MAR 10 2010

**510(k) Summary**

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date: 14 August 2009

Submitter: INO Therapeutics
2902 Dairy Drive
Madison, Wisconsin 53718

Primary Contact Person: Larry Lepley
Associate Director, Regulatory Affairs
608-226-3415

Secondary Contact Person: David Trueblood
Director, Regulatory Affairs
908-608-3910

Device: Trade Name: INOmax DS (Delivery System)

Common/Usual Name: Nitric Oxide Administration Apparatus (primary)
Nitric Oxide Administration Apparatus, Back-up System
Nitric Oxide Analyzer
Nitrogen Dioxide Analyzer

Classification Names: Class II – 21CFR868.5165, MRN (primary)
Class II – 21CFR868.5165, MRO

Product Code: Class II – 21CFR868.2380, MRP
Class II – 21CFR868.2385, MRQ

Predicate Device(s): K061901; INOmax DS (Delivery System)

Device Description:

The INO Therapeutics INOmax DS represents the continuing evolution of the Datex-Ohmeda (now GE Healthcare) INOvent Delivery System design. Its published performance specifications are not significantly different from the INOvent. The INOmax DS design incorporates a reconfiguration of hardware, electronic circuitry and software resulting in a more compact, stylish, modern, user-friendly and easier manufactured product.

Intended Use: The INOmax DS delivery system delivers INOmax® (nitric oxide of 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.

Technology: The INOmax DS (Delivery System) employs the same functional scientific technology as its predicate devices.

Determination of Substantial Equivalence: Summary of Non-Clinical Tests:

The INOmax DS (Delivery System) and its applications comply with voluntary standards as detailed in Section 17-20 of this premarket submission. The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Testing on unit level (Module verification)
- Integration testing (System verification)
- Final acceptance testing (Validation)
- Performance testing (Verification)
- Safety testing (Verification)

Summary of Clinical Tests:

The subject of this premarket submission, INOmax DS (Delivery System), did not require clinical studies to support substantial equivalence.

Conclusion: INO Therapeutics considers the INOmax DS (Delivery System) to be as safe, as effective, and performance is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAR 10 2010

Mr. Larry Lepley
Associate Director, Regulatory Affairs
INO Therapeutics
2902 Dairy Drive
Madison, Wisconsin 53718

Re: K092545
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, MRQ
Dated: February 5, 2010
Received: February 12, 2010

Dear Mr. Lepley:

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 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); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/Centers_Offices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):

Device Name: INOmax DS (Delivery System)

Indications for Use:

The INOmax DS delivery system delivers INOmax® (nitric oxide of 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.

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Prescription Use_X___ AND/OR Over-The-Counter Use_ _
(Part 21 CFR 801 Subpart D) (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)

L Schultz

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

510(k) Number: K092547