510(k) Summary

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

Date: December 18, 2009

Submitter: INO Therapeutics/Ikaria
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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: Apparatus, Nitric Oxide Delivery, or Apparatus, Nitric Oxide Backup Delivery, Class II – 21 CFR 868.5165

Product Code: MRN (primary), MRQ, MRP, MRQ

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

Device Description: The INOmax DS2 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.

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: All revisions of INOmax DS utilize component technology to deliver Nitric Oxide gas to the patient. The components consist of the Delivery System unit, the blender, a stand/cart and the NO gas tanks. In this revision the INOmax DS technological characteristic of design has changed with the inclusion of patient data storage and additional operation alarms. This modification of design does not affect the intent of INOmax DS in the delivery of NO gas for the target population of neonatal patients. The patient data storage was included for patient administration and the additional alarms were added to aid in the safe administration of the NO gas.

The fundamental scientific technology remains the same in the concept of the INOmax DS. The proposed INOmax DS includes ergonomic changes related to two specific areas of use;

- data collection for the collection of patient parameters/device usage
- additional notifications/alerts (visual and audible) to alert the user of operational events.

These additional functions required the INOmax DS to be modified to accommodate the additional components for data

transfer utilizing Infrared communication and the change in the Graphic User Interface (GUI) for visual notifications.

Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:

The INOmax DS and its applications comply with voluntary standards as detailed in Section 9 and 17 of this premarket submission.

The hardware changes made to the INOmax DS, to implement the INOmax DS infrared features consisted of adding additional hardware to provide infrared communications to an INOmeter mounted on the INOmax DS gas cylinders. The new hardware did not change the original hardware which controlled all the original INOmax DS functions. The additional electrical connections to the original hardware were connections to the common power source and a serial data link connected to the battery and the monitoring processor. Thus, no extensive retesting of the original INOmax DS was deemed necessary.

The SVRS testing, the summary of which is described in appendix J of this submission, thoroughly tested all requirements of the software, including the NO delivery and gas monitoring performance. The successful completion of these tests demonstrated that the INOmax DS (Version 2) met the performance requirements of the original product and the new requirements of the revised device.

The INOmax DS revision complies to "Guidance Document for Premarket Notification Submissions for Nitric Oxide Delivery Apparatus, Nitric Oxide Analyzer and Nitrogen Dioxide Analyzer" (January 24, 2000) FDA-1157

The results of testing verified that the additional communication of patient data through Infrared transmission and additional alarms did not alter the safety or effectiveness of the INOmax DS operation.

Summary of Clinical Tests:

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

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

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

APR 15 2010

Mr. Larry Lepley
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United States

Re: K093922
Trade/Device Name: INOmax DS
Regulation Number: 21 CFR 868.5165
Regulation Name: Nitric Oxide Administration Apparatus
Regulatory Class: II
Product Code: MRN, MRO, MRP, MRQ
Dated: March 15, 2010
Received: March 16, 2010

Dear Mr. Larry 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. 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); 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/CentersOffices/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/MedicalDevices/Safety/ReportaProblem/default.htm 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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
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Enclosure

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