K033779

PULMONOX MEDICAL INC.

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Telephone # (780) 451-3660
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510(K) SUMMARY

JAN 2 6 2004

2003-12-02

Contact:
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Edmonton, AB.
Canada T5H 3P9

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

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

Predicate Device: ViaNOx 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 plumbing 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

Other than the items listed in the table below, all other technological characteristics between the original and the new, modified device remain unchanged.

Comparison of...	Modified	Original
Configuration	Single cylinder gas supply plumbing. Large or small cylinder may be utilized. Cart may be separated into two parts to release "caddy" for small cylinder use separate from large cylinder and large cylinder stand.	Dual cylinder gas supply plumbing. Large cylinder use only. Cart not configurable into separate components.
Manual delivery system	Alarm for inadequate oxygen supply.	Rely on user to ensure adequate oxygen supply.
Compatible Ventilators	Bio-Med Devices MVP 10 added to list of compatible ventilators	As per original submission

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 as applicable to this modification only. 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

JAN 2 6 2004

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

Re: K033779
Trade/Device Name: ViaNOx Delivery System, Model II
Regulation Number: 21 CFR 868.5165
Regulation Name: Nitric oxide administration apparatus
Regulatory Class: II
Product Code: MRN, MRP, MRQ
Dated: January 7, 2004
Received: January 8, 2004

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.

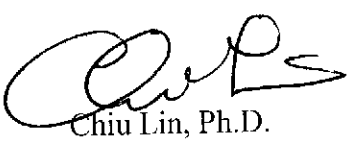
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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



Chiu Lin, Ph.D.
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

510(k) Number (if known): K033779

Device Name: ViaNOx Delivery System, Model II

Indications For 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.

Prescription Use ___√___ **AND/OR** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IFNEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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