June 30, 2023

Airgas Therapeutics
Steve Miller
V.P. Regulatory and Compliance
12800 West Little York Road
Houston, TX 77041

Re: K212409
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: January 30, 2023
Received: January 31, 2023

Dear Steve Miller:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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)*
K212409

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.**

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

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**510(k) SUMMARY**

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

**A. DATE**

**May 31, 2023**

**B. SUBMITTER / SPONSOR**

Airgas Therapeutics
12800 West Little York Road
Houston, TX 77041

Contact Person: Steve Miller
Airgas Therapeutics
V.P. Regulatory and Compliance
Phone (713) 896-2280

**C. DEVICE**

| | |
|---|---|
| Trade Name of Device: | ULSPIRA TS Nitric Oxide Therapy System |
| Common or Usual Name: | Nitric Oxide Administration Apparatus (Primary)<br>Nitric Oxide Administration Apparatus (Backup)<br>Nitric Oxide Analyzer<br>Nitrogen Dioxide Analyzer<br>Oxygen Gas Analyzer |
| Classification: | Class II- 21 CFR 868.5165 |
| Classification Name: | Nitric Oxide Administration Apparatus |

Product Codes: MRN (Primary), MRO, MRP, MRQ, CCL

**D. PREDICATE DEVICE** K200389, INOmax DSIR Plus

**E. REFERENCE DEVICE(S)** K171696, NOxBOXi Nitric Oxide Delivery System

K193481, AeroNOx 2.0 Nitric Oxide Titration & Monitoring 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, $NO_2$, and $O_2$ 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, $NO_2$ and $O_2$ 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, $NO_2$ and $O_2$ 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 $O_2$ 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 $O_2$, for iNO therapy which allows continuous treatment during transit within hospitals.

## H. TECHNOLOGICAL CHARACTERISTICS - COMPARISON TO PREDICATE

| **Device name** | INOmax $DS_{IR}$ Plus | Ulspira TS | Comparison |
|---|---|---|---|
| **Comparison of general attributes, indication, patient population, operating environment, etc.** | | | |
| *Product code(s)* | - MRN<br>- MRP<br>- MRQ | - MRN, MRO<br>- MRP<br>- MRQ<br>- CCL | Similar; the additional product codes (MRO – Apparatus Nitric Oxide Back-up delivery, CCL – Analyzer O2) are also part of the INOmax DSIR Plus system. |
| *Regulation number* | - 21 CFR 868.5165 | - 21 CFR 868.5165 | Identical |
| *Regulation Description* | - Nitric oxide administration apparatus | - Nitric oxide administration apparatus | Identical |

| **Device name** | INOmax $DS_{IR}$ Plus | Ulspira TS | Comparison |
|---|---|---|---|
| *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.<br><br>The INOmax DSIR Plus provides continuous integrated monitoring of inspired $O_2$, $NO_2$, and NO, and a comprehensive alarm system.<br><br>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.<br><br>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.<br><br>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.<br><br>*(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, $NO_2$ and $O_2$ concentrations for a patient undergoing inhaled Nitric Oxide (iNO) therapy.<br><br>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.<br><br>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:<br>• Continuous integrated monitoring for inspired NO, $NO_2$ and $O_2$ and a comprehensive alarm system.<br>• A touch-screen user interface with a waveform display of the ventilation device flow as measured in the inspiratory limb.<br>• 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 $O_2$ pressure alarm when using an oxygen cylinder.<br>• An automated emergency dosing algorithm activated by certain high-risk alarms, which impact patient dosing, to avoid sudden cessation of therapy.<br>• Compatibility with a wide inspiratory flow rate range of 0.25-120 l/min, utilizing an automatically detected low or high flow sensor.<br>• An internal battery which provides at least two hours of uninterrupted therapy and a 12V DC inlet for additional external battery access.<br>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 $O_2$, for iNO therapy which allows continuous treatment during transit within hospitals. | Similar<br><br>Both devices deliver controlled concentrations of NO into the inspiratory limb of a respiratory device circuit. Both devices contain gas monitors with alarms for NO, $O_2$ and $NO_2$.<br><br>Ulspira TS system facilitates cylinder switching.<br><br>Ulspira TS system has an emergency dosing algorithm to avoid sudden cessation of therapy, activated by certain high-risk alarms.<br><br>Ulspira TS system has a broader inspiratory flow rate range utilizing two flow sensors, high and low.<br><br>Indications for both devices follow the respective drug labeling for nitric oxide (currently neonates). |

