K070867

APR 27 2007

INO Therapeutics

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| Date Prepared: | March 22, 2007 |
| Contact Person: | Richard K. Bourne, Ph.D., Vice President, Regulatory Affairs |
| Subject: | 510(k) Summary of Safety and Effectiveness Information for INOmax DS. This summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 1992 and 21CFR 807.92. |
| Proprietary Name: | INOmax DS |
| Common Name(s): | Nitric Oxide Administration Apparatus (primary)<br>Nitric Oxide Administration Apparatus, Back-up System<br>Nitric Oxide Analyzer<br>Nitrogen Dioxide Analyzer |
| Classification(s): | Class II - 21CFR868.5165, MRN (primary)<br>Class II - 21CFR868.5165, MRO<br>Class II - 21CFR868.2380, MRP<br>Class II - 21CFR868.2385, MRQ |
| Panel: | Anesthesiology |
| Predicate Device(s): | INO Therapeutics' INOmax DS (Delivery System) (primary)<br>510 (k) Number K061901<br>Datex-Ohmeda INOvent Delivery System (now GE Healthcare)<br>510(k) Number K974562 |
| Patient Population: | The targeted patient population is neonates. This is derived from the INOmax drug package labeling. |
| Clinical Setting: | The primary targeted clinical setting is the Neonatal Intensive Care Unit (NICU) and secondary targeted clinical setting is the transport of neonates. This is derived from the INOmax drug package labeling. |

Technology: The technology utilized in the INOmax DS is very similar to the Datex-Ohmeda INOvent Delivery System (now GE Healthcare), with many of the subsystems and components being unchanged.

| Specification | INOvent Delivery System | INOmax DS |
|---|---|---|
| Indications for Use | Similar to INOmax DS | Except battery backup is 6 hours and provides an integrated backup system for delivering a fixed flow of NO into a constant flow of breathing circuit gas to produce a constant concentration of NO. |
| Physical Dimensions | Height 215mm<br>Width 350mm<br>Depth 430mm<br>Weight 21Kg | Height 220mm<br>Width 350mm<br>Depth 160mm<br>Weight 5.5Kg |
| Ventilator Compatibility | Similar to INOmax DS | Except 2-60 L/min for inspiratory flow for neonatal and 4-120L/min for adult. |
| NO Delivery | Similar to INOmax DS | Except NO set resolution is 0.1/1/5 ppm depend on range, accuracy is +/-20% indicated or 2 ppm whichever greater, and NO inlet pressure is 1.7 to 2.3 Bar (25 to 33 psig). |
| NO Cylinder INOmax™ | Same as INOmax DS | Same |
| Gas Monitoring | Similar to INOmax DS | Except NO range resolution is 0 to 10ppm +/- (20% of reading +0.5ppm), calibration span is daily zero with span at pre-use test if needed, and NO accuracy is +/-20% of reading +0.5ppm. |
| Injector Module | Same as INOmax DS | Same |
| NO delivery Shut Off | Same as INOmax DS | Same |
| Calibration Gas Cylinders | NO Cal gas 40-80 ppm +/- 4%<br>$NO_2$ Cal gas 10-15 ppm +/- 10% | INOcal calibration gas, INO Therapeutics LLC<br>NO Cal gas 45 ppm +/- 4%<br>$NO_2$ Cal gas 10 ppm +/- 10% |
| Electrical Specifications | Similar to INOmax DS | Except no nurse call and battery back-up is 6 hours. |
| Environmental Specifications | Similar to INOmax DS | Except ambient operation and storage pressure are 57 to 110 kPa (430 to 825 mmHg) and |
| NO Back-up Delivery | 20 ppm @ 15 L/min. | 0.25 L/min when delivered into 10L/min provides 20 ppm, plus INOblender may also be used. |

Material(s) The materials selected were based upon INO Therapeutics' INOmax DS (Delivery System) and Datex-Ohmeda INOvent Delivery System (now GE Healthcare),

Device Description: The INOmax DS provides a constant dose of INOmax (nitric oxide) therapy gas into the inspiratory limb of the ventilator circuit. The INOmax DS uses a "dual-channel" design to ensure the safe delivery of INOmax.

The first channel has the delivery CPU, the flow controller and the injector module to ensure the accurate delivery of NO. The second channel is the monitoring system, which includes a separate monitor CPU, the gas cells (NO, $NO_2$ and $O_2$ cells) and the user interface including the display and alarms. The dual-channel approach to delivery and monitoring permits INOmax delivery independent of monitoring but also allows the monitoring system to shutdown INOmax delivery if it detects a fault in the delivery system such that the NO concentration could become greater than 100 ppm. INOmax drug is stored as a gas mixture of $NO/N_2$ in an aluminum cylinder at a nominal pressure of 2200 psig.

