January 17, 2025

Airgas Therapeutics LLC
℅ Mikel Alberdi
President
Drug Device Consulting
13014 North Dale Mabry Highway, #326
Tampa, Florida 33618

Re: K242374
Trade/Device Name: ULSPIRA TS™ Nitric Oxide Therapy System
Regulation Number: 21 CFR 868.5165
Regulation Name: Nitric Oxide Administration Apparatus
Regulatory Class: Class II
Product Code: MRN, MRO, MRP, MRQ, CCL
Dated: December 20, 2024
Received: December 20, 2024

Dear Mikel Alberdi:

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.

Submission Number *(if known)*

K242374

Device Name

ULSPIRA TS™ Nitric Oxide Therapy System

Indications for Use *(Describe)*

The Ulspira TS Nitric Oxide Therapy System is intended for use by healthcare professionals for the delivery of nitric oxide (NO) and the monitoring of inspired NO, NO2 and O2 concentrations for a patient undergoing inhaled Nitric Oxide (iNO) therapy.

The Ulspira TS must only be used in accordance with the indications, contraindications, warnings and precautions described in the nitric oxide drug packaging inserts and labeling and is indicated for use in term and near-term (>34weeks gestation) neonates with hypoxic respiratory failure associated with clinical or echocardiographic evidence of pulmonary hypertension. The primary targeted clinical setting is the Neonatal Intensive Care Unit (NICU) and secondary targeted clinical setting is the transport of neonates. Refer to this material prior to use.

The Ulspira TS primary NO therapy system delivers NO gas in the 0-80 ppm range while in the Constant Rate or flow sensing modes. This includes:
• Continuous integrated monitoring for inspired NO, NO2 and O2 and a comprehensive alarm system.
• A touch-screen user interface with a waveform display of the ventilation device flow as measured in the inspiratory limb.
• Cylinder handling facilitated by manual or an automatic cylinder switch which is reactive to the detected gas supply state of NO cylinders, and a low O2 pressure alarm when using an oxygen cylinder.
• An automated emergency dosing algorithm activated by certain high-risk alarms, which impact patient dosing, to avoid sudden cessation of therapy.
• Compatibility with a wide inspiratory flow rate range of 0.25-120 l/min, utilizing an automatically detected low or high flow sensor.
• An internal battery which provides at least two hours of uninterrupted therapy and a 12V DC inlet for additional external battery access.
The integrated Ulspira TS pneumatic backup NO therapy system provides backup NO delivery capability that is intended to deliver a continuous flow of NO mixed with O2, for iNO therapy which allows continuous treatment during transit within hospitals.

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.

510(k) SUMMARY

The following summary is provided in accordance with 21 CFR 807.92:

A. DATE

January 17, 2025

B. APPLICANT

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United States

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C. CORRESPONDENT

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United States

Contact Person: Mr. Mikel Alberdi
Drug Device Consulting
(813) 708-8303
malberdi@drugdeviceconsulting.com

D. DEVICE

Device Trade Name:	UlSPIRA TS™ Nitric Oxide Therapy System
Common Name:	Nitric Oxide Administration Apparatus
Classification:	Class II - 21 CFR 868.5165
Classification Name:	Apparatus, Nitric Oxide Delivery
Product Codes:	MRN (Primary), MRO, MRP, MRQ, CCL

E. PREDICATE DEVICE

K212409 - Ulspira TS Nitric Oxide Therapy System

F. DEVICE DESCRIPTION

Ulspira TS Nitric Oxide Therapy System delivers physician-prescribed NO therapy gas and monitors inspired Nitric Oxide, Nitrogen Dioxide, and Oxygen gas in combination with a respiratory device.

The main device functionalities of the Ulspira TS Nitric Oxide Therapy System include:

- A primary delivery system to administer NO gas into a respiratory device circuit.

- Monitoring of NO, NO2, and O2 gas concentrations close to the patient interface.

- System includes a user interface that contains all controls used to set the NO delivery and monitoring parameters. All set parameters as well as other information are shown on the user interface screen.

- The system will produce visual and audible alarms if vital parameters vary beyond preset or default limits.

