September 19, 2024

Parker Hannifin Corporation
Deanna Perry
Regulatory Compliance Specialist
245 Township Line Road
Hatfield, Pennsylvania 19440

Re: K241465
Trade/Device Name: Midas Flowmeter; eAVS
Regulation Number: 21 CFR 868.5330
Regulation Name: Breathing Gas Mixer
Regulatory Class: Class II
Product Code: BZR, CBN
Dated: August 16, 2024
Received: August 16, 2024

Dear Deanna Perry:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Bradley Q. Quinn -S

Bradley Quinn
Assistant Director
DHT1C: Division of Anesthesia,
Respiratory, and Sleep 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K241465

Device Name
Midas Flowmeter;
eAVS

Indications for Use *(Describe)*
The Midas Flowmeter is intended for use as a continuous flow conscious sedation system to deliver a mixture of nitrous oxide and oxygen gases to a patient. When used with the electronic automatic vacuum switch (eAVS), the Midas Flowmeter is used to control the 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510K SUMMARY

1. Date of Submission

May 23, 2024

2. Sponsor

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

Contact Person: Deanna Perry
Phone: 215-660-8104
Email: deanna.perry@parker.com

3. Subject Device

Trade Name	Porter Midas™ Flowmeter	eAVS
Common or Usual Name	Breathing gas mixer	Scavenging apparatus
Classification Name	Mixer, breathing gases, anesthesia inhalation	Gas scavenging apparatus
Product Classification	Class II	Class II
Regulatory Class	21 CFR 868.5330	21 CFR 868.5430
Product Code	BZR	CBN
Model Numbers	6020	EAVS-5000
	6120	

4. Primary Predicate Device

FlowStar Touch Digital Mixer Flowmeter, K222794

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

5. Reference Device

Nitronox Scavenger Plus, K223452

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

6. Device Description

The Midas Flowmeter is used within a healthcare environment during a nitrous oxide (N_2O)/oxygen (O_2) conscious sedation system. The device is a digitally controlled, software driven, continuous flow device that precisely meters nitrous oxide and oxygen medical gases and delivers gas mixtures to a conscious, spontaneously breathing patient.

The Midas Flowmeter uses electronic mechanisms to control the flowrate and mixture percentage of gases delivered to a patient.

The optional eAVS is an accessory to the Midas Flowmeter. It is used within the nitrous oxide/oxygen conscious sedation system to allow removal of waste analgesic gases through a connected vacuum source. The eAVS 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 eAVS is specifically designed to work with the Midas Flowmeter and all functionality control of the eAVS has been integrated into the user interface of the Midas Flowmeter.

The Midas Flowmeter may be configured into in two different configurations. First, a remote configuration (model number: 6120), allowing the touchscreen display module to be mounted on a cabinet while the control module is located within the cabinet. Second, a portable configuration (model number: 6020), allowing the touchscreen display module to be connected to the control module and mounted onto a cart to other mounting options for portability.

7. Intended Use / Indications for Use

The Midas Flowmeter is intended for use as a continuous flow conscious sedation system to deliver a mixture of nitrous oxide and oxygen gases to a patient. When used with the electronic automatic vacuum switch (eAVS), the Midas Flowmeter is used to control the scavenging of waste analgesic gas.

8. Technological Characteristics

The Midas Flowmeter uses electronic mechanisms to control the flowrate and mixture percentage of gases delivered to a patient. The device contains a manifold block assembly that includes valves to control gas flowrate to allow for variable flowrate. The device includes flow sensors that measure the gas flowrate. The device also incorporates a microcontroller unit to regulate flowrate, a Bluetooth module for wireless communication with a paired iPadOS device (iPad only), and a touchscreen interface for user inputs.

The Midas Flowmeter provides several onboard diagnostic and alert capabilities that can tell the user if the Midas Flowmeter has encountered a problem. Onboard diagnostics include:

- Valve leak checks at powerup,
- Communication checks,
- Inability to achieve desired mixed gas flowrate,
- Inability to achieve desired oxygen flowrate.

