October 30, 2026

Airgas Therapeutics, LLC
% Mikel Alberdi
President
Drug Device Consulting
13014 N. Dale Mabry Hwy., #326
Tampa, Florida 33618

Re: K253095
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: September 22, 2026
Received: September 22, 2026

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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 Office of Industry and Consumer Education (OICE) to ask a question about a specific regulatory topic. See the OICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-office-industry-and-consumer-education-oice) for more information or contact OICE by email (AskOICE@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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253095 S002

Please provide the device trade name(s).

ULSPIRA TS™ Nitric Oxide Therapy System (IN000102)

Please provide your Indications for Use below.

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 Nitric Oxide Therapy System 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.

Please select the types of uses.	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☒ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☐ Adults (22 years old and greater)

Airgas Therapeutics
an Air Liquide company

510(k) SUMMARY for Ulspira TS - K253095

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

A. DATE
October 30,2026

B. APPLICANT
Airgas Therapeutics
6141 Easton Rd.
P.O. Box 310
Plumsteadville PA 18949
United States
Contact Person: Mr. Timothy Warren
Airgas Therapeutics
Senior Director of Quality and Regulatory Affairs
(215) 766-7407 x3034
tim.warren@airgas.com

C. CORRESPONDENT
Drug Device Consulting
13014 North Dale Mabry Highway, #326
Tampa FL 33618
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 AND REFERENCE DEVICES
K242374 - Ulspira TS Nitric Oxide Therapy System -Primary predicate
K212409 - Ulspira TS Nitric Oxide Therapy System -Reference device
K200389 - INOMAX DSIR Plus -Reference device

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.
- The 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.

Airgas Therapeutics
an Air Liquide company

H. COMPARISON with predicate

The modified Ulspira TS Nitric Oxide Delivery System has the same intended use as the previously cleared Ulspira TS Nitric Oxide Delivery System (K242374) and the first Ulspira TS Nitric Oxide Therapy System version approved by the FDA (K212409).
All features between the subject device K253095, the predicate device (K253095) and reference devices (K212409 and K200389) are identical except those described in the table below.

Feature / Specification	INOMAX DSIR Plus K200389- reference device	Ulspira TS Nitric Oxide Therapy System K212409 - reference device	Ulspira TS Nitric Oxide Therapy System K242374- primary predicate	Ulspira TS Nitric Oxide Therapy System K253095- subject Device	Comparison
Comparison of general attributes, indication, patient population, operating environment,					
Product Code (s)	-MRN -MRP -MRQ	-MRN, -MRO -MRP -MRQ -CCL	-MRN, -MRO -MRP -MRQ -CCL	-MRN, -MRO -MRP -MRQ -CCL	Identical
Regulation number	21 CFR 868.5165	21 CFR 868.5165	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	• 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

Airgas Therapeutics
an Air Liquide company

Indications for use	The INOmax DSIR Plus delivery system delivers INOMAX (nitric oxide for inhalation) therapy gas into the inspiratory limb of the patient breathing circuit in a way that provides a constant concentration of nitric oxide (NO), as set by the user, to the patient throughout the inspired breath. It uses a specially designed injector module, which enables tracking of the ventilator waveforms and the delivery of a synchronized and proportional dose of NO. It may be used with most ventilators. The INOmax DSIR Plus provides continuous integrated monitoring of inspired O2, NO2, and NO, and a comprehensive alarm system. The INOmax DSIR Plus incorporates a battery that provides up to 6 hours of uninterrupted NO delivery in the absence of an external power source. The INOmax DSIR Plus includes a backup NO delivery capability that provides a fixed flow of 250 mL/min of NO which along with user supplied 10 L/min of oxygen provides 20 ppm in the gas flow to a patients breathing circuit. It may also use the INOblender for backup. The target patient population is controlled by the drug labeling for INOMAX and is currently neonates. The primary targeted clinical setting is the Neonatal Intensive Care Unit (NICU) and secondary targeted clinical setting is the transport of neonates. (Ref. K200389)	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	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	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	Identical for Ulspira TS Ulspira TS vs DSIR plus: Both devices deliver (via a primary or a backup system) controlled concentrations of NO into the inspiratory limb of a respiratory device circuit. Both devices contain gas monitors with alarms for NO, O2 and NO2. Differences in technological characteristics (e.g. operating modes, cylinder switching, emergency dosing, backup battery and backup delivery system) described in the indications for use statements are discussed below in respective sections. The conclusion is that the general purpose is the same and technological differences do not raise any concerns about safety or effectiveness for the subject device compared to the predicate.

