March 10, 2020

International Biomedical
Amy Pieper
Director of Regulatory Affairs
8206 Cross Park Drive
Austin, Texas 78754

Re: K193481
Trade/Device Name: AeroNOx 2.0 Nitric Oxide Titration & Monitoring System
Regulation Number: 21 CFR 868.5165
Regulation Name: Nitric Oxide Administration Apparatus
Regulatory Class: Class II
Product Code: MRN
Dated: February 7, 2020
Received: February 10, 2020

Dear Amy Pieper:

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)*
K193481

Device Name
AeroNOx 2.0 Nitric Oxide Titration & Monitoring System

Indications for Use *(Describe)*
The AeroNOx 2.0 is intended to provide a constant controlled concentration of nitric oxide in breathing gas by delivering a constant controlled flow of nitric oxide into the inspiratory limb of a mechanical ventilator that operates using a continuous constant flow of fresh gas into the inspiratory limb of the ventilator. The AeroNOx 2.0 is also intended to be used with a flow inflating manual ventilator (an AeroNOx 2.0 accessory), by introducing controlled flows of nitric oxide into the fresh gas flow to the manual ventilator. It is also intended to monitor nitric oxide, nitrogen dioxide, and oxygen concentrations in the breathing gas.
The AeroNOx 2.0 is intended to be used within a hospital or during air or ground transport outside the hospital.

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.

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Special 510(k): Device Modification
AeroNOx 2.0 Nitric Oxide Titration & Monitoring System

510(k) SUMMARY

Submitter Information:
International Biomedical
8206 Cross Park Drive
Austin, TX 78754
U.S.A.

Regulatory Affairs Contact:
Amy Pieper
Director of Regulatory Affairs
(512) 873-0033 - phone
(512) 873-9090 - fax

Date Summary Prepared: December 13, 2019

Device Identification:

Trade Name: AeroNOx 2.0 Nitric Oxide Titration & Monitoring System
Common Name: Nitric Oxide Delivery System
Regulatory Class: II
Regulation: 868.5165
Product Code: MRN
Panel: Anesthesiology

Predicate Device:

AeroNOx 2.0 Nitric Oxide Titration & Monitoring System (K093260)

Device Description:

The AeroNOx 2.0 nitric oxide delivery system is specifically designed for the transmission and control of gaseous nitric oxide (NO) in parts per million (ppm) concentrations. It is divided into two main components: the delivery component and an analysis component. These two components are mounted into a single enclosure.

The delivery component is designed to deliver a constant flow of nitric oxide gas into the main gas stream of a constant flow ventilator or a modified flow inflating manual resuscitator (see "AeroNOx Bagger" and "INOstat Bagger" below). The nitric oxide gas is titrated into the ventilator's gas delivery tubing at a point at least 30cm upstream of the gas analysis port to ensure adequate gas mixing prior to patient delivery.

The analysis component of the AeroNOx 2.0 is designed to measure nitric oxide, nitrogen dioxide and oxygen from the ventilator tubing or flow inflating manual resuscitator on the inspiratory side, prior to patient administration. The analysis system consists of one nitric oxide electrochemical cell, one nitrogen dioxide electrochemical cell, one galvanic oxygen sensor, and a pump to draw the gas sample from the ventilator's bulk gas flow for analysis within the block that mounts sensors.

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AeroNOx 2.0 Nitric Oxide Titration & Monitoring System

In addition, two variations of a modified flow inflating manual resuscitator are available to use as back-up systems in the event of ventilator failure, AeroNOx failure, or a combination of these two. Both resuscitators are disposable, single patient use devices. These are described below:

1. The "AeroNOx Bagger" flow inflating manual resuscitator is designed for use with the AeroNOx. It can be used completely independent of the ventilator.
2. The "INOstat Bagger" flow inflating manual resuscitator is designed to be used in conjunction with a regulator with a fixed output flow in order to supply a constant nitric oxide dose completely independent of the AeroNOx and ventilator.

Intended Use:

The AeroNOx 2.0 is intended to provide a constant controlled concentration of nitric oxide in breathing gas by delivering a constant controlled flow of nitric oxide into the inspiratory limb of a mechanical ventilator that operates using a continuous constant flow of fresh gas into the inspiratory limb of the ventilator. The AeroNOx 2.0 is also intended to be used with a flow inflating manual ventilator (an AeroNOx accessory), by introducing controlled flows of nitric oxide into the fresh gas flow to the manual ventilator. It is also intended to monitor nitric oxide, nitrogen dioxide, and oxygen concentrations in the breathing gas. The AeroNOx 2.0 is intended to be used within a hospital or during air or ground transport outside the hospital.

