K052663

INO Therapeutics

NOV - 4 2005

7601-B Murphy Drive
Middleton, WI 53562 USA
Tel. 608-831-4401 / Fax. 608-831-4409

Subject:	510(k) Summary of Safety and Effectiveness Information for the INO Therapeutics INOblender
Proprietary Name:	INOblender
Common Name:	Nitric Oxide Administration Apparatus - Back-up System
Classification:	Class II, 21CFR868.5165, MRO
Panel:	Anesthesiology
Contact Person:	Frederick Montgomery, Vice President, Medical Devices

The 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 1992.

The INOblender is substantially equivalent to the Fadassi Medical FM-1 NO Blender, which was cleared by FDA with 510(k) premarket notification numbers K003665 and K011874.

Indications for use: The INOblender provides user set concentrations of inhaled Nitric Oxide (NO), in a balance of nitrogen, mixed into a user settable constant flow of oxygen gas that is being delivered to a patient. The intended use for the INOblender is as a back up to a primary nitric oxide delivery system or for short term attended use when a primary delivery device cannot practicably be used. This intended use includes applications within a medical facility and transport outside of a medical facility. The INOblender is not intended for use as a primary NO delivery system for long-term use.

The INOblender was designed to comply with the limited applicable portions of the following:

1. CGA 626: Medical NO Gas Connections.
2. IEC 60601-1: Medical Electrical Equipment (for general requirements).
3. FDA Guidance Document for Premarket Notification Submissions for Nitric Oxide Delivery Apparatus, Nitric Oxide Analyzer and Nitrogen Dioxide Analyzer.

The materials selected were based upon the Fadasis FM-1 NO Blender and the Datex-Ohmeda INOvent Delivery System.

All testing indicated the INOblender met its design input specifications, design output specifications, hazard analysis and risk control requirements. Testing completed included:

1. INOblender Test Plan
2. INOblender Integrity Test Report
3. INOblender Reliability Testing
4. INOblender Verification Test Report
5. INOblender Testing Against Predicate Test Plan

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INO Therapeutics INOblender

Device Name – Proprietary:
INOblender

Device Name – Common:
Nitric Oxide Mixer

Device Name – Classification:
Nitric Oxide Administration Apparatus, Back-up System

Device Panel:
Anesthesiology

Device Classification:
Class II – 21CFR868.5165, 73 MRO

Predicate Devices:
Fadasis Medical, Inc.
FM-1 NO Blender
510(k) Numbers K001874, K003665

Performance Standards:
To the best of INO Therapeutics' knowledge, performance standards have not been promulgated by FDA for this device.

Establishment Registration Number:
9062609

Owner/Operator Number:
3004531588

Facility Information:
INO Therapeutics LLC
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Middleton, WI 53562
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 4 2005

Mr. Frederick Montgomery
Vice President, Medical Devices
INO Therapeutics
7601-B Murphy Drive
Middletown, Wisconsin 53562

Re: K052663
Trade/Device Name: INO Therapeutics INOblender
Regulation Number: 21 CFR 868.5165
Regulation Name: Nitric Oxide Administration Apparatus
Regulatory Class: II
Product Code: MRO
Dated: October 25, 2005
Received: October 26, 2005

Dear Mr. Montgomery:

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 such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
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

510(k) Number (if known):

Device Name: INO Therapeutics INOblender

Indications For Use:

The INOblender provides user set concentrations of inhaled Nitric Oxide (NO), in a balance of nitrogen, mixed into a user settable constant flow of oxygen gas that is being delivered to a patient. The intended use for the INOblender is as a back up to a primary nitric oxide delivery system or for short term attended use when a primary delivery device cannot practicably be used. This intended use includes applications within a medical facility and transport outside of a medical facility. The INOblender is not intended for use as a primary NO delivery system for long-term use.

Prescription Use X and/or Over-the-Counter-Use ____
(Part 21 CFR 801 Subpart D) (Part 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)

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

510(k) Number K052663