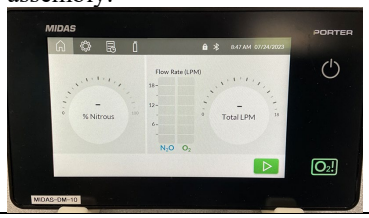
The eAVS controls the rate at which disposal of the gases exhaled by the patient is conducted. The flowmeter senses when eAVS is attached with a communication cable and

switches its power on. The eAVS consists of a valve used to control scavenging flowrate, a flow sensor used to measure the rate of scavenging flow, and a scavenger controller board to communicate to the Midas Flowmeter. The eAVS maintains its valve opening and flow measurements independently of the flowmeter. The flowmeter controller periodically requests the scavenger flow rate for display to the user interface. The vacuum flow can be increased or decreased by the user, with commands being routed from the user interface to the eAVS by the flowmeter.

9. Comparison of the Technological Characteristics with the Predicate Device

Table 1: Device and Primary Predicate Product Overview

Product Features	Subject Device Parker Hannifin Corporation's Porter Midas™ Flowmeter and optional eAVS	Predicate Device Baldus Sedations GmbH & Co. KG FlowStar Touch Digital Mixer Flowmeter K222794	Comments
Intended Use	The Midas Flowmeter and optional eAVS is intended for use as a continuous flow conscious sedation system to deliver a mixture of nitrous oxide and oxygen gases to a patient. When used with the eAVS, the Midas Flowmeter is used to control the scavenging of waste analgesic gas.	The FlowStar Touch Digital Mixer Flowmeter is intended for administering an adjustable mixture of Nitrous Oxide analgesic gas and Oxygen to a conscious, spontaneously breathing patient.	**Same.** The FlowStar Touch Mixer is only intended to mix nitrous oxide and oxygen. While the Midas Flowmeter is intended to mix nitrous oxide and oxygen and remove waste analgesic gas while the eAVS is attached.
Prescription Use or Over the Counter	Prescription Use	Prescription Use	**Same.** Both devices are prescription use.
Principle of Operation	Software driven, continuous flow system.	Software driven, continuous flow system.	**Same.** Both devices are software driven devices that mix nitrous oxide and oxygen continuously to delivery to a patient through a breathing circuit during a procedure.
Where Used	To be used by healthcare professionals in a healthcare setting.	To be used by healthcare professionals in a healthcare setting.	**Same.** Both devices are intended for use by a healthcare professional in a healthcare setting.
Patient Contact	The Midas Flowmeter is designed for indirect patient contact.	The FlowStar Touch Digital Mixer Flowmeter is designed for indirect patient contact.	**Same**.

Product Features	Subject Device Parker Hannifin Corporation's Porter Midas™ Flowmeter and optional eAVS	Predicate Device Baldus Sedations GmbH & Co. KG FlowStar Touch Digital Mixer Flowmeter K222794	Comments
			Both devices are not design for indirect patient contact.
Gas delivery	Gas mixture delivery is continuous. Oxygen Flush: Minimum 20 LPM Oxygen Flow: 1.0-18.0 PLM Oxygen %: 30%-100% Oxygen Resuscitator Flow: 225-390 L/min Nitrous Oxide Flow: 0-12.6 LPM Nitrous Oxide %: 0-70% Mixed Gas Flow: 1.1 – 18.0 LPM	Gas mixture delivery is continuous. Oxygen Flush: 40-55 L/min Oxygen Flow:1.0-18 L/min Oxygen %: 30%-100% Oxygen Resuscitator Flow: 100-250 L/min Nitrous Oxide Flow: 0-12.6 L/min Nitrous Oxide %: 0-70% Mixed Gas Flow: 3-18 L/min	**Similar.** Performance characteristics have similar ranges that support appropriate gas mixing and delivery to support continuous flow conscious sedation.
Gas input fittings	DISS connector (Diameter Index Safety System) O_2 Inlet: DISS 1240 N_2O Inlet: DISS 1040A O_2 Outlet: DISS 1240 demand valve (male thread)	DISS connector (Diameter Index Safety System)	**Same.** Both devices use DISS Fittings.
Displays	The display module consists of the following components: an off-the-shelf touchscreen LCD, an off-the-shelf Single Board Computer (SBC), a painted cover glass, a capacitive switch overlay, and a Display Interface Board. The touchscreen LCD, SBC, painted cover glass and capacitive switch overlay are provided as a finished assembly called the touchscreen display assembly. 	Touch Panel Display 	**Similar.** Both have user adjustment controls, power button, O_2 flush, and similar touchscreens. Differences are limited to user interface layout.
Power Source	**Power Supply Specification:** 80-264 VAC 47-63Hz **Device Usage Specification:** 100-240 VAC 50-60 Hz	110-230 V 50-60 Hz	**Similar.** The Midas Flowmeter power supply is rated for outside normal limits (nominal), to allow for international use.