| **Device name** | INOmax $DS_{IR}$ Plus | Ulspira TS | Comparison |
|---|---|---|---|
| *Physical dimensions and weight (excl. carrier/cart)* | *Weight:* 5.3 kg<br>*Width:* 350 mm<br>*Depth:* 160 mm<br>*Height:* 220 mm | *Weight:* 7.0 kg<br>*Width:* 320 mm<br>*Depth:* 150 mm<br>*Height:* 300 mm | Different but substantially equivalent |
| *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* | 6h | 2h | Different, however both devices meet the US Food and Drug Administration special controls guidance. |
| *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 | Substantially equivalent<br>Both devices include alarms for failures in injection/delivery and for stop in delivery/no treatment of patient. The Ulspira TS system also includes specific alarms in relation to the respiratory device/ventilator flow. |
| *Power Supply/Battery Alarms* | Yes | Yes | Substantially equivalent<br>Both devices include alarm(s) for low battery power, additionally the Ulspira TS system also includes technical alarms in relation to failures in different parts of the power supply system. |
| *NO, $NO_2$, $O_2$ Monitoring Alarms* | Yes | Yes | Substantially equivalent |

| **Device name** | INOmax $DS_{IR}$ Plus | Ulspira TS | Comparison |
|---|---|---|---|
| **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 predicate 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.<br><br>(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.<br><br>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. | Different, but substantially equivalent. Both devices support fixed dose mode(s) that delivers a user set dose of NO into the inspiratory limb of the respiratory device circuit based on the measured respiratory device flow.<br><br>The Jet Sense mode of the Ulspira TS system is specifically optimized in relation to a specific respiratory device<br><br>The Ulspira TS system supports a Constant Rate mode as part of the primary delivery system that provides NO into the inspiratory limb of the respiratory device circuit, based on a user set respiratory device flow and user set NO dose. A similar function for the INOmax DSIR Plus is the integrated pneumatic backup system when used with the on screen feedback for estimated NO dose. This integrated pneumatic backup system provides a fixed flow of NO into the inspiratory limb of the respiratory device circuit and the on screen feedback indicates estimated dose and monitored values. |
| **Backup NO administration system** | | | |
| *Backup power source* | 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 $O_2$ flow, to the patient via a resuscitator. | Different, but the special control applicable for these devices describes both types of systems. |
| *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** | INOmax $DS_{IR}$ Plus | Ulspira TS | 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* | 230 ml/min | 150 ml/min | Minor difference. The Ulspira TS system meets its measuring accuracy requirements with a lower sample flow rate from the patient's breathing circuit. |
| **NO gas analysis** | | | |
| *Integrated NO Gas Analyzer* | Yes | Yes | Identical |
| *NO measurement accuracy* | +- (0.5 ppm +20 % of actual concentration) in the range 0-10 ppm<br><br>+- (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<br><br>+- (0.5 ppm +10 % of actual concentration) in the range 20-120 ppm | Different, but substantially equivalent |
| *NO Measurement range* | 0 - 100 ppm | 0 - 120 ppm | Different. The Ulspira TS system is verified for and facilitates NO measurement in a wider range. |
| **$NO_2$ 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 - 10 ppm | 0 - 30 ppm | Different. The Ulspira TS system is verified for and facilitates $NO_2$ measurement in a wider range. |

| **Device name** | INOmax $DS_{IR}$ Plus | Ulspira TS | Comparison |
|---|---|---|---|
| **$O_2$ gas analysis** | | | |
| *Integrated $O_2$ Gas Analyzer* | Yes | Yes | Identical |
| *$O_2$ measurement accuracy* | ± 3% volume fraction (v/v) | ±(2.5 % volume fraction + 2.5 % of gas concentration) | Different, but substantially equivalent. The Ulspira TS meets requirements as specified in the special control applicable for this device. |
| *$O_2$ measurement range* | 18 - 100 % | 18 - 100 % | Identical |

