AUG 1 4 2003

K023014

PULMONOX
PULMONOX MEDICAL INC.
Suite 200, 10835 – 120 Street, Edmonton, Alberta, Canada, T5H 3P9
Telephone # (780) 451-3660
Fax # (780) 452-0169

# 510(k) Summary

2003-03-03

**Contact:**
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5243-53 Ave.
Tofield, AB.
Canada T0B 4J0

Telephone: 780-451-3660
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**Device Name:** ViaNOx Delivery System™ (VDS)

**Common Names:** Nitric Oxide Delivery Apparatus, Nitric Oxide Analyzer and Nitrogen Dioxide Analyzer

**Predicate Device:** INOvent® Delivery System

**Device Description:**

The ViaNOx Delivery System controls the delivery of pharmaceutical grade $NO/N_2$ into the breathing gas stream passing down the inspiratory limb of a patient circuit. The injected flow of $NO/N_2$ is controlled to maintain a steady concentration of $NO/N_2$ within the inspiratory limb at all times, both during and between breaths. Constant concentration operation is accomplished by continuously measuring the flow in the inspiratory limb and adjusting the injected $NO/N_2$ flow rate accordingly. The measure and adjust process is very rapid, and thus provides essentially immediate tracking of changes in the inspiratory flow rate and pattern.

The device consists of a cart, a gas manifold connecting the gas supply to the device, a manual NO delivery system for use with a user supplied manual resuscitator and oxygen supply, a control panel, an NO Delivery Module and the main unit which houses the electronics and most of the software and to which all other components connect.

**Intended Use:**

> "The ViaNOx Delivery System is a nitric oxide administration device intended to add nitric oxide to gases that are to be breathed by a patient, and to be used in conjunction with a ventilator or other breathing system. The ViaNOx includes a nitric oxide, nitrogen dioxide, and oxygen monitor intended to monitor the concentration of these gases in respiratory gas mixtures during administration of nitric oxide."

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## Comparison of Technological Characteristics

| Comparison of... | INOvent delivery system for nitric oxide therapy | ViaNOx Delivery System™ |
|---|---|---|
| Intended use | a) deliver a near constant concentration of nitric oxide into a patient's breathing circuit<br>b) monitor delivered concentrations of nitric oxide and nitrogen dioxide | Same. |
| Method of operation | a) Delivery: utilizes an injection module located in the patient's breathing circuit which injects nitric oxide gas proportional to the carrier gas flow in order to provide a constant concentration of nitric oxide to the patient<br>b) Analysis: uses a side stream sampling method and electrochemical cells to analyze the gas.<br>c) Delivery and analysis independent of each other | a) Same.<br>b) Same.<br>c) Same. |
| Configuration | Available for use at the bedside (table mount or cart mount) or on transport. | Bedside, cart mounted use only. |
| Materials | All parts that may come into contact with the delivery gas are made from materials which will not adulter the NO gas. | Same. |

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| Comparison of... | INOvent delivery system for nitric oxide therapy | ViaNOx Delivery System™ |
|---|---|---|
| **Manual delivery system** | The INOvent Delivery System provides for nitric oxide delivery using a manual delivery system as outlined in their operating instructions on pages 8-1 to 8-3. The system works by connecting an oxygen source to the INOvent O2 inlet and then connecting a user supplied self-inflating bagger to the INOvent NO/O2 outlet. The "NO/O2 outlet" delivers NO from the INOvent combined with oxygen (user supplied to the "O2 inlet").<br><br>The INOvent also provides for manual resuscitation as described on pages 6-13 to 6-15 of the operating manual. In these applications, the Injector Module is used to control the NO concentration to the manual resuscitator using various configurations. | The ViaNOx Delivery System provides for manual ventilation in much the same manner except that the circuitry is external to and located on the front of the device. The INOvent has a flow meter on their device. The VDS utilizes the user supplied flow meter.<br><br>The ViaNOx Delivery System is not designed for use with manual resuscitators in this manner. |
| **Set NO range** | 0-80 ppm, set by user with delivery limitations dependent upon the total breathing gas flow. | Same. |
| **Sample gas flow** | 230 ml/minute | 200 ml/minute |
| **Net effect of sample gas removal and NO gas delivery** | Sample gas flow, in conjunction with delivery gas flow, may affect oxygen delivery, delivered tidal volumes, bias flow and/or trigger sensitivity in some ventilators. | Same. |
| **NO delivery shut down** | To prevent certain risks to the patient, the nitric oxide delivery flow is discontinued under defined conditions. The user is notified. | Same, although there is some minor differences in the defined conditions. |