Product Features	Subject Device Parker Hannifin Corporation's Porter Midas™ Flowmeter and optional eAVS	Predicate Device Baldus Sedations GmbH & Co. KG FlowStar Touch Digital Mixer Flowmeter K222794	Comments
Monitoring and Alarms	The Midas Flowmeter uses onboard diagnostics to conduct self-checks at start-up and during operation. When an issue is detected, a notification will appear in the Notification Display and is accompanied by a continuous, audible alert. An audible notification may be silenced but the visual notification remains on screen until corrected. **O_2 Alerts:** Unable to provide the requested flow of O_2; Oxygen valve failed too fully close. **N_2O Alerts:** Unable to provide the requested flow of N_2O; Nitrous Oxide valve failed too fully close. **Flush Flow Low:** O_2 Flush flow rate is below 19.5 LPM. **Other Alerts:** sensor faults, communication failures, software errors, scavenger failures, leak detection,	The FlowStar Touch Digital Mixer Flowmeter for Analgesia device has an alarm system which generates an alarm in the case of an insufficient O_2 supply. The device will shut off the sedation when the O_2 supply reaches a critical level. **Check O_2:** If no oxygen is being supplied, the unit emits visual and acoustic information signals **Check N_2O:** If no nitrous oxide is being supplied, the unit emits visual and acoustic information signals. This also happens if the pressure is too low or there is a measurement section failure **O_2 Minimum Flow 3 l/min:** Visual and acoustic signals: The O_2 minimum flow is 3 l/min. The mixture administered can never contain less than 1 liter of O_2. **Max. Flow Reached:** Once the maximum total flow (18 l/min) is reached, this is signaled visually in the top right and a signal tone sound. **Flush Flow Low:** This message appears if the flow rate is less than the minimum value of 18 l/min when the O_2 Flush button is pressed. The alarms are equivalent to those of the predicate.	**Similar.** The FlowStar Touch Mixer Flowmeter has an alarm system, where Midas Flowmeter has notifications and alerts to inform the end user of actions to be reviewed. The Midas Flowmeters includes more detailed alerts for various aspects (i.e., software and scavenger features).

Table 2: Accessory and Reference Product Overview

Product Features	Subject Device Parker Hannifin Corporation's eAVS	Reference Device Parker Hannifin Corporation's Nitronox® Scavenger Plus K223452	Comments
Intended Use	When used with the eAVS, the Midas Flowmeter is used to control the scavenging of waste analgesic gas.	The Scavenger Plus is intended to control the vacuum flowrate for scavenging of waste analgesic gas.	**Same.** Both devices are intended to remove waste analgesic gas.

Product Features	Subject Device Parker Hannifin Corporation's eAVS	Reference Device Parker Hannifin Corporation's Nitronox® Scavenger Plus K223452	Comments
Target Population	Adults and pediatrics	Adults and pediatrics	**Same.** Both devices have the same target population.
Prescription Use or Over the Counter	The eAVS is for prescription use only.	The Scavenger Plus is for prescription use only.	**Same.**
Where used	To be used by healthcare professionals in a healthcare setting.	To be used by healthcare professionals in a healthcare setting.	**Same**. Both devices are intended for use by a healthcare professional in a healthcare setting.
Control of Flow/Pressure	The eAVS consists of a valve used to control scavenging flowrate, an air flow sensor used to measure the rate of scavenging flow, and a control board to communicate to the Midas Flowmeter.	The Scavenger Plus receives waste gas from the exhalation line of the breathing circuit, where it travels to the reservoir bag before being removed by the vacuum source. The adjustable orifice and valves control the rate at which the gas is removed.	**Different.** The eAVS relies on the software mechanisms to communicate the control of vacuum flowrate. While, Scavenger Plus is a fully pneumatically device.
Connection Port - Inlet	19mm port to connect to the exhalation line of a breathing circuit	19mm port to connect to the exhalation line of a breathing circuit	**Same.** Both devices have the same size inlet connection port.
Connection Port - Outlet	3/8-inch (9.25 mm) hose barb	3/8-inch (9.25 mm) hose barb	**Same.** Both devices have the same size outlet connection port.