- The system includes an integrated pneumatic back-up system for manual hand bagging in order to deliver NO therapy in the event of a failure of the primary delivery system and during manual ventilation.

The Ulspira TS system consists of the base unit, the mobile cart and bedside rail holder, and various components and accessories, including the gas regulators and patient kits for use with validated respiratory devices.

G. INDICATIONS FOR USE

The Ulspira TS Nitric Oxide Therapy System is intended for use by healthcare professionals for the delivery of nitric oxide (NO) and the monitoring of inspired NO, NO2 and O2 concentrations for a patient undergoing inhaled Nitric Oxide (iNO) therapy.

The Ulspira TS must only be used in accordance with the indications, contraindications, warnings and precautions described in the nitric oxide drug packaging inserts and labeling and is indicated for use in term and near-term (>34weeks gestation) neonates with hypoxic respiratory failure associated with clinical or echocardiographic evidence of pulmonary hypertension. The primary targeted clinical setting is the Neonatal Intensive Care Unit (NICU) and secondary targeted clinical setting is the transport of neonates. Refer to this material prior to use.

The Ulspira TS primary NO therapy system delivers NO gas in the 0-80 ppm range while in the Constant Rate or flow sensing modes. This includes:
• Continuous integrated monitoring for inspired NO, NO2 and O2 and a comprehensive alarm system.
• A touch-screen user interface with a waveform display of the ventilation device flow as measured in the inspiratory limb.
• Cylinder handling facilitated by manual or an automatic cylinder switch which is reactive to the detected gas supply state of NO cylinders, and a low O2 pressure alarm when using an oxygen cylinder.

• An automated emergency dosing algorithm activated by certain high-risk alarms, which impact patient dosing, to avoid sudden cessation of therapy.
• Compatibility with a wide inspiratory flow rate range of 0.25-120 l/min, utilizing an automatically detected low or high flow sensor.
• An internal battery which provides at least two hours of uninterrupted therapy and a 12V DC inlet for additional external battery access.

The integrated Ulspira TS pneumatic backup NO therapy system provides backup NO delivery capability that is intended to deliver a continuous flow of NO mixed with O2, for iNO therapy which allows continuous treatment during transit within hospitals**.**

H. TECHNOLOGICAL COMPARISON

Ulspira TS Nitric Oxide Therapy System modifications include a modification of the labeling to include six additional respiratory devices. The Ulspira TS Nitric Oxide Therapy System with the additional respiratory devices has the identical intended use and uses the same device hardware as the cleared Ulspira TS Nitric Oxide Therapy System predicate device. All features are identical except for those described in the table below.

Device name	**Ulspira TS (K212409)**	**Ulspira TS (Proposed Device)**	**Comparison**
Comparison of general attributes, indication, patient population, operating environment, etc.			
Product code(s)	MRN	MRN	Identical
Regulation number	21 CFR 868.5165	21 CFR 868.5165	Identical
Regulation Description	- Nitric oxide administration apparatus (Nitric oxide delivery/backup delivery) - Nitric oxide analyzer - Nitrogen dioxide analyzer	- Nitric oxide administration apparatus (Nitric oxide delivery/backup delivery) - Nitric oxide analyzer - Nitrogen dioxide analyzer	Identical
Indications for Use	The Ulspira TS Nitric Oxide Therapy System is intended for use by healthcare professionals for the delivery of nitric oxide (NO) and the monitoring of inspired NO, NO2 and O2 concentrations for a patient undergoing inhaled Nitric Oxide (iNO) therapy and must only be used in accordance with the indications, contraindications, warnings and precautions described in the nitric oxide drug packaging inserts and labeling (currently neonates). Refer to this material prior to use. The Ulspira TS primary NO therapy system delivers NO gas in the 0-80 ppm range while in the Constant Rate or flow sensing modes. This includes: • Continuous integrated monitoring for inspired NO, NO2 and O2 and a comprehensive alarm system. • A touch-screen user interface with a waveform display of the ventilation device flow as measured in the inspiratory limb. • Cylinder handling facilitated by manual or an automatic cylinder switch which is reactive to the detected gas supply state of NO cylinders, and a low O2 pressure alarm when using an oxygen cylinder.	The Ulspira TS Nitric Oxide Therapy System is intended for use by healthcare professionals for the delivery of nitric oxide (NO) and the monitoring of inspired NO, NO2 and O2 concentrations for a patient undergoing inhaled Nitric Oxide (iNO) therapy and must only be used in accordance with the indications, contraindications, warnings and precautions described in the nitric oxide drug packaging inserts and labeling (currently neonates). Refer to this material prior to use. The Ulspira TS primary NO therapy system delivers NO gas in the 0-80 ppm range while in the Constant Rate or flow sensing modes. This includes: • Continuous integrated monitoring for inspired NO, NO2 and O2 and a comprehensive alarm system. • A touch-screen user interface with a waveform display of the ventilation device flow as measured in the inspiratory limb. • Cylinder handling facilitated by manual or an automatic cylinder switch which is reactive to the detected gas supply state of NO cylinders, and a low O2 pressure alarm when using an oxygen cylinder.	Identical

