APR 4 2006

Analytical Industries Inc.

2855 Metropolitan Place, Pomona, CA 91767 USA Tel: 909-392-6900, Fax: 909-392-3665, e-mail: info@aii1.com

K053407

10 510(k) Summary

[As Required by 21 CFR 807.92]

Owner / Submitter of 510(k):	Analytical Industries Inc. 2855 Metrolpolitan Place Pomona, CA 91767 Tel: 909-392-6900, fax: 909-392-3665 e-mail: prindiblepj@earthlink.net; prindiblepj@aii1.com
Establishment Registration No.:	9021044
Contact:	Patrick J. Prindible
Date of Summary:	November 30, 2005
Trade Name:	Analytical Industries Inc.
Common Name:	Oxygen Analyzer/Monitor
Classification Name:	Oxygen Gas Analyzer/Monitor
Regulation Number:	868.1720
Classification Panel:	Anesthesiology
Regulatory Class:	IIb
Product Code:	73 CCL

Predicate Device(s):	510(k) #K002382 Analytical Industries AII 2000 Oxygen Analyzer
	510(k) #K000700 Sensidyne Monitor Analyzer (add'l reference only)

Device Description:	The AII 2000 Series Oxygen Analyzers and Monitor can be positioned on a table top or pole (tripod wire stand and V-mount dovetail attachments are mounted on the back of the unit) and are readily portable from one location to another. They provide continuous, fast, reliable and accurate oxygen measurements of up to 100% oxygen levels delivered by medical oxygen delivery equipment and respiratory care systems. The heart of each unit is the oxygen sensor, a self-contained galvanic fuel cell sensor. The sensor is specific to oxygen and The relationship between the sensor's signal and changes with the oxygen concentration is both proportional and linear.

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A battery powered state-of-the-art micro-processor converts the sensor's signal output representing the partial pressure of oxygen in the gas stream being analyzed. The resulting oxygen reading is displayed by a large easy to read backlit liquid crystal display (LCD) that has a resolution of 0.1% oxygen. The microprocessor is controlled from a keypad and provides features like system diagnostics, warning indicators, controls and an alarm capability for continuous monitoring that enhance both safety and effectiveness.

Intended Use:

The AII 2000 Series Oxygen Analyzers & Monitor are intended to measure and display the concentration of oxygen in breathing gas mixtures. The intended use is only to verify, spot check or continuously monitor, oxygen concentrations in circumstances where the oxygen concentration is controlled and set by other medical devices such as oxygen/air blenders, flow meters or other control devices.

Comparison of Technological Characteristics:

Feature	**AII 2000A/HC Analyzer**	**AII 2000M Monitor**	**AII 2000 Analyzer #K002382**	**Sensidyne Analyzer #K000700**	**Sensidyne Monitor #K000700**
Intended Use	Spot check	Continuously monitor	Spot check	Spot check	Continuously monitor
Oxygen Sensor	Galvanic	Galvanic	Galvanic	Galvanic	Galvanic
Range	0-100%	0-100%	0-100%	0-100%	0-100%
Display Resolution	0.1%	0.1%	0.1%	0.1%	0.1%
Controls	Keypad	Keypad/Menu	Pushbutton, thumbwheel	Keypad	Keypad/Menu
Low Battery Warning	Visual	Visual	Visual	Visual	Visual
Low Sensor Warning	Visual	Visual	NA	Unknown	Unknown
Alarms	NA	HI LO oxygen	NA	NA	HI LO oxygen
Alarm System	NA	Visual/Audible	NA	NA	Visual/Audible
Power Source	2x AA Batteries	2x AA Batteries	1x 9V Battery	2x AA Batteries	2x AA Batteries

Non-clinical Testing Data:

Verification and validation of the software design and analyzer performance was conducted and documentation of both the bench testing and third party testing can be found in Section 9. The bench testing was based on the guidance document "Software Validation per General Principles of Software Validation; Final Guidance for Industry and FDA Staff" issued January 11, 2002.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 4 2006

Mr. Patrick J. Prindible
Analytical Industries, Incorporated
2855 Metropolitan Place
Pomona, California 91767

Re: K053407
Trade/Device Name: Analytical Industries Incorporated AII 2000 Series Oxygen Analyzer/Monitor
Regulation Number: 868.1720
Regulation Name: Oxygen Gas Analyzer
Regulatory Class: Class II
Product Code: CCL
Dated: March 27, 2006
Received: March 28, 2006

Dear Mr. Prindible:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-__. 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 Part 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.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

2855 Metropolitan Place, Pomona, CA 91767 USA Tel: 909-392-6900, Fax: 909-392-3665, e-mail: info@aii1.com

8 Indications for Use

510(k) Number (if known): _____

Device Name: Analytical Industries Inc. AII 2000 Series Oxygen Analyzer/Monitor

Indications for Use:

The Analytical Industries Inc. AII 2000 Series Oxygen Analyzers & Monitors are intended to measure and display the concentration of oxygen in breathing gas mixtures. The intended use is only to verify, spot check or continuously monitor, oxygen concentrations in circumstances where the oxygen concentration is controlled and set by other medical devices such as oxygen/air blenders, flow meters or other control devices.

Prescription Use ___Yes___ AND/OR Over-the-Counter Use _____

Concurrence of CDRH, Office of Device Evaluation (ODE)

[signature]

...Neurology, General Hospital,
...Control, Dental Devices

K053407