The cylinder is attached to a high pressure regulator which incorporates a pressure gauge that indicates cylinder pressure when the cylinder valve is open. The cylinder regulator is attached via tubing to the INOmax DS using one of the two $NO/NO_2$ quick connect inlets on the back of the machine.

The INOmax enters the back of the INOmax DS, passes through a filter, then a safety shutoff valve, which is open under normal operations.

An injector module is placed in the ventilator gas flow between the ventilator inspiratory outlet and the humidifier. Based on the ventilator flow, the INOmax cylinder concentration and set INOmax dose, the proportional solenoid delivers INOmax into the ventilator circuit via the injector module. This allows the INOmax DS to deliver a constant dose of INOmax regardless of the ventilator flow pattern or breath rate.

A flow sensor inside the INOmax DS also monitors the NO flow out of the machine. A check valve is included prior to the INOmax DS drug outlet to prevent pressure effects from the ventilator breathing circuit interfering with the NO flow sensor reading.

The INOmax DS gas monitoring system provides monitored values for inspired NO, $NO_2$, and $O_2$. The sample gas is withdrawn from the breathing circuit and goes through a water trap to remove excess water, a zero valve, a sample pump and finally a sample flow sensor to the gas monitoring cells. The zero valve allows the gas cells to be zeroed (during low calibration) without having to disconnect the sample line from the breathing circuit. The pump and sample flow sensor ensure a constant sample gas flow rate is maintained to the monitoring cells.

The gas monitoring cells are electrochemical; they are specific to each gas and provide an electronic signal, which is proportional to the concentration of the gas present.

If the delivery system does go into shut down, the INOmax DS has an integrated backup function which provides a fixed flow of INOmax (0.25L/min) into the injector module using a pneumatic on/off switch and a restrictor built into the delivery side of the system. This fixed flow of INOmax will provide 20 ppm of NO when the continuous ventilator gas flow is 10 L/min. The backup is only for short term use until a replacement delivery system can be obtained. An alarm will warn the user if the backup system is turned on while the main delivery system is in use for INOmax delivery.

Indications for Use: The INOmax DS 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 DS provides continuous integrated monitoring of inspired $O_2$, $NO_2$, and NO, and a comprehensive alarm system.

The INOmax DS incorporates a battery that provides up to 6 hours of uninterrupted NO delivery in the absence of an external power source.

The INOmax DS 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.

Testing: The testing indicated the INOmax DS met its design input specifications, design output specifications and risk analysis requirements. Testing completed included:

1. Validation of ventilators

Standard(s): The INOmax DS was designed to comply with the applicable portions of the following product standards

1. FDA Guidance Document for Premarket Notification Submissions for Nitric Oxide Delivery Apparatus, Nitric Oxide Analyzer and Nitrogen Dioxide Analyzer (Special Controls).
2. IEC 60601-1, plus amendments: Medical Electrical Equipment

3. IEC 60601-1-2: EMC/EMI
4. IEC 60601-1-4: Programmable Systems
5. IEC 60601-1-8: Alarms
6. CGA V-1: Medical Cylinder Connections
7. ASTM F-1462-93: Oxygen Analyzers
8. ASTM F-1054-87: Conical Fittings

The ventilators that are the subject of this application are marketed devices cleared through the 510(k) Premarket Notification Process.

Conclusions:

The INOmax DS device described in this Notice has the same intended use and indications, technological characteristics, and principles of operation and software applications as the previously cleared predicate device (INOmax DS:K061901). The only difference is that newly validated ventilators have been qualified with the INOmax DS. This difference does not present any new issues of safety or effectiveness. This device is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 27 2007

Richard K. Bourne, Ph.D.
Vice President, Regulatory Affairs
INO Therapeutics LLC
6 Route 173
Clinton, New Jersey 08809

Re: K070867
Trade/Device Name: INOmax DS (Delivery System)
Regulation Number: 21 CFR 868.5165
Regulation Name: Nitric Oxide Administration Apparatus
Regulatory Class: II
Product Code: MRN, MRO, MRP and MRQ
Dated: March 28, 2007
Received: March 29, 2007

Dear Dr. Bourne:

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 (240) 276-0120. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.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): K070867

Device Name: INOmax DS (Delivery System)

Indications for Use:

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Prescription Use ___X__ (Part 21 CFR 801 Subpart D) and/or Over-the-Counter-Use _____ (Part 21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number: K070867