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K120216

MAY 16 2012

GeNO LLC
2941 Oxbow Circle
Cocoa, FL 32936

T - (321) 785-2601
F - (321) 785-2460

Official Contact: Alex Chaharom
Director of Quality Assurance

Proprietary or Trade Name: GeNOsyl™ MV-1000

Classification / CFR / Classification Name:

Product Code	CFR	Classification name
MRN	868.5165	Nitric oxide administration apparatus, primary delivery system
MRO	868.6165	Nitric oxide administration apparatus, backup delivery system
MRP	868.2380	Nitric oxide gas analyzer
MRQ	868.2385	Nitrogen dioxide gas analyzer

Class: All are Class 2

Predicate Devices: Ikaria INOmax DS – K061901

Device Description:
GeNOsyl MV-1000 Delivery System includes four components:

1. Nitric oxide administration apparatus, primary delivery system
2. Nitric oxide gas analyzer
3. Nitrogen dioxide gas analyzer
4. Nitric oxide administration apparatus, backup delivery system

The nitric oxide administration apparatus adds nitric oxide to gases that are to be inhaled by the patient. The nitric oxide administration apparatus is to be used in conjunction with a ventilator or other breathing gas administration system. The concentration of nitric oxide is maintained approximately constant during the inspiratory flow regardless of the variation in flow rate within the inspiratory portion of the respiratory cycle. The concentration of inspired nitric oxide will or must be set by the user, typically in the range of 0 to 80 parts per million (ppm).

The administration apparatus includes a pressure regulator and connectors with fittings which are specific for nitric oxide gas cylinders, containing 800 ppm nitric oxide in nitrogen. The nitric oxide delivery apparatus shall minimize the time that nitric oxide is mixed with oxygen and thus minimize the concentration of nitrogen dioxide in the gas inhaled by the patient. In the presence of O_2, some conversion of nitric oxide to nitrogen dioxide will occur. The GeNOsyl™ administration apparatus includes a cartridge which will serve a dual purpose: a mixing chamber and to convert any transient nitrogen dioxide to nitric oxide prior to inhalation by the patient.

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The administration device includes two nitric oxide gas concentration analyzers, a nitrogen dioxide gas analyzer, and an oxygen analyzer with a programmable alarm system. Gas analyzers shall be identified in the labeling for the nitric oxide gas administration device. The administration device also includes an instantaneous backup circuit that delivers a fixed flow of NO and can be activated by the user in case of device failure.

Nitric oxide and nitrogen dioxide gas analyzers are devices intended to measure the concentration of nitric oxide and nitrogen dioxide in respiratory gas mixtures during administration of nitric oxide. The gas should be sampled from the inspiratory limb of the patient circuit. The nitric oxide gas analyzer includes provisions for setting upper and lower measured nitric oxide concentrations at which an alarm will be activated. The nitrogen dioxide gas analyzer includes provisions for setting upper measured nitrogen dioxide concentrations at which an alarm will be activated and a shutdown condition will stop the NO injection.

The delivery system shall include a nitric oxide administration apparatus for use as a "backup" system for administration of nitric oxide when the main administration apparatus cannot be used.

Principle of Operation

The MV-1000 injects a constant volume of nitric oxide into the inspiratory limb of the ventilator circuit to deliver a constant concentration of nitric oxide to the patient.

The NO gas is introduced by means of a mass flow controller into the inspiratory limb of the ventilator, on the dry side of the breathing circuit.

The MV-1000 delivery system is designed to deliver nitric oxide independently from the monitoring activities. This allows the monitoring system to shutdown nitric oxide delivery if a fault is detected in the system.

The MV-1000 delivery system requires a source of pharmaceutical grade nitric oxide gas at a concentration of 800 ppm in nitrogen.

The nitric oxide enters the back of the MV-1000 delivery system and a volume of gas is injected into the inspiratory limb, on the dry side of the breathing circuit, to achieve the concentration that is set by the user. Prior to reaching the patient, the gas passes through the GeNO Cartridge, which serves two (2) functions: 1) as mixing chambers and 2) to convert any NO_2 which may have been formed in the breathing circuit back to NO to deliver a constant dose of NO to the patient.

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Indications for Use:
The GeNOsyl™ MV-1000 delivers nitric oxide (NO) 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.

It is indicated to be used with the Bio-Med Devices CV-2+ ventilator.

It provides continuous integrated monitoring of inspired O_2, NO_2, and NO, and a comprehensive alarm system.

It incorporates a battery that provides up to 1 hour of uninterrupted NO delivery in the absence of an external power source.

It 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 patient's breathing circuit.