## I. NON-CLINICAL PERFORMANCE DATA

The following verification and validation activities have been performed to demonstrate that the design output of the modified devices meet the design input requirements:

- System (System test, regression tests, free user testing, comparative/waveform testing)
- Software (Code review, static code analysis, unit tests, integration tests)
- Performance testing (verification including primary & backup NO delivery, gas monitoring, & compatibility with ventilators identified in labeling)
- Safety testing (verification)
- Biocompatibility testing (Volatile organic compounds, particulate matter, leachable substances for prolonged contact duration)
- Reprocessing testing (Multiple reprocessing, method effectiveness validation)
- Human factors validation
- Respiratory device validation

The device has been verified and validated in compliance with the following product standards and US FDA Guidance documents:

- FDA guidance - Premarket Notification Submissions for Nitric Oxide Delivery Apparatus, Nitric Oxide Analyzer and Nitrogen Dioxide Analyzer (January 24, 2000)
- FDA guidance - Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process"
- (September 4, 2020)
- FDA guidance - Applying Human Factors and Usability Engineering to Medical Devices.(February 3, 2016)
- ANSI/AAMI ES 60601-1:2005 + A1 2012, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance,
  Recognition Number: 19-4
- IEC 60601-1-2:2014, Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and Test
  Recognition Number: 19-8
- IEC 60601-1-8:2006 + A1:2012, Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral standard: General requirements, test and guidance for alarm systems in medical electrical equipment and medical electrical systems
  Recognition Number: 5-76

- [1]ISO 80601-2-12:2011, Medical electrical equipment -- Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators
  Recognition Number: 1-98
- [2]ISO 80601-2-55:2018, Medical electrical equipment – Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors
  Recognition Number: 1-140
- IEC 62133-1:2017, Secondary Cells And Batteries Containing Alkaline Or Other Non-Acid Electrolytes – Safety Requirements For Portable Sealed Secondary Cells, And For Batteries Made From Them, For Use In Portable Applications – Part 1: Nickel Systems
- [Rec. Number2-258] ISO 10993-1:2018
  Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process
- [Rec. Number2-245] ISO 10993-5:2009
  Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- [Rec. Number2-296] ISO 10993-10:2021
  Biological evaluation of medical devices - Part 10: Tests for sensitization
- [Rec. Number2-255] ISO 10993-11:2017
  Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
- [Rec. Number2-237] ISO 10993-17:2002
  Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances
- [Rec. Number2-291] ISO 10993-23:2021
  Biological evaluation of medical devices - Part 23: Tests for irritation
- [Rec. Number1-134] ISO 18562-1:2017
  Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 1: Evaluation and testing within a risk management process
- [Rec. Number1-135] ISO 18562-2:2017
  Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 2: Tests for emissions of particulate matter
- [Rec. Number1-136] ISO 18562-3:2017
  Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 3: Tests for emissions of volatile organic compounds
- [Rec. Number1-137] ISO 18562-4:2017
  Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 4: Tests for leachables in condensate
- [Rec. Number2-295] USP-NF M98900_01_01
  <151> Pyrogen Test (USP Rabbit Test)

In addition, the following standards have been applied for gas-connectors:
The connector to High-Pressure $O_2$ gas is in accordance with CGA V-5:2008
Recognition Number: 1-81

[1] Parts applicable for respiratory device validation
[2] Applicable for $O_2$ monitoring

The NO gas regulator cylinder connection is in accordance with CGA V-1:2013
Recognition Number: 1-100

## J. CONCLUSIONS

The above described non-clinical 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.