APR 2 2 2005 K050423

510(k) Summary

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

1) Submitter name, address, contact

Roche Diagnostics
9115 Hague Rd.
Indianapolis, IN 46250
(317) 521-7688

Contact Person: Dimitris Demirtzoglou

Date Prepared: February 17, 2005

2) Device name

Proprietary name: Roche Diagnostics pH electrode on the OMNI Modular, C and S Analyzers

Common name: Electrode, Blood Gases (PCO2, PO2) and pH

Classification name: Electrode, Blood Gases (PCO2, PO2) and pH

3) Predicate device

The OMNI Analyzers (OMNI Modular, OMNI C and OMNI S) are substantially equivalent to the AVL model 995-Hb pH/blood gas analyzer (K895317) and the CIBA-Corning Model 288 blood gas system (K872888). The AVL 995-Hb and CIBA-Corning 288 were the analyzers used in the studies described in the peer reviewed literature articles.

4) Device Description

Expansion of the intended use for the pH electrode on the OMNI Modular, OMNI C and OMNI S analyzers to allow for the measurement of pH in pleural fluid.

Continued on next page

510k Summary, Continued

5.) Intended Use

We have expanded the claim for the pH electrode to include the following text:

Pleural Fluid:

The Omni (Modular, C and S) can be used for the measurement of ph in pleural fluid, as long as care is taken to ensure that the specimen to be analyzed is clear of fibrin clots or other debris which may block the sample transport system.

The pH measurement of pleural fluid can be a clinically useful tool in the management of patients with parapneumonic effusions.

6.) Similarities and Differences

The table on the next page indicates the similarities and differences between the pH electrodes in the OMNI Analyzers, the AVL model 995-Hb pH/blood gas analyzer (literature article #1) and the CIBA-Corning Model 288 blood gas analyzer (literature article #2).

Feature/Claim	OMNI Analyzers (Modular, C and S)	AVL Model 995-Hb	CIBA-Corning Model 288
pH Measuring Principle	OMNI uses the Sorensen 1909 principle which is based on the measurement of hydrogen ion (H^+) concentration.	SAME	SAME
Electrode Membrane	H^+ sensitive glass membrane	SAME	SAME
Reference Electrode	Ag/AgCl	Colomel	Ag/AgCl
Concentration of the KCl Reference Solution	1.2 M	0.6 M	4 M

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR 2 2 2005

Mr. Dimitris Demirtzoglou
Roche Diagnostics
9115 Hague Road
PO Box 50457
Indianapolis, IN 46250

Re: k050423
Trade/Device Name: OMNI Modular, OMNI C and OMNI S Analyzer (pH Electrode)
Regulation Number: 21 CFR 862.1120
Regulation Name: Blood gases (Pco2, Po2) and blood pH test system
Regulatory Class: Class II
Product Code: CHL
Dated: February 17, 2005
Received: February 18, 2005

Dear Mr. Demirtzoglou:

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 Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (240)276-0484. 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,

Jean M. Cooper MS, DVM

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: OMNI Modular, OMNI C and OMNI S Analyzer (pH Electrode)

Indications For Use:

We have expanded the claim for the pH electrode to include the following text:

Pleural Fluid:

The Omni (Modular, C and S) can be used for the measurement of ph in pleural fluid, as long as care is taken to ensure that the specimen to be analyzed is clear of fibrin clots or other debris which may block the sample transport system.

The pH measurement of pleural fluid can be a clinically useful tool in the management of patients with parapneumonic effusions.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K050493