Patient Population:
The target patient population is controlled by the drug labeling for FDA approved NO and is currently neonates.

Environment of Use:
The GeNOsyl™ MV-1000 is intended to be used in Hospital, e.g., NICU and Intra-hospital transport settings.

Comparison to Predicates

Features	GeNOsyl™ MV-1000
Indications for use	The GeNOsyl™ MV-1000 delivers nitric oxide (NO) 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. Delivers NO at a constant flow. It is indicated to be used with the Bio-Med Devices CV-2+ ventilator. It provides continuous integrated monitoring of inspired O_2, NO_2, and NO, and a comprehensive alarm system. It incorporates a battery that provides up to 1 hour of uninterrupted NO delivery in the absence of an external power source. It 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 patient's breathing circuit.

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Features	GeNOsyl™ MV-1000
Environment of Use	Hospital, e.g., NICU Intra-hospital transport
Patient Population	The target patient population is controlled by the drug labeling for FDA approved NO and is currently neonates.
Principle of Operation	Utilizes a source of NO gas which is injected into the patient breathing circuit as part of a ventilator circuit. Continuous in-line monitoring is performed to measure concentrations of O_2, NO_2, NO In-line gas sampling is performed near the patient to measure NO_2 A cartridge is placed in the inspiratory limb of the patient breathing circuit to act as a gas mixture / blender and to convert any NO_2 to NO prior to gas delivery to the patient. This is considered an added safety feature which the predicate does not have.
System Design	Includes analyzers for: O_2 NO – 2 sensors provided NO, Back-up system
Compliance with Standards	Guidance Document for Premarket Notification Submissions for Nitric Oxide Delivery Apparatus, Nitric Oxide Analyzer and Nitrogen Dioxide Analyzer
Injector Module	Delivers a constant flow which in combination with the in-line cartridge provides a constant and fixed level of NO. Outlet connector 15 mm / 22 mm
Injection Flow	Constant
Method used to mix NO gas and ventilator air	In-line cartridge design facilitates mixing / blending of NO and ventilator gases for a more consistent and constant NO / air mixture. The cartridge element is made of ascorbic acid which converts any NO2 to NO and thus reduces the potential of any transient NO2 being delivered to the patient
NO Delivery shutoff	Yes
Calibration Gas	NO Cal Gas 45 ppm ± 4% NO_2 Cal Gas 10 ppm ± 10%
Battery Back-up	Up to 1 hour

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Features	GeNOsyl™ MV-1000
Alarms	NO Low alarm NO High alarm NO_2 high alarm O_2 low alarm O_2 high alarm Low battery alarm Low gas pressure alarm High gas pressure alarm NO Gas Leak Sampling gas occlusion include full water trap Sampling gas line disconnected (while dosing) Bad NO sensor or calibration required Injector Module Failure Flow Sensor Cable may be disconnected NO Internal high pressure NO Internal low pressure Patient gas exceeded Hardware failure
Method of sampling	Side stream gas sampling of ~ 230 ml/min which is analyzed and then exhausted to room air
NO delivery (set)	0 - 80 ppm (800 ppm cylinder)
NO Resolution (set)	0.1 / 1 / 2 ppm depending upon NO range
Accuracy	± 20% or 2 ppm whichever is greater @ 21°C
NO inlet pressure	0.17 Bar to 0.66 Bar (2.5 to 9.5 psi)
Maximum NO supply pressure	0.66 Bar (9.5 psi)
Minimum NO supply pressure	0.17 Bar (2.5 psi)
Range of NO Injection Flow	0 – 1 LPM
Injection Flow	Constant
Maximum Circuit Pressure	N/A
Maximum NO concentration / Ventilator Mean Flow rate	Ventilator Mean Flow rate — Maximum NO Delivered < 9 LPM — 80 ppm ± 20% 9 – 10 LPM — 75 ppm ± 20% > 10 < 15 LPM — 55 ppm ± 20% > 15 < 20 LPM — 35 ppm ± 20%
Maximum NO_2 which can be delivered to the patient	< 3 ppm typically < 0.5 ppm

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Features	GeNOsyl™ MV-1000	
Physical Dimensions	Max Weight	15.9 kg (35 lbs)
	Max Width / Depth	14 inches W x 20 inches D
	Max Height	9 inches
Ventilator Compatibility	Inspiratory Flow rate	2 – 120 LPM
	Respiratory rate	6 – 80 BPM
	Airway Peak pressure	0 – 70 cm H_2O
	PEEP	0 – 20 cm H_2O
	Bio-Med Devices CrossVent 2 – K942938	
Operating Conditions	Temperature	5 to 40°C
	Humidity	15 to 95% RH
	Ambient Pressure	68 to 106 kPa
Storage Conditions	Temperature	-20 to 60°C
	Humidity	15 to 95% RH
	Ambient Pressure	57 to 110 kPA
Electrical	Line Voltage:	110V-125V
	Input Power	110 VA
	Input Fuse:	3 A
	Classification	Class 1, Type B