10. Non-clinical Performance Data

The test strategy for the Midas Flowmeter and optional eAVS included performance bench testing of the device characteristics, safety features, and control mechanism. The results of the testing demonstrated that the Midas Flowmeter and optional eAVS met all of the acceptance criteria for functional, operational, and performance characteristics and therefore there are no different questions of safety or efficacy related to the subject device. A list of performance bench tests conducted on the Midas Flowmeter and eAVS is provided below.

- Gas Flow Rate Adjustment
- Touchscreen Display
- Working with Barriers
- Software Updates and Corruption
- Scavenger
- Bag Tee

- Button Functionality
- Accuracies and Faults
- Language
- Tolerance
- Life Testing
- Bluetooth

The Midas Flowmeter and optional eAVS were test to different Recognized Consensus Standards. The results of the testing demonstrated that the Midas Flowmeter and optional eAVS met all of the acceptance criteria for functional, operational, and performance characteristics and therefore there are safe and effective and are substantially equivalent to the predicate devices. Testing confirmed compliance with the applicable portions of the following standards:

- IEC 60601-1:2005 +AMD1:2012+AMD2:2020, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2014, AMD1:2020, Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbance– Requirements and tests
- ISO 18562:2017, Biocompatibility evaluation of breathing gas pathways in healthcare applications (Parts 1, 2, & 3)
- ISO 15001:2010, Anesthetic and Respiratory Equipment – Compatibility with Oxygen
- IEC 62366-1:2015/AMD1:2020, Medical devices -- Application of usability engineering to medical devices
- ANSI HE 75:2009 (R)2018, Human Factors Engineering
- AAMI TIR12, Designing, Testing, And Labeling Medical Devices Intended for Processing by Health Care Facilities
- AAMI ST98, A Compendium of Processes, Materials, Test Methods, And Acceptance Criteria for Cleaning Reusable Medical Devices testing at Nelson Labs
- ASTM D4169-22, Standard Practice for Performance Testing of Shipping Containers and Systems
- IEC 60601-1-11:2020, Medical Electrical Equipment - Part 1-11: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Requirements for Medical Electrical Equipment and Medical Electrical Systems Used in The Home Healthcare Environment
- ISO 11195:2018, Gas mixers for medical use – Stand-alone gas mixers

11. Clinical Data

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

12. Substantial Equivalence Discussion

Both the Midas Flowmeter subject device and FlowStar Touch Digital Mixer Flowmeter (K222794) predicate device have the same intended use, use environment, operating principle,

and fundamental technology with similar technological characteristics. Both devices are intended for administering a mixture of nitrous oxide and oxygen to a conscious, spontaneously breathing patient. The differences between the two devices are limited to the monitoring system, external interface connector, and device configurations. The features and performance characteristics are determined to be substantially equivalent through comparison of the Midas Flowmeter with the primary predicate device.

Both the optional eAVS subject device and Nitronox Scavenger Plus (K223452) reference device have the same intended use, use environment, operating principle, and fundamental technology with similar technological characteristics. Both devices are intended to be used to remove waste gas in a healthcare facility environment with a vacuum source. Both devices have features for maintaining the scavenging pressure to ensure proper removal of waste gas. The differences between the two devices are limited to software and design characteristics. The incorporation of the eAVS features to extent the indications for use of the Midas Flowmeter to include gas scavenging control is determined to be substantially equivalent through comparison of the eAVS with the reference device.

13. Conclusions

It has been shown in this 510(k) submission that the differences between the Midas Flowmeter and optional eAVS and the primary predicate and secondary predicate devices do not raise any different questions regarding safety and efficacy. The Midas Flowmeter and optional eAVS are determined to be substantially equivalent to the predicate and reference devices.