June 17, 2020

Mallinckrodt Manufacturing LLC
% Jamie Yieh
Director, Global Regulatory Affairs
Mallinckrodt Hospital Products Inc.
1425 U.S. Route 206
Bedminster, New Jersey 07921

Re: K200389
Trade/Device Name: INOmax DSIR Plus
Regulation Number: 21 CFR 868.5165
Regulation Name: Nitric Oxide Administration Apparatus
Regulatory Class: Class II
Product Code: MRN, MRQ, MRP
Dated: May 15, 2020
Received: May 18, 2020

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,

Todd Courtney
Assistant Director
DHT1C: Division of ENT, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200389

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 most ventilators.

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 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.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) SUMMARY

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

Submitter Information

Date:	February 14, 2020
Company:	Mallinckrodt Manufacturing, LLC 6603 Femrite Drive Madison, Wisconsin 53718
Contact Person:	Jamie Yieh Director, Regulatory Affairs, Devices
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Secondary Contact Person:	David Trueblood
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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) K131686

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 most ventilators.

The INOmax® DSIS 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 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}® 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 **only** changes to the device include**s** the labeling for compatibility with respiratory care device.

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$_{IR}$® - K131686	INOmax DS$_{IR}$® Plus with additional ventilator and breathing devices
Labeling for compatibility with ventilator devices	A variety of transport, neonatal, adult/ped, high frequency and anesthesia ventilators, nasal CPAP and nasal high flow cannulas.	Additional ventilator devices include: • Covidien PB 980 (K131252) • GE Healthcare Carescape R860 (K142679) • Fisher & Paykel Healthcare RT330 Breathing Circuit and Optiflow Jr (Class I, 510(k) Exempt under 21 CFR 868.5340)) • Bunnell Inc Life Pulse 204 (P850064) • Drager Perseus A500 (K133886) • Fisher & Paykel Healthcare Airvo 2 (K131895) • Drager Carina (K072885) • Maquet Servo u/n (K151814) • Hamilton C3 (K161450) • IMT Medical Bellavista (K163127) • Maquet Flow-i (K160665) • Bio-Med TV-100 (K173973) • Phillips V60 (K102985)

Summary of Nonclinical Tests

In the most recent predicate 510(k) [K131686], the Ventilator/Gas Delivery System Validation Test Protocol was accepted and the outcomes were used as justification on clearance of the submission and modification in labelling for compatibility with respiratory care device.

Specifically in K131686 clearance, the labelling of the INOmax DSIR was being updated to add the following compatible respiratory care devices:

- Hamilton C1 Ventilator (K120574)
- Hamilton T1 Ventilator (K120670)

The Ventilator/Gas Delivery System Validation Test Protocol was used to validated the hazards were mitigated. Since the 510(k) clearance, the protocol has had insignificant differences between validation protocol versions. Ultimately, the requirements necessary for the operation of the INOmax DSIR passed.

Mallinckrodt now has combined the data into a Summary of Bench Testing. This Bench Testing was conducted across all platforms to demonstrate that the INOmax DSIR® Plus performs within

published specifications. The Hazards identified were from Risk Input that were thru Ventilator Validation based on a protocol which again was recently cleared thru K131686.

Summary of Clinical Tests

The subject of this premarket submission, INOmax DS_{IR}® Plus with updated labeling to interface with additional ventilator and breathing devices, 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.