

OCT 18 1995

10-2395

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850Re: K952736  
Percent Oxygen Sensor  
Dated: July 14, 1995  
Received: July 18, 1995  
Regulatory Class: II (two)  
Product Code: 73 CCLMr. Patrick J. Prindible  
Analytical Industries, Inc.  
449 West Allen Avenue, Suite 105  
San Dimas, California 91773

Dear Mr. Prindible:

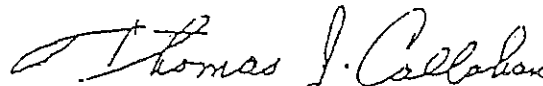
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976; the enactment date of the Medical Device Amendments or to devices that have 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 (Pre-market 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (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 immediately will allow you to begin marketing your device as described in your 510(k) premarket notification. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market; but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. 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), promotion, or advertising please contact the Office of Compliance, Promotion and Advertising Policy Staff (HFZ-300) at (301) 594-4639. Other general information on your responsibilities under the Act

may be obtained from the Division of Small Manufacturers Assistance at their  
toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,



Thomas J. Callahan, Ph.D.  
Acting Director  
Division of Cardiovascular,  
Respiratory, and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health



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

Page 2 – Mr. Patrick J. Prindible

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" (21 CFR 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

**Analytical Industries Inc.**

2855 Metropolitan Place, Pomona, CA 91767 USA Tel: 909-392-6900, Fax: 909-392-3665, e-mail: [info@aia.com](mailto:info@aia.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)

*Handwritten signature*

Medical Technology, General Hospital,  
Federal Dental Devices

R053407