Special 510(k): Device Modification
AeroNOx Nitric Oxide Titration & Monitoring System
October 13, 2009

K093260

SECTION 2: DEVICE SUMMARY

1. Device Name:
   Device Trade Name: AeroNOx Nitric Oxide Titration & Monitoring System
   Common/Classification Name: AeroNOx Nitric Oxide Delivery Device

2. Address and Registration Number:
   International Biomedical, Ltd.
   8508 Cross Park Drive
   Austin, TX 78754
   FDA Registration #: 1625392

   DEC 16 2009

3. Device Class:
   Nitric Oxide Delivery Apparatus are classified as Class II, Product Code MRN, Anesthesiology.

4. Predicate Device Information:
   The predicate device is the AeroNOx Nitric Oxide Titration & Monitoring System, K000653, 8/4/00.

5. Labeling:
   The product labeling has been changed to add three additional ventilators to the list of validated ventilators in the user manual. No other labeling changes have been made. A copy of the revised manual is included in the submission.

6. Intended Use:
   The AeroNOx 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 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 is intended to be used within a hospital or during air or ground transport outside the hospital.

   The intended use of the AeroNOx has not changed.

   The indications for use statement can be found in attachment 2.

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7. Device Description and Comparison:

The AeroNOx 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 titration delivery system and the NO/NO2/O2 analyzer. These two components are mounted into a single enclosure.

The construction materials are compatible with NO and will not contaminate the gas stream. A stainless steel, two stage regulator with CGA 626 gas fittings is coupled to a calibrated, high accuracy NO mass flow meter and precision metering valve. The NO is titrated continuously via tubing nearest to the ventilator outlet circuit where it is diluted by the ventilator gas flow. Initial NO flow required to approximate a desired NO concentration is estimated by calculation and verified by the monitoring component of the system. We have also included a look-up table for specific ventilator settings, AeroNOx NO flow setting and expected NO2 production based on 100% Oxygen source, in the operating manual.

The AeroNOx analyzer continuously draws a sample from the ventilator circuit on the distal point of the inspiratory circuit nearest the patient wye connection. The sensors then measure NO and NO2 concentration in parts per million and Oxygen in %. The sensors operate by electrochemical means. NO, O2 and NO2 molecules diffuse across a membrane and react in the electrolyte solution augmenting an electrical current between the anode and cathode. The augmented current is proportional to the NO, O2 and NO2 concentration.

The AeroNOx analyzer has been designed so that the user can set alarm limits to ensure that deviations in NO and NO2 can be monitored. These alarms are visual and audible. An oxygen analyzer is also incorporated into the system to act as a secondary monitor to display the fractional inspired oxygen concentration.

No device modifications have been made from the predicate device. The only modification made is to the list of ventilators that may connect to the AeroNOx in the Operator's Manual (page 22).

8. Substantial Equivalence:

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

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

In summary, the AeroNOx Nitric Oxide Titration & Monitoring System described in this submission is, in our opinion, substantially equivalent to the predicate device.

INDICATIONS FOR USE STATEMENT

Applicant's Name:

International Biomedical, Ltd.

510(k) Number:

K093260

Device Name:

AeroNOx Nitric Oxide Titration & Monitoring System

Indications for Use:

The AeroNOx 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 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.
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

DEC 1 6 2009

Mrs. Amy Pieper
Director of Regulatory Affairs
International Biomedical, Limited
8508 Cross Park Drive
Austin, Texas 78754

RE: K093260
Trade/Device Name: AeroNOx Nitric Oxide Titration & Monitoring System
Regulation Number: 21CFR 868.5165
Regulation Name: Nitric Oxide Delivery System
Regulatory Class: II
Product Code: MRN
Dated: November 18, 2009
Received: November 19, 2009

Dear Mrs. 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. 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.

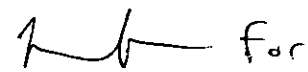
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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,



Anthony D. Watson, BS, MS, MBA
Director
Division of Anesthesiology, General Hospital,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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

510(k) Number: K093260