April 20, 2023

Mallinckrodt Manufacturing LLC
% David Trueblood
Senior Director, Regulatory Affairs, Devices
6603 Femrite Drive
Madison, Wisconsin 53718

Re: K211153
Trade/Device Name: INOmax DS_{IR}® Plus
Regulation Number: 21 CFR 868.5165
Regulation Name: Nitric Oxide Administration Apparatus
Regulatory Class: Class II
Product Code: MRN, MRQ, MRP
Dated: February 16, 2023
Received: February 21, 2023

Dear Jamie Yieh:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ting Song -S

for
James J. Lee, PhD
Director
DHT1C: Division of Sleep Disordered Breathing,
Respiratory and Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211153

Device Name
INOmax® DSIR Plus

Indications for Use *(Describe)*
The INOmax® DSIR Plus 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 ventilators and respiratory care devices that the INOmax DSIR Plus has been validated with.

The INOmax® DSIR Plus provides continuous integrated monitoring of inspired O2, NO2, and NO, and a comprehensive alarm system.

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

The INOmax® DSIR Plus 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 INOmax® DSIR Plus must only be used in accordance with the indications, contraindications, warnings and precautions described in the nitric oxide drug packaging inserts and labeling and is indicated for use in term and near-term (>34weeks gestation) neonates with hypoxic respiratory failure associated with clinical or echocardiographic evidence of pulmonary hypertension. INOmax DSIR Plus is indicated for a maximum of 14 days of use. The primary targeted clinical setting is the Neonatal Intensive Care Unit (NICU) and secondary targeted clinical setting is the transport of neonates.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

5. 510(K) SUMMARY

510(k) Summary

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

Submitter Information

Date:	March 30, 2023
Company:	Mallinckrodt Manufacturing, LLC 6603 Femrite Drive Madison, Wisconsin 53718
Contact Person:	David M. Trueblood Senior Director, Regulatory Affairs, Devices
Email:	David.trueblood@sbiopharma.com
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FAX:	908.238.6402
Secondary Contact Person:	Erica Mullaney
Email:	Erica.mullaney@sbiopharma.com
Telephone:	353 87 1193048

Identification of the Device

Device Trade Name:	INOmax DS_{IR}® Plus (Delivery System)
Common Name:	Nitric Oxide Administration Apparatus (primary) 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), MRQ, MRP

Predicate Device(s) K200389

Description of Device The INOmax DS_{IR}® Plus 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® DSIR Plus 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 ventilators and respiratory care devices that the INOmax DSIR Plus has been validated with.

The INOmax® DSIR Plus provides continuous integrated monitoring of inspired O_2, NO_2, and NO, and a comprehensive alarm system.

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

The INOmax® DSIR Plus 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 INOmax® DSIR Plus must only be used in accordance with the indications, contraindications, warnings and precautions described in the nitric oxide drug packaging inserts and labeling and is indicated for use in term and near-term (>34weeks gestation) neonates with hypoxic respiratory failure associated with clinical or echocardiographic evidence of pulmonary hypertension. INOmax DSIR Plus is indicated for a maximum of 14 days of use. 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}® Plus 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}® Plus, the significant changes to the device include the labeling and main circuit board.

Determination of Substantial Equivalence

The modified INOmax DS_{IR}® Plus has the same intended use as the previously cleared INOmax DS_{IR}®. All features are identical except those described in the table below.

Comparison to Predicate Device

Feature / Specification	**INOmax DS_{IR}® Plus-K131686**	**INOmax DS_{IR}® Plus Device Modification**
DSIR Head	DSIR Head	Modified DSIR head with RoHS compliant electrical components, revised mounting method for pneumatic pressure switch, supplier change to LCD component in touchscreen display, revised shroud around display for improved ferrite fit, monitoring board changes to eliminate potential ADC override, and changed to an equivalent indium tin oxide glass display
Injector Module	Injector Module	Modified injector module with updated exterior color and design and RoHS compliant electrical components
Power Supply	Power Supply	Modified power supply due to obsolescence and added protection components
Disk Filter	Patient Sample Gas Line Disk Filter, 0.5 mircon	2-stage filter (coalescing media is glass fiber 1.0 micron and hydrophobic media is PTFE 0.2 micron)
Software	Software	Modified brand name to Mallinckrodt, added transmission of timestamp when cylinder is open to INOmeter, minor modifications to troubleshooting help, and minor sustaining changes to resolve anomalies
Main circuit board	Main circuit board	The INOmax DSIR main board has been redesigned due to the obsolescence of the sound and Ethernet chips. This includes inclusion of new components, board layout updates and an update in software drivers to support the new chips.
Sustaining Changes	N/A	Part obsolescence and minor sustaining changes to improve reliability and manufacturability.

Summary of Nonclinical Tests

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

- Risk Analysis
- Requirements Review

- Design Reviews
- Testing on unit level (module verification)
- Integration testing (system verification)
- Performance testing (verification)
- Safety testing (verification)
- Biocompatibility testing of new materials in accordance with the FDA recognized standards in the ISO 18562 and ISO 10993 series.

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

- IEC 60601-1:2005 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2014 General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests

Summary of Clinical Tests

The subject of this premarket submission, INOmax DS_{IR}® Plus, did not require clinical studies to support substantial equivalence.

Conclusion

Mallinckrodt Manufacturing, LLC considers the INOmax DS_{IR}® Plus to be as safe and as effective as the predicate device, with performance substantially equivalent to the predicate device.