K131685

5. 510(K) SUMMARY

510(k) Summary

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

Submitter Information

Date:	July 8, 2013
Company:	INO Therapeutics doing business as Ikaria 2902 Dairy Drive Madison, Wisconsin 53718
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NOV 29 2013

Identification of the Device

Device Trade Name:	INOmax $DS_{IR}^{®}$ (Delivery System)
Common Name:	Nitric Oxide Administration Apparatus (primary) Nitric Oxide Administration Apparatus, Back-up System Nitric Oxide Analyzer Nitrogen Dioxide Analyzer
Classification Name:	Apparatus, Nitric Oxide Delivery, or Apparatus, Nitric Oxide Backup Delivery
Device Classification:	Class II – 21 CFR 868.5165
Product Code:	MRN (Primary), MRO, MRP, MRQ

Predicate Device(s) K061901, K070867, K071516, K080484, K081691, K090958, K092545, K093922, K110344, K110635, K113272, K121021, K130605

Description of Device The INOmax $DS_{IR}^{®}$ 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. The delivery system can also shut down delivery if it detects certain serious problems with the monitoring system.

Intended 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.

Technology

All revisions of INOmax DS_{IR}® 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 of the INOmax DS_{IR}®, the software and labeling have been updated.

Determination of Substantial Equivalence

The INOmax $DS_{IR}^{®}$ modifications included an update of the software to version 3.0 and modified labeling to identify compatibility with two additional respiratory care devices. The INOmax $DS_{IR}^{®}$ with software version 3.0 and additional respiratory care devices has the same intended use and uses the same device hardware as the cleared INOmax $DS_{IR}^{®}$ predicate device. All features are identical except those described in the table below.

Comparison to Predicate Device

Feature / Specification	**INOmax $DS_{IR}^{®}$ - K130605**	**INOmax $DS_{IR}^{®}$ with software version 3.0 and additional respiratory care devices**
Low-range Gas Sensor Calibration	This calibration is initiated manually by the user by pressing the "Low Cal" button on the calibration screen.	This calibration can still be initiated manually but the calibration is initiated automatically when the device is turned on and is initiated automatically every 12 hours while in continuous operation at a constant dose.
Purge During Pre-Use Checkout	The purge step is accomplished by instructing the user to set a NO dose of 40 ppm using the control wheel on the device.	After the first step of the Pre-Use Checkout, the user presses the "Next" button on the Pre-Use Checkout wizard screen and this automatically initiates the purge step.
Other User Convenience Features	The steps required for pre-use checkout, gas cell calibration, use of backup NO delivery mode and troubleshooting of alarms are all described in the device labeling.	In addition to the instructions in the device labeling, wizards are available on the user interface to guide the user through the required steps for these functions.
Alarms/Alerts	Delivery Failure for NO > 100 ppm	This alarm has been modified so that the device will stop NO delivery if the NO concentration exceeds 100 ppm for 12 seconds but will automatically resume NO delivery if the NO concentration drops back below 100 ppm for 12 seconds. Previously this condition caused a device shutdown and required the user to restart the device to resume delivery.
	Delivery Failure	One system voltage condition during which this alarm was triggered has been eliminated.
	Not Applicable	A new alarm was added for a failure during the newly added automatic low-range calibration and is indicated as "Low Calibration Failed". This alarm was added because the automatic low-range calibration can occur while the device is not attended by the user, so it is important to notify the user if this calibration is not successful.

Feature / Specification	INOmax $DS_{IR}^{®}$ - K130605	INOmax $DS_{IR}^{®}$ with software version 3.0 and additional respiratory care devices
Labeling for compatibility with respiratory care devices	A variety of transport, neonatal, adult/ped, high frequency and anesthesia ventilators, nasal CPAP and nasal high flow cannulas.	Additional respiratory care devices include: Hamilton C1 Ventilator (K120574) Hamilton T1 Ventilator (K120670)

Summary of Nonclinical Tests

The following quality assurance measures were applied to the modification of the system:

- Risk analysis
- Formative usability study
- Requirements reviews
- Design reviews
- Testing on unit level (module verification)
- Integration testing (system verification)
- Performance testing (verification)
- Safety testing (verification)

Support for the substantial equivalence of the INOmax DSIR® was provided as a result of risk management and testing which included electrical safety, performance and software tests. This testing includes conformity to the FDA recognized consensus standards and voluntary standards as follows:

- IEC 60601-1:2005: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2007 General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests
- IEC 60601-1-8:2006 General requirements for basic safety and essential performance – Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems.

A formative usability study was conducted per ANSI/AAMI HE75 Human Factors Engineering, Design of Medical Devices, to aid in the development of requirements and software verification confirmed the INOmax $DS_{IR}^{®}$ is compliant with its system level requirements and that the new/modified user convenience features and alarms function as specified.

To confirm compatibility with the new respiratory care devices, both devices were set up and calibrated according to the manufacturer's recommendations and tested using the settings established for each respiratory care device test. The INOmax $DS_{IR}^{®}$ was set up and calibrated according to the manufacturer's recommendations.

Five INOmax $DS_{IR}^{®}$ settings were used [0 (baseline), 1, 5, 20, 40, and 80 ppm] for each setting and mode of ventilation, as well as the Backup mode.

The measured values on the INOmax $DS_{IR}^{®}$ were also recorded along with any anomalies found.

The testing concluded four requirements necessary for the operation of the INOmax $DS_{IR}^{®}$ and the two respiratory care devices to be compatible:

- O2 dilution
- Effect on delivered pressures
- INOmax $DS_{IR}^{®}$ delivery accuracy
- NO_2 generation

Testing Conclusion:
The INOmax $DS_{IR}^{®}$ performed within published specifications when used with each of the ventilators in both primary and backup delivery.

Summary of Clinical Tests

The subject of this premarket submission, INOmax $DS_{IR}^{®}$, with updated software and interfaced to each of the selected respiratory care devices, did not require clinical studies to support substantial equivalence.

Conclusion

INO Therapeutics/Ikaria considers the INOmax $DS_{IR}^{®}$ to be as safe and as effective as the predicate device, with performance substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

November 29, 2013

Mr. Robert Bovy
Associate Director, Regulatory Affairs
INO Therapeutics
2902 Dairy Drive
MADISON WI 53718

Re: K131686
Trade/Device Name: INOmax $DS_{IR}^{®}$ (Delivery System)
Regulation Number: 21 CFR 868.5165
Regulation Name: Nitric Oxide Administration Apparatus
Regulatory Class: II
Product Code: MRN, MRQ, MRP
Dated: October 28, 2013
Received: October 30, 2013

Dear Mr. Bovy:

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 contact 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. 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,

Kwame O. Ulmer -S for

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K131686

4. INDICATIONS FOR USE STATEMENT

Indications for Use

510(k) Number (if known):
Device Name: INOmax® DS
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.

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Prescription Use_X_ And/Or Over the Counter Use_____
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nayan J. Patel -S
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