Device name	Ulspira TS (K212409)	Ulspira TS (Proposed Device)	Comparison
	• An automated emergency dosing algorithm activated by certain high-risk alarms, which impact patient dosing, to avoid sudden cessation of therapy. • Compatibility with a wide inspiratory flow rate range of 0.25-120 l/min, utilizing an automatically detected low or high flow sensor. • An internal battery which provides at least two hours of uninterrupted therapy and a 12V DC inlet for additional external battery access. The integrated Ulspira TS pneumatic backup NO therapy system provides backup NO delivery capability that is intended to deliver a continuous flow of NO mixed with O2, for iNO therapy which allows continuous treatment during transit within hospitals.	• An automated emergency dosing algorithm activated by certain high-risk alarms, which impact patient dosing, to avoid sudden cessation of therapy. • Compatibility with a wide inspiratory flow rate range of 0.25-120 l/min, utilizing an automatically detected low or high flow sensor. • An internal battery which provides at least two hours of uninterrupted therapy and a 12V DC inlet for additional external battery access. The integrated Ulspira TS pneumatic backup NO therapy system provides backup NO delivery capability that is intended to deliver a continuous flow of NO mixed with O2, for iNO therapy which allows continuous treatment during transit within hospitals.	
Physical dimensions and weight (excl. carrier/cart)	*Weight:* 7.0 kg *Width:* 320 mm *Depth:* 150 mm *Height:* 300 mm	*Weight:* 7.0 kg *Width:* 320 mm *Depth:* 150 mm *Height:* 300 mm	Identical
NO gas connectors	*CGA 626*	*CGA 626*	Identical
NO Injection location	NO injection connected between ventilator and humidifier.	NO injection connected between ventilator and humidifier.	Identical
Battery backup	Yes	Yes	Identical
Battery backup time	2h	2h	Identical
Power Supply - Main	Voltage: 100-240V, 50 - 60Hz	Voltage: 100-240V, 50 - 60Hz	Identical
Automated Pre-Use check	Yes	Yes	Identical
Alarms			
NO Delivery/Flow Sensor Alarms	Yes	Yes	Identical
Power Supply/Battery Alarms	Yes	Yes	Identical
NO, NO_2, O_2 Monitoring Alarms	Yes	Yes	Identical
Primary NO administration system			
NO administration principle	NO delivery into the inspiratory limb of a ventilation device's patient circuit.	NO delivery into the inspiratory limb of a ventilation device's patient circuit.	Identical
Range of NO gas concentration delivered	0-80 ppm	0-80 ppm	Identical
NO delivery accuracy	±20% or 2 ppm, whichever is the greatest.	±20% or 2 ppm, whichever is the greatest.	Identical
Operating Modes	The subject device incorporates two modes (Autosense and Jet Sense) that provides a user set dose of NO into the inspiratory limb of the respiratory device circuit, based on the measured respiratory device flow. The subject device also includes a third mode, Constant Rate, which provides flow of NO (0.5 - 60 l/min) into the inspiratory limb of the respiratory device circuit.	The subject device incorporates two modes (Autosense and Jet Sense) that provides a user set dose of NO into the inspiratory limb of the respiratory device circuit, based on the measured respiratory device flow. The subject device also includes a third mode, Constant Rate, which provides flow of NO (0.5 - 60 l/min) into the inspiratory limb of the respiratory device circuit.	Identical
Backup NO administration system			
Backup power source	Pneumatic system	Pneumatic system	Identical
Backup NO Administration	Backup system delivering a user set concentration of NO, via adjustment of O_2 flow, to the patient via a resuscitator.	Backup system delivering a user set concentration of NO, via adjustment of O_2 flow, to the patient via a resuscitator.	Identical
Backup NO delivery accuracy	Within ±20% of set value or ±2 ppm, whichever is the greatest.	Within ±20% of set value or ±2 ppm, whichever is the greatest.	Identical