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|---|---|---|
| **Measurement Accuracy** | All gas sensors:<br>+/- 3% full scale at 20° C | All values measured at 20°C and 1 atm barometric pressure<br>**NO:** +/- {0.5 ppm + 20% of the reading at NO values ≤ 20 ppm} AND +/- {0.5 ppm + 10% of the reading at NO values greater than 20 ppm}<br>**NO2:** +/- {20% of the reading OR 0.5 ppm whichever is greater}<br>**O2:** +/- 3% absolute |
| **Sensor response time** | All gas sensors:<br>Rise time of 30 seconds (10-90%) | Same. |
| **Temperature** | Operating: +10 to +40°C<br>Storage: -15 to +50°C | Same, except storage is to -20°C. |
| **Humidity** | Operating: 20-95% RH non-condensing<br>Storage: 10-95% RH non-condensing | Same. |
| **Ambient Pressure** | Operating: 600 to 800 mm Hg<br>Storage: 87 to 800 mm Hg | Operation: 585 to 765 mmHg<br>Storage and Transport: 522 to 765 mmHg |
| **Battery** | a) sealed lead acid battery<br>b) 30 minutes back up when fully charged<br>c) 10 hours to full charge | a) same, sealed lead acid battery<br>b) 30 minutes back up when fully charged<br>c) 6 hours to full charge |
| **Alarms** | High, medium and low priority alarms with adjustable volume and 120 second alarm silence. | Same with minor variations in defaults and setting ranges. |
| **Electrical Input Voltage** | 100-120/220-240 VAC at 50-60 Hz | 100-120/220-240 VAC at 50-60 Hz |

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| Comparison of... | INOvent delivery system for nitric oxide therapy | ViaNOx Delivery System™ |
|---|---|---|
| Display and user controls | One electroluminescent display for all parameters and menus. User controls the device with a control wheel and buttons. | One backlit LCD display with multiple screens for all parameters and menus. User controls the device using the touch screen buttons. |
| Calibration | Can be performed during patient NO gas administration, but inspired gases are not monitored and gas monitoring alarms are disabled. | Same. |
| Standards Met | UL 2601-1, CAN/CSA C22.2 No. 601.1 for medical electrical equipment. | Same. |

## Non-Clinical Performance Data

Non-clinical testing for the ViaNOx Delivery System was completed in accordance with the Guidance Document for Premarket Notification Submissions for Nitric Oxide Delivery Apparatus, Nitric Oxide Analyzer and Nitrogen Dioxide Analyzer released by the FDA on January 24, 2000. All testing was performed as recommended where applicable and where not applicable, or where testing deviated from the recommendations, an explanation as to how the ViaNOx Delivery System met safety and efficacy concerns was documented.

## Conclusions

Based on the non-clinical testing performance and the comparison to the predicate, the ViaNOx Delivery System is safe for use and is substantially equivalent to the predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 14 2003

Ms. Paula Tomat
QA/RA Manager
Pulmonox Medical Incorporated
Suite 200, 10835-120 Street
Edmonton, Alberta T5H 3P9
CANADA

Re: K023014
Trade/Device Name: ViaNOx Delivery System
Regulation Number: 868.5165
Regulation Name: Nitric Oxide Delivery Apparatus
Regulatory Class: II
Product Code: MRN, MRP, MRQ
Dated: June 13, 2003
Received: June 16, 2003

Dear Ms. Tomat:

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. 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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

# Indications for Use

**Applicant**
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**Device Name:** ViaNOx Delivery System™

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**PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)**

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** Over-the-Counter-Use _____
(per 21 CFR 801.109)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K023014