March 5, 2023

Parker Hannifin Corporation
Dylan Alu
Regulatory Compliance Manager
245 Township Line Road
Hatfield, Pennsylvania 19440

Re: K223452
Trade/Device Name: Nitronox Scavenger Plus
Regulation Number: 21 CFR 868.5430
Regulation Name: Gas-scavenging apparatus
Regulatory Class: Class II
Product Code: CBN
Dated: February 1, 2023
Received: February 3, 2023

Dear Dylan Alu:

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 and Part 809); 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,

James J. Lee -S

James J. Lee, Ph.D.
Director
DHT1C: Division of 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)*
K223452

Device Name
Nitronox® Scavenger Plus

Indications for Use *(Describe)*
The Nitronox® Scavenger Plus is intended to control the vacuum flowrate for scavenging of waste analgesic gas.

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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SECTION 5

510K SUMMARY

5.1 Date of Submission

November 15, 2022

5.2 Sponsor

Parker Hannifin Corporation
Precision Fluidics Division
245 Township Line Road
Hatfield, PA 19440

Contact Person: Dylan Alu
Phone: 215-660-8132
Email: Dylan.alu@parker.com

5.3 Subject Device

Name of Device: Nitronox® Scavenger Plus

Common or Usual Name: Scavenging apparatus

Classification Name: Gas scavenging apparatus

Regulatory Class: Class II, 21 CFR 868.5430

Product Code: CBN

5.4 Predicate Device

G. Dundas Passive Waste Gas Scavenger, K080039

This predicate has not been subject to a design-related recall.

5.5 Device Description

The Nitronox® Scavenger Plus (Scavenger Plus) is used within a nitrous oxide/oxygen conscious sedation system to allow removal of waste analgesic gases through a connected vacuum source. The device is used during a dental or medical procedure in a healthcare facility environment. The device is not intended to be used for general anesthesia. The Scavenger Plus is operated by a licensed healthcare professional during conscious sedation of a patient.

The Scavenger Plus connects the exhalation line of the patient's breathing circuit to vacuum tubing from the vacuum source and controls the vacuum flowrate (i.e., scavenging flowrate). The rate at which the gas is removed (i.e., scavenged) is specified by the Scavenger Plus, which uses a control knob and reservoir bag to limit the amount of vacuum applied to the exhalation line of the breathing circuit.

5.6 Intended Use

The Scavenger Plus is intended to control the vacuum flowrate for scavenging of waste analgesic gas.

5.7 Comparison of the Technological Characteristics with the Predicate Device

Table 5-1: Proposed and Predicate Product Overview

Product Features	**Subject Device** **Parker Hannifin Corporation's Scavenger Plus**	**Predicate Device** **G. Dundas Co. Inc.'s Passive Waste Gas Scavenger K080039**	**Comments**
Classification	Class II	Class II	Same
Product Code	CBN	CBN	Same
Regulation Number	§868.5430	§868.5430	Same
Regulation Name	Gas Scavenging Apparatus	Gas Scavenging Apparatus	Same
Intended Use	The Scavenger Plus is intended to control the vacuum flowrate for scavenging of waste analgesic gas.	The Passive Waste Gas Scavenger is intended to be used for the scavenging of waste anesthetic gases from anesthesia machines used during the provision of general anesthesia to adults and children.	Same. Both devices are intended for scavenging of waste gas.

Product Features	Subject Device Parker Hannifin Corporation's Scavenger Plus	Predicate Device G. Dundas Co. Inc.'s Passive Waste Gas Scavenger K080039	Comments
Principle of Operation	The Scavenger Plus uses a scavenging method that relies on the gas in the manifold and reservoir bag to create a system of pressure between the entry side and vacuum source. This pressure balance allows for all of the gas that enters the device manifold to then be pulled through the device to the connected vacuum source.	The Passive Waste Gas Scavenger uses a scavenging method that relies on the pressure of the waste gas to transfer the gas from the scavenger to the vacuum source.	Similar. Both devices use a scavenging method that relies on control of flow/pressure and a connected vacuum source.
Functional Characteristics	The waste gas enters the Scavenger Plus through the exhalation line of the connected breathing circuit. The gas then travels through the internal cavity that connects the reservoir bag, under-pressure valve, and over-pressure valve. The gas remains within the manifold and reservoir bag. Gas is removed by the connected vacuum source.	The inlet port is attached to the ventilation system of the anesthesia machine. During operation, waste gases from the patient are transferred into the scavenger by the outlet pressure supplied by the ventilator. The gases will then travel through the scavenger into a non-recirculating exhaust system.	Similar. Waste gases from the patient are transferred into the scavenger and then are removed from the healthcare environment.
Pressure Limit	Under normal operating conditions (75 L/min flow through the inlet), the pressure shall not exceed 3.0 cm H2O.	Under normal operating conditions (75 L/min flow through the inlet), the pressure shall not exceed 3.0 cm H2O.	Same. Both devices meet Section 201.103.1.1.1 of ISO 80601-2-13, which states that under normal operating conditions (75 L/min flow through the inlet), the pressure shall not exceed 3.0 cm H2O.

5.8 Non-clinical Performance Data

The test strategy for the Scavenger Plus included performance bench testing of the device characteristics, safety features, and control mechanism. The results of the testing demonstrated that the Scavenger Plus met all of the acceptance criteria for functional, operational, and performance characteristics and therefore there are no new questions of safety or efficacy related to the subject device.

5.9 Clinical Data

The characteristics of the Scavenger Plus do not require clinical investigation due to safety and efficacy being supported by non-clinical testing performed. The verification and validation testing of the Scavenger Plus was found to be acceptable and supports the claims of substantial equivalence.

5.10 Substantial Equivalence Discussion

Both the subject device and predicate device have the same intended use, use environment and similar technological characteristics. Both devices are intended to be used to remove waste gas in a healthcare facility with an vacuum system. Both devices use valves to maintain the appropriate scavenging pressure to remove waste gas. Both devices have features for maintaining the scavenging pressure to ensure proper removal of waste gas. The main difference is that the subject device is used with analgesic gas, which has lower associated risks than the predicate device which uses anesthetic gas.

5.11 Conclusions

It has been shown in this 510(k) submission that the differences between the Scavenger Plus and the predicate device do not raise any new questions regarding safety and efficacy. The Scavenger Plus is determined to be substantially equivalent to the referenced predicate device.