oxygen mixture pressure rises above 40 psi.	Different
Security feature	Key Lock allows healthcare provider to turn device ON/OFF; in the "OFF" position device will not deliver nitrous oxide gas; with the key turned in the "ON" position, mixed gas can be supplied.	None.	New Feature

Characteristic	Subject: Nitronox Plus	Predicate: Nitronox (K760766)	Comparison
Accessories	- Medical Breathing Circuit; - Face mask; - Mouth Piece; - Oxygen & nitrous oxide supply hose; - Oxygen & nitrous oxide; - E-stand mobile cart; - Two Cylinder Cart; - Wall arm mount;	- Medical Breathing Circuit; - Face mask; - Mouth Piece; - Oxygen & nitrous oxide supply hose; - Oxygen & nitrous oxide; - E-stand mobile cart; - Two Cylinder Cart; - Wall arm mount;	Same
Pressure regulation	Force-balanced system of diaphragms/poppets/springs	Force-balanced system of diaphragms/poppets/springs	Same
Gas mixing mechanism	Adjustable dual stem/orifice	Factory set dual stem/orifice	Different
Demand mechanism	Demand Valve	Demand Valve	Same
Gauge type	Bourdon Tube	Bourdon Tube	Same
Alarm type	Pneumatic whistle	Pneumatic whistle	Same
Safety Features	O_2 Piloted System: Shut off mixer output if O_2 pressure drops.	O_2 Piloted System: Shut off mixer output if O_2 pressure drops.	Same
	DISS fittings to prevent misconnection of gas supply.	DISS fittings to prevent misconnection of gas supply.	Same
	Activated only via patient inspiratory effort (self-administration principle).	Activated only via patient inspiratory effort (self-administration principle).	Same
	In the event of N_2O supply failure, 100% O_2 will be supplied.	In the event of N_2O supply failure, 100% O_2 will be supplied.	Same
	Dual diaphragms prevent reverse gas flow between supplies.	Dual diaphragms prevent reverse gas flow between supplies.	Same
	Audible alarm for low inlet pressure.	Audible alarm for increased mix pressure.	Different
	Emergency Air Intake Valve, if O_2 pressure is lost patient can breathe ambient air.	None.	New Feature
	Key lock system prevents unauthorized use of device.	None.	New Feature

5.7. Summary of Non-clinical Performance Testing as Basis for Substantial Equivalence

The results of performance testing demonstrate that the Nitronox Plus meets all design input requirements, including functional, operational, and performance requirements. Performance testing was conducted to verify performance characteristics, safety features, capabilities compared to the predicate device, and biocompatibility; validate reprocessing activities; and ensure usability of the device to meet patient needs when used as intended. The results of the performance testing support the conclusion that the subject device is substantially equivalent to the predicate device.

Risk management processes were applied throughout product development. Results of the comprehensive risk analysis conclude that the benefits associated with the design modifications for new and enhanced safety systems exceed any residual risk. The remaining risks are acceptable when weighed against the benefits provided to patients when using the device. None of the residual risks outweigh the benefits of using the Nitronox Plus system for its intended use.

5.8. Conclusions

The indications for use, principles of operation, and technological characteristics of the subject device are similar to the predicate device. Differences between the subject and predicate devices are limited to minor differences in the technology used to adjust the mixture ratio, triggering conditions of audible alarms, and addition of the emergency air intake and key lock safety features. Performance testing supports the conclusion that the subject device is as safe and effective as the predicate device, and therefore the two devices are substantially equivalent.