K011874

Fadasis Medical, Inc.

7601-B Murphy Drive, Middleton, WI 53562
Phone (608) 831-0025, ext. 276, FAX (608) 831-2202

JUL 20 2001

Subject:	510(k) Summary of Safety and Effectiveness Information for the Fadasis Medical FM-1 NO Blender
Proprietary Name:	Fadasis Medical FM-1 NO Blender
Common Name:	Nitric Oxide Administration Apparatus - Back-up System
Classification:	Class II, 21CFR868.5165, MRO
Panel:	Anesthesiology
Contact Person:	Raymond Riddle, Vice President, Regulatory Affairs

RRiddle 6/12/01

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

The Fadasis Medical FM-1 NO Blender is substantially equivalent to the Fadasis FM-1 NO Blender, which was cleared by FDA with 510(k) premarket notification number K003665. The purpose of this Special 510(k) was to allow the use of PEEK, rather than stainless steel, in the capillary tubes.

Indications for use: The FM-1 NO Blender 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 FM-1 NO Blender is as a back up to a primary nitric oxide delivery system or for short term attended use when a primary delivery device cannot be used. In this capacity, it can be used with a self-inflating manual resuscitator bag. This intended use includes applications within a medical facility and transport outside of a medical facility. The FM-1 NO blender is not intended for use as a primary NO delivery system for long term use. (Note: These indications for use are unchanged form K003665.

The Fadasis Medical FM-1 NO Blender was designed to comply with the limited applicable portions of the following:

1. CGA 626: Medical NO Gas Connections.
2. IEC 601-1: 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 primarily based upon the Datex-Ohmeda INOvent Delivery System. New validation and verification completed included the FTIR Testing of PEEK. Validation and verification for 510(k) K003665 included FM-1 NO Blender 5-15 lpm Performance Characteristics Testing, FM-1 NO Blender Validation with Self Inflating Manual Resuscitator Bags, FM-1 NO Blender Validation of the Concentration Profile When Used with Self Inflating Manual, Resuscitator Bags, FM-1 NO Blender Regulator Check Function, FM-1 NO Blender 5-15 lpm Failure Testing, FM-1 NO Blender Material Compatibility Information, FM-1 NO Blender Drop Test and FM-1 NO Blender Packaging and Shipping Validation. All testing indicated the FM-1 NO Blender met its design input specifications, design output specifications, hazard analysis and risk control requirements.

Device Name – Proprietary:	Fadasis Medical FM-1 NO Blender
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 Product Code: MRO
Predicate Devices:	Fadasis Medcial FM-1 NO Blender FDA 510(k) log number K003665
Performance Standards:	To the best of Fadasis Medical's knowledge, performance standards have not been promulgated by FDA for this device.
Owner/Operator Number:	9042308
Establishment Registration Number:	2135137
Facility Information:	Fadasis Medical, Inc. 7601-B Murphy Drive Middleton, WI 53562 Telephone: (608) 831-0025 Fax: (608) 831-2202
Device Background:	The new FM-1 NO blender is identical to the predicate FM-1 NO blender with the exception of the capillary tube material, which has been changed to PEEK from stainless steel. The use of this material has been validated via FTIR testing, as required by FDA Guidance Document for Premarket Notification Submissions for Nitric Oxide Delivery Apparatus, Nitric Oxide Analyzer and Nitrogen Dioxide Analyzer. The original device performance validation data was obtained using both stainless steel and PEEK capillary tubes. Because of inadequate testing of PEEK, the use of this material was removed from the original 510(k) until further testing was completed; thus prompting this Special 510(k).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 0 2001

Mr. Raymond T. Riddle
Fadasis Medical, Inc.
7601-B Murphy Drive
Middleton, WI 53562

Re: K011874
FM-1 NO Blender
Regulation Number: 868.5165
Regulatory Class: II (two)
Product Code: 73 MRO
Dated: July 3, 2001
Received: July 9, 2001

Dear Mr. Riddle:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might

have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K011874

Device Name: Fadasis Medical, Inc. FM-1 NO Blender

Indications For Use:

The FM-1 NO Blender 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 FM-1 NO Blender is as a back up to a primary nitric oxide delivery system or for short term attended use when a primary delivery device cannot be used. In this capacity, it can be used with a self-inflating manual resuscitator bag. This intended use includes applications within a medical facility and transport outside of a medical facility. The FM-1 NO blender is not intended for use as a primary NO delivery system for long term use.

Note: These indications for use are unchanged from K003665

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and
Neurological Devices

510(k) Number: K011874

Prescription Use ✓ OR Over-The-Counter Use
(Per 21CFR801.109) (Optional Format 1-2-96)