Airgas Therapeutics
an Air Liquide company

Feature / Specification	INOMAX DSIR Plus K200389- reference device	Ulspira TS Nitric Oxide Therapy System K212409 - reference device	Ulspira TS Nitric Oxide Therapy System K242374- primary predicate	Ulspira TS Nitric Oxide Therapy System K253095- subject Device	Comparison
		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.	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.	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.	
Physical dimensions and weight (excl. carrier/cart)	Weight: 5.3 kg Width: 350 mm Depth: 160 mm Height: 220 mm	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	Weight: 7.0 kg Width: 320 mm Depth: 150 mm Height: 300 mm	Identical for Ulspira TS Ulspira TS and iNOMAX DSIR Plus : Different but substantially equivalent
NO gas connectors	CGA 626	CGA 626	CGA 626	CGA 626	Identical
NO injection location	NO injection connected between ventilator and humidifier.	NO injection connected between ventilator and humidifier.	NO injection connected between ventilator and humidifier.	NO injection connected between ventilator and humidifier.	Identical
Battery backup	Yes	Yes	Yes	Yes	Identical

Airgas Therapeutics
an Air Liquide company

Feature / Specification	INOMAX DSIR Plus K200389- reference device	Ulspira TS Nitric Oxide Therapy System K212409 - reference device	Ulspira TS Nitric Oxide Therapy System K242374- primary predicate	Ulspira TS Nitric Oxide Therapy System K253095- subject Device	Comparison
Battery backup time	6h	2h	2h	2h	Identical for Ulspira TS Ulspira TS vs DSIR +: The special control applicable for this device stipulates "Backup power should be demonstrated to have the duration of the ventilators listed for use with the device, or for at least 20 minutes" and stipulates "On medical devices equipped with a battery back-up system, the battery, when charged fully, should be capable of supplying power for normal operation for the time duration specified in the device specifications, and consistent with its intended use". The subject device meets the special controls and therefore the difference does not raise new questions regarding safety and effectiveness.
Automated Pre-Use Check	Yes	Yes	Yes	Yes	Identical
ALARM					
NO Delivery/Flow Sensor Alarms	Yes	Yes	Yes	Yes	Identical

Airgas Therapeutics
an Air Liquide company

Feature / Specification	INOMAX DSIR Plus K200389- reference device	Ulspira TS Nitric Oxide Therapy System K212409 - reference device	Ulspira TS Nitric Oxide Therapy System K242374- primary predicate	Ulspira TS Nitric Oxide Therapy System K253095- subject Device	Comparison
Power Supply/Battery Alarms	Yes	Yes	Yes	Yes	Identical For Ulspira TS Ulspira TS vs DSIR+: Both devices include alarm(s) for low battery power where the subject device also includes technical alarms in relation to failures in different parts of the power supply system. This difference is not considered to raise new questions regarding safety and effectiveness. Both the subject and predicate device show audible and visual battery depletion warning(s) according to respective device specification stated in the manual for each device. Also the special control applicable for this device, stipulates "When a battery back-up is provided, audible and visual battery depletion warning indicators should be provided that activate when the battery depletes to a level of charge that is approaching the lower limit of power that can operate the device within its specification". Therefore this difference is not considered to raise new questions regarding safety and effectiveness.
NO, NO2, O2 Monitoring Alarms	Yes	Yes	Yes	Yes	Identical for Ulspira TS Ulspira TS vs DSIR+: Both devices include alarms for general monitoring/gas analysis failure and for failures in NO, NO2 and O2 sensors. The subject device corresponding alarm in relation to the predicate device Water Trap Bottle Full alarm is the Sampling line blocked alarm, which will be triggered if the water trap is full
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.	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	0-80 ppm	0-80 ppm	Identical