Device name	Ulspira TS (K212409)	Ulspira TS (Proposed Device)	Comparison
Gas analysis (NO, NO_2, O_2) – General characteristics			
Breathing circuit sample source location	On the inspiratory limb of the breathing circuit, after the humidifier.	On the inspiratory limb of the breathing circuit, after the humidifier.	Identical
Sample flow rate	150 ml/min	150 ml/min	Identical
NO gas analysis			
Integrated NO Gas Analyzer	Yes	Yes	Identical
NO measurement accuracy	+- (0.5 ppm +20 % of actual concentration) in the range 0-20 ppm +- (0.5 ppm +10 % of actual concentration) in the range 20-120 ppm	+- (0.5 ppm +20 % of actual concentration) in the range 0-20 ppm +- (0.5 ppm +10 % of actual concentration) in the range 20-120 ppm	Identical
NO Measurement range	0 - 120 ppm	0 - 120 ppm	Identical
NO_2 gas analysis			
Integrated NO_2 Gas Analyzer	Yes	Yes	Identical
NO_2 measurement accuracy	±(20% or 0.5 ppm), whichever is the greatest.	±(20% or 0.5 ppm), whichever is the greatest.	Identical
NO_2 measurement range	0 - 30 ppm	0 - 30 ppm	Identical
O_2 gas analysis			
Integrated O_2 Gas Analyzer	Yes	Yes	Identical
O_2 measurement accuracy	±(2.5 % volume fraction + 2.5 % of gas concentration)	±(2.5 % volume fraction + 2.5 % of gas concentration)	Identical
O_2 measurement range	18 - 100 %	18 - 100 %	Identical
Software			
Software version	Version 1.5	Version 1.6 <u>Software Changes:</u> - Improvements in onscreen appearance - correct minor items noted during software testing	Substantially Equivalent: Minor updates/ differences The changes in the software are minor and would not require a 510(k) submission to justify the changes in accordance with FDA Guidance Deciding When to Submit a 510(k) for a Software Change to an Existing Device.
User Manual			
User Manual	Original	Revision 5 Updated to add new respiratory devices	Substantially Equivalent: Minor updates/ differences

I. NON-CLINICAL TESTS SUMMARY & CONCLUSION

Summary of Nonclinical Tests:

The testing concluded that ULSPIRA TS Nitric Oxide Therapy System is compatible with the selected ventilators.

The seven ventilators, and the ULSPIRA TS Nitric Oxide Therapy System, were set up and calibrated according to the manufacturer's recommendations, and tested using the settings established for each ventilator.

Multiple levels of nitric oxide delivery were evaluated [0 (baseline), 1, 5, 20, 40, and 80 ppm].

The following conditions were evaluated for the ULSPIRA TS Nitric Oxide Therapy System when used in conjunction with the ventilators:

- Connection of the systems
- Accuracy of applied NO
- O2 dilution
- NO2 formation
- Alarm functionality
- Influence on ventilator performance

Nonclinical Testing Conclusion:

The ULSPIRA TS Nitric Oxide Therapy System performed within specifications when used with each ventilator.

J. CONCLUSIONS

The above described nonclinical data support the substantial equivalence of the device with the predicate device. The supporting hardware, and the software verification and validation and usability testing demonstrate that the Ulspira TS Nitric Oxide Therapy System performs as intended in the specified use conditions. Risk assessments and completed testing did not raise different questions of safety and effectiveness. Airgas Therapeutics concludes that the performance data for the subject device shows that it is substantially equivalent to the cleared predicate device.