Classification Name	**Nitric oxide analyzer**
NO Range	0 - 10 ppm
NO Resolution	0.1 ppm
Accuracy	± (20% of reading + 0.5) ppm
NO Range	10 - 100 ppm
NO Resolution	0.1 ppm
Accuracy	± (10% of reading + 0.5) ppm

Classification Name	**Nitrogen dioxide analyzer**
NO_2 Range	0 - 10 ppm
NO_2 Resolution	0.1 ppm
Accuracy	± (20% of reading + 0.5) ppm

Classification Name	**Nitric oxide administration apparatus, Back-up system**
Flow rate	Fixed flow – 250 mL/min
Separate system from main delivery	Yes uses a manual resuscitation bag for ventilator support
Monitoring	Monitoring of NO, NO_2, O_2 can continue even in the back-up mode

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Performance Testing:
Testing included:

- NO delivery apparatus
- NO analyzer
- NO_2 analyzer
- Electrical safety
- Electromagnetic compatibility (EMC)
- Performance
- Environmental
- Mechanical safety
- Biocompatibility
- Ventilator Compatibility
- Endurance

Standards and FDA Guidance:
The GeNOsyl™ MV-1000 was designed to comply with the applicable portions of the following Guidance and Standards.

- Guidance Document for Premarket Notification Submissions for Nitric Oxide Delivery Apparatus, Nitric Oxide Analyzer and Nitrogen Dioxide Analyzer, January 24, 2000
- IEC 60601-1: 2005 Medical Electrical Equipment – General Requirements for Basic Safety and Essential Performance
- IEC 60601-1-1: 2000 Medical Electrical Equipment – General Requirements for Safety – Collateral Standard: Safety requirements for medical electrical systems
- IEC 60601-1-2: 2001 Medical Electrical Equipment – General Requirements for Safety - Collateral Standard: Electro-magnetic Compatibility- Requirements and Tests (Includes AMENDMENT 1, ANSI/AAMI/IEX 60601-1-2:2001/a1:2004)Amendment 1: 2004
- IEC 60601-1-8: 2006 Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
- ISO 21647:2004 Medical electrical equipment - Particular requirements for the basic safety and essential performance of respiratory gas monitors
- IEC 62304: 2006 Medical Device Software – Software Lifecycle Processes
- EN ISO 10993-1:2003 Biological evaluation of medical devices - Part 1: Evaluation and testing (ISO 10993-1:2003)
- ISO 5356-1:2004 Anaesthetic and respiratory equipment - Conical connectors: Part 1: Cones and sockets.

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Substantial Equivalence
The GeNOsyl™ MV-1000 is viewed as substantially equivalent to the predicate device because:

Indications –
The proposed indications for use are identical to the predicate, INOmax DS (K061901).

Environment of Use –
The proposed environments of use are identical to the predicate, INOmax DS (K061901) except we are not seeking clearance for use in inter-hospital transport conditions.

Patient Population –
The proposed patient population is identical to the predicate, INOmax DS (K061901).

Technology / Design / Features –
The technology of the GeNOsyl™ NO_2 analyzer is similar to the predicate, INOmax DS (K061901).

Materials –
The materials have been tested per ISO 10993 and are similar to the predicate, INOmax DS (K061901).

Performance Specifications –
The proposed device's performance and specifications are equivalent to the predicate.

Conclusion:
The GeNO LLC GeNOsyl™ MV-1000 has been demonstrated to be substantially equivalent for safety and effectiveness for its indicated use as compared to the predicate.

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

Mr. Paul Dryden
Regulatory Consultant
GeNO LLC
2941 Oxbow Circle
Cocoa, Florida 32926

MAY 16 2012

Re: K120216
Trade/Device Name: GeNOsyl™ MV - 1000
Regulation Number: 21 CFR 868.5165
Regulation Name: Nitric Oxide Administration Apparatus
Regulatory Class: II
Product Code: MRN
Dated: May 8, 2012
Received: May 10, 2012

Dear Mr. Dryden:

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.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K120216 (To be assigned)

Device Name: **GeNOsyl™ MV-1000**

Indications for Use:

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Prescription Use XX (Part 21 CFR 801 Subpart D) **or** **Over-the-counter use __** (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

L Schutter

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

510(k) Number: K120216