Airgas Therapeutics
an Air Liquide company

Feature / Specification	INOMAX DSIR Plus K200389- reference device	Ulspira TS Nitric Oxide Therapy System K212409 - reference device	Ulspira TS Nitric Oxide Therapy System K242374- primary predicate	Ulspira TS Nitric Oxide Therapy System K253095- subject Device	Comparison
NO delivery accuracy	±20% or 2 ppm, whichever is the greatest.	±20% or 2 ppm, whichever is the greatest.	±20% or 2 ppm, whichever is the greatest.	±20% or 2 ppm, whichever is the greatest.	Identical
Operating Modes	The reference device incorporates one mode that provides a user set dose of NO into the inspiratory limb of the respiratory device circuit, based on the measured respiratory device flow. (Note. The integrated pneumatic backup provides a fixed flow (0.25 l/min) of NO.)	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.	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 for Ulspira TS Ulspira TS vs DSIR+: The difference in this feature is not considered to raise additional questions of safety and effectiveness as the subject device features has been validated with acceptable results as part of the submission K212409
Backup NO administration system					
Backup power source	Pneumatic system	Pneumatic system	Pneumatic system	Pneumatic system	Identical
Backup NO Administration	Backup system delivering a constant flow of NO to the inspiratory limb of a ventilation device patient circuit	Backup system delivering a user set concentration of NO, via adjustment of O2 flow, to the patient via a resuscitator.	Backup system delivering a user set concentration of NO, via adjustment of O2 flow, to the patient via a resuscitator.	Backup system delivering a user set concentration of NO, via adjustment of O2 flow, to the patient via a resuscitator.	Identical for Ulspira TS Ulspira TS vs DSIR+: The special control applicable for this device describes both types of systems therefore this difference is assessed not to raise new questions of safety and effectiveness.
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.	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
Gas analysis (NO,NO2,O2) - General characteristics					
Breathing circuit sample source	On the inspiratory limb of the breathing circuit, after the	On the inspiratory limb of the breathing circuit, after the	On the inspiratory limb of the breathing circuit, after the	On the inspiratory limb of the breathing circuit, after the	Identical

Airgas Therapeutics
an Air Liquide company

Feature / Specification	INOMAX DSIR Plus K200389- reference device	Ulspira TS Nitric Oxide Therapy System K212409 - reference device	Ulspira TS Nitric Oxide Therapy System K242374- primary predicate	Ulspira TS Nitric Oxide Therapy System K253095- subject Device	Comparison
location	humidifier.	humidifier.	humidifier.	humidifier.	
Sample flow rate	230 ml/min	150 ml/min	150 ml/min	150 ml/min	Identical for Ulspira TS Ulspira TS vs DSIR+: The subject device meets its measuring accuracy requirements with a lower sample flow rate from the patient's breathing circuit. This difference is not considered to raise new questions regarding safety and effectiveness.
NO gas analysis					
Integrated NO Gas Analyzer	Yes	Yes	Yes	Yes	Identical
NO measurement accuracy	+- (0.5 ppm +20 % of actual concentration) in the range 0-10 ppm +- (0.5 ppm +10 % of actual concentration) in the range 10-100 ppm	+- (0.5 ppm +20 % of actual concentration) in the range 0-20 ppm +- (0.5	+- (0.5 ppm +20 % of actual concentration) in the range 0-20 ppm +- (0.5	+- (0.5 ppm +20 % of actual concentration) in the range 0-20 ppm +- (0.5	Identical for Ulspira TS Ulspira TS vs DSIR+: The subject device meets the accuracy requirements specified in the special control applicable for this device, therefore this difference is not considered to raise new questions regarding safety and effectiveness.
NO Measurement range	0 - 100 ppm	0 - 120 ppm	0 - 120 ppm	0 - 120 ppm	Identical for Ulspira TS Ulspira TS vs DSIR+: The subject device is verified for and facilitates NO measurement in a wider range. This difference is not considered to raise new questions regarding safety and effectiveness.
NO2 gas analysis					
Integrated NO2 Gas Analyzer	Yes	Yes	Yes	Yes	Identical
NO2 measurement	±(20% or 0.5 ppm), whichever is	±(20% or 0.5 ppm), whichever is	±(20% or 0.5 ppm), whichever is	±(20% or 0.5 ppm), whichever is	Identical

Airgas Therapeutics
an Air Liquide company

Feature / Specification	INOMAX DSIR Plus K200389- reference device	Ulspira TS Nitric Oxide Therapy System K212409 - reference device	Ulspira TS Nitric Oxide Therapy System K242374- primary predicate	Ulspira TS Nitric Oxide Therapy System K253095- subject Device	Comparison
accuracy	the greatest.	the greatest.	the greatest.	the greatest.	
NO2 measurement range	0 - 10 ppm	0 - 30 ppm	0 - 30 ppm	0 - 30 ppm	Identical for Ulspira TS Ulspira TS vs DSIR+: The subject device meets the range requirements specified in the special control applicable for this device, appendix 001 section 3.3.1 a, therefore this difference is not considered to raise new questions regarding safety and effectiveness.
O2 gas analysis					
Integrated O2 Gas Analyzer	Yes	Yes	Yes	Yes	Identical
O2 measurement accuracy	± 3% volume fraction (v/v)	±(2.5 % volume fraction + 2.5 % of gas concentration)	±(2.5 % volume fraction + 2.5 % of gas concentration)	±(2.5 % volume fraction + 2.5 % of gas concentration)	Identical for Ulspira TS Ulspira TS vs DSIR+: The subject device meets requirements as specified in the special control applicable for this device, therefore the difference is not considered to raise new questions regarding safety and effectiveness.
O2 measurement range	18 - 100 %	18 - 100 %	18 - 100 %	18 - 100 %	Identical
Additional features subject to this 510(k)					