Substantial Equivalence:

The AeroNOx 2.0 is substantially equivalent to the AeroNOx 2.0 Nitric Oxide Titration & Delivery System that is currently marketed with regards to intended use, safety and effectiveness.

The intended use of the AeroNOx 2.0 is unchanged from the predicate device

	Proposed (K193481) AeroNOx 2.0 Nitric Oxice Titration & Monitoring System	Predicate K093260/A001 AeroNox 2.0 Nitric Oxide Titration & Monitoring System
Indications for Use	The AeroNOx 2.0 is intended to provide a constant controlled concentration of nitric oxide in breathing gas by delivering a constant controlled flow of nitric oxide into the inspiratory limb of a mechanical ventilator that operates using a continuous constant flow of fresh gas into the inspiratory limb of the ventilator. The AeroNOx 2.0 is also intended to be used with a flow inflating manual ventilator (an AeroNOx accessory), by introducing controlled flows of nitric oxide into the	The AeroNOx 2.0 is intended to provide a constant controlled concentration of nitric oxide in breathing gas by delivering a constant controlled flow of nitric oxide into the inspiratory limb of a mechanical ventilator that operates using a continuous constant flow of fresh gas into the inspiratory limb of the ventilator. The AeroNOx 2.0 is also intended to be used with a flow inflating manual ventilator (an AeroNOx accessory), by introducing controlled flows of nitric oxide into the

Special 510(k): Device Modification
AeroNOx 2.0 Nitric Oxide Titration & Monitoring System

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Environment for Use	Hospital or Air/Ground Transport	Hospital or Air/Ground Transport
Patient Population	Neonatal	Neonatal
Prescriptive	Yes	Yes
Patient Connection	None	None
Operation Characteristics	NO Sensor: Electro-chemical Sensor integrated into device NO2 Sensor: Electro-chemical Sensor integrated into device O2 Sensor: Galvanic Sensor integrated into device	NO Sensor: Electro-chemical Sensor integrated into device NO2 Sensor: Electro-chemical Sensor integrated into device O2 Sensor: Galvanic Sensor integrated into device
Inlet Pressure	14 to 155 Bar	14 to 155 Bar
Outlet Pressure/Connection Type	1.7 to 2.4 Bar/CGA 626	1.7 to 2.4 Bar/CGA 626
Power Rating	100-240 VAC @ 50/60 Hz, 3A	100-240 VAC @ 50/60 Hz, 3A
D/C Battery Backup	Yes	Yes
Electrical Safety	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-6 IEC 60601-1-8 IEC 60601-1-12	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-6 IEC 60601-1-8 IEC 60601-1-12
Case (Exterior) Materials	Plastic (Cast Urethane)	Plastic (Cast Urethane)
Internal Airway Path Materials	Tygon tubing; stainless steel	Tygon tubing; stainless steel
Accessory Materials	Polypropylene Tubing; Tygon tubing; Stainless Steel Hose/Regulator	Polypropylene Tubing; Tygon tubing; Stainless Steel Hose/Regulator

Modification:

The modification is to add additional ventilators to the list of approved ventilators with which the AeroNOx 2.0 can be used. No device modifications have been made from the predicate device. AeroNOx 2.0 has the same fundamental scientific technology and intended use as the predicate device.

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Bench Testing:

The following tests were performed based on the labeling modification to add additional ventilators to the Operator's Manual.

- Ventilator Compatibility Testing

The AeroNox 2.0 met all the performance requirements as outlined above and thus can be found to be substantially equivalent to the predicate devices.

Conclusion:

The modified AeroNOx 2.0 has the following similarities to the previous AeroNOx 2.0 model that already has 510(k) clearance:

- The same intended use
- Use the same operating principle
- Incorporate the same basic design and electronic circuitry
- Incorporate the same materials

In summary, the AeroNOx 2.0 is substantially equivalent to the AeroNOx Nitric Oxide Titration & Delivery System that is currently marketed with regards to intended use, safety and effectiveness.