Airgas Therapeutics
an Air Liquide company

Feature / Specification	INOMAX DSIR Plus K200389- reference device	Ulspira TS Nitric Oxide Therapy System K212409 - reference device	Ulspira TS Nitric Oxide Therapy System K242374- primary predicate	Ulspira TS Nitric Oxide Therapy System K253095- subject Device	Comparison
User Manual and addendum	A variety respiratory devices and configurations (transport, neonatal, adult/ped, high frequency and anesthesia ventilators, nasal CPAP and nasal high flow cannulas) are present in the Operational Manual rev03 notably: ● Spontaneous breathing patient on a mask circuit ; ● Fisher & Paykel - Optiflow Breathing Circuit (High flow nasal cannula) - validated for use in United State ● Draeger Evita - validated for use in United State	A variety of respiratory devices have been approved and validated for use with the Ulspira TS. ● Bunnell LifePulse 203 ● Dräger Babylog 8000 plus ● Dräger Babylog VN500 ● Fisher & Paykel Bubble CPAP ● Fisher & Paykel Optiflow High Flow Therapy ● Getinge Servo-n ● Getinge Servo-u ● Getinge Servo-i ● Sensormedics 3100A ● Viasys Infant Flow SIPAP	Additional respiratory devices have been approved and validated for use with the Ulspira TS. ● Bunnell LifePulse 204 ● Hamilton Medical C6 ● Hamilton Medical S1/G5 ● Hamilton Medical T1/C1/MR1 ● Puritan Bennett PB980 ● Sensormedics 3100B ● Vapotherm Precision Flow	Additional respiratory devices include: ● Draeger - Evita V600/V800 ● Fisher and Paykel - Optiflow + ● Fisher and Paykel - Neopuff ● Spontaneous breathing on a mask circuit The Ulspira TS User Manual and Addendum have been updated in accordance with these additions.	Ulspira TS: Substantially Equivalent: The differences between K212409, K242374 and the subject devices are minor updates/ differences. Ulspira TS Vs DSIR+: The following ventilators are also listed as validated with INOMAX DSIR+: - Fisher and Paykel Optiflow Breathing Circuit: neonatal and pediatric/adult patient category - Fisher and Paykel NeoPuff infant resuscitator - Spontaneous breathing on a mask circuit (22mm)
NO gas hose *NO regulator*	Not a reference device	The accessories and components used in the K212409 are: ● NO gas hose of 1m (ULSIN00129) ● NO regulator (ULSIN00176)	The accessories and components used in the K242374 are: ● NO gas hose of 1m (ULSIN00129) ● NO regulator (ULSIN00176)	Additional components and accessories include : ● NO gas hose of 1.1m (ULSIN000329) ● NO regulator with easy view (ULSIN000342)	For Ulspira TS: substantially equivalent: - NO regulator : Since the change is limited to the external body of the component and the breathing gas pathway remains identical in terms of materials and of gas-contacting surface area, the new version of the NO gas regulator CGA 626 (IN000342) does not modify the indirect patient exposure to gas pathway materials and does not create a new worst case. The introduction of IN000342 is not a significant change and does not impact the safety and effectiveness of the Ulspira TS. - On the basis of the identical material formulation, the identical manufacturer and manufacturing process, the identical nature and duration of patient contact, and an increase in gas-contacting surface area of less than 10 % whose emission profile is known and identical to that of the tested article, the 1.10 m NO gas hose (IN000329) is biologically equivalent to the predicate 1 m NO gas hose (IN000129). The differences are not considered to raise new questions regarding safety and effectiveness.

I. Non-clinical tests summary & Clinical tests summary

Summary of Nonclinical Tests:

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

The additional respiratory devices 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 respiratory device.

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 respiratory devices:

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

This submission has no impact and modification on Biocompatibility, Software, Reprocessing testing, Human factors validation, System (system test, regression tests, free user testing, comparative/waveform testing), used standards in comparison with the predicate K212409.

Nonclinical Testing Conclusion:

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

Summary of Clinical test

This section is not applicable to this submission. The subject of this premarket submission, Ulspira TS Nitric Oxide Therapy System with updated labeling to interface with additional respiratory devices, did not require clinical studies to support substantial equivalence.

J. CONCLUSIONS

The above described nonclinical data support the substantial equivalence of the device with the predicate device and reference devices, and demonstrate that the Ulspira TS Nitric Oxide Therapy System performs as intended in the specified use conditions. Airgas Therapeutics concludes that the performance data for the subject device shows that it is substantially equivalent to the cleared predicate device and as safe and as effective as the predicate device, with performance substantially equivalent to the predicate device.