K032311

OCT 17 2003

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 Corporation
9115 Hague Rd.
Indianapolis, IN 46250
Contact Person: Jennifer Tribbett
Date Prepared: July 25, 2003

2) Device name

Proprietary name: Omni S Analyzer

Common name or Classification Name: Automated analyzer for the measurement of pH, blood gases, electrolytes, hematocrit, glucose, lactate, urea/BUN, total hemoglobin, oxygen saturation, oxyhemoglobin, deoxyhemoglobin, carboxyhemoglobin and methemoglobin.

3) Predicate device

We claim substantial equivalence to the current legally marketed Omni Modular Analyzer (K990092) and the Omni C Analyzer (K013373).

4) Device Description

The Omni S analyzer represents a combined pH, blood gas, electrolyte, glucose, lactate, urea/BUN, total hemoglobin, hemoglobin derivatives, hematocrit and oxygen saturation test system classified as a Class II device based on the individual test parameters measured.

5) Intended use

The Roche Diagnostics Omni S Analyzer is a fully automated critical care analyzer intended to be used for the measurement of pH, PO2, PCO2, sodium, potassium, ionized calcium, chloride, hematocrit, glucose, lactate, urea/BUN, total hemoglobin, oxygen saturation, oxyhemoglobin, deoxyhemoglobin, carboxyhemoglobin and methemoglobin in samples of whole blood, serum, plasma and aqueous solutions as appropriate.

Continued on next page

Comparison to Predicate Device

Intended Use

As shown in the following comparison table the intended use of the OMNI S covers the measurements of the parameters currently available on the OMNI Modular system with the addition of the oxygen saturation parameter of the OMNI C.

Topic	OMNI S Analyzer	OMNI Modular Analyzer (K990092)	OMNI C Analyzer (K013373)
Intended Use	Omni S Analyzer is intended to be used for the measurement of pH, PO2, PCO2, sodium, potassium, ionized calcium, chloride, hematocrit, glucose, lactate, urea/BUN, total hemoglobin, **oxygen saturation**, oxyhemoglobin, deoxyhemoglobin, carboxyhemoglobin and methemoglobin in samples of whole blood, serum, plasma and aqueous solutions as appropriate.	Omni Modular Analyzer is intended to be used for the measurement of pH, PCO2, PO2, total hemoglobin, deoxyhemoglobin, oxyhemoglobin, carboxyhemoglobin, methemoglobin, sulfhemoglobin sodium, potassium, chloride, ionized calcium, hematocrit, glucose, lactate and urea nitrogen,in samples of whole blood, serum, plasma and aqueous solutions as appropriate.	Omni C Analyzer is intended to be used for the measurement of pH, PO2, PCO2, sodium, potassium, ionized calcium, chloride, hematocrit, total hemoglobin, and **oxygen saturation** in samples of whole blood, serum, plasma and aqueous solutions as appropriate.

Comparison to Predicate Device, Continued

Similarities and differences from predicate devices

The information listed below describes the similarities and differences between the Omni S analyzer and the predicate Omni Modular and Omni C analyzers.

Topic	Description
Parameters Measured	pH, PO2, PCO2, sodium, potassium, ionized calcium, chloride, hematocrit, glucose, lactate, urea/BUN, total hemoglobin, oxygen saturation, oxyhemoglobin, deoxyhemoglobin, carboxyhemoglobin and methemoglobin Same as the combination of Omni Modular and Omni C parameters. **Omni Modular**: pH, PCO2, PO2, total hemoglobin, deoxyhemoglobin, oxyhemoglobin, carboxyhemoglobin, methemoglobin, sulfhemoglobin sodium, potassium, chloride, ionized calcium, hematocrit, glucose, lactate and urea nitrogen **Omni C**: pH, PO2, PCO2, sodium, potassium, ionized calcium, chloride, hematocrit, total hemoglobin, and oxygen saturation
Sample Types	Same as Omni Modular and Omni C: Whole blood, serum, plasma and aqueous (QC material and dialysis) solutions
Blood Gases (pO2, pCO2, pH)	The Omni S has incorporated the same blood gas modules as utilized in the Omni Modular and Omni C analyzers.
ISE (sodium, potassium, calcium, chloride)	The Omni S has incorporated the same ISE modules as utilized in the Omni Modular and Omni C analyzers.
tHB and SO2	The Omni S has incorporated the same tHb (total hemoglobin) and SO2 (oxygen saturation) sensor as utilized in the Omni C analyzer.
MSS (glucose, lactate, urea/BUN) chamber	The Omni S has incorporated similar types of MSS sensors as utilized in the Omni Modular analyzer; however, the Omni S uses Braunstein instead of PACE technology for the glucose and lactate parameters. The Omni S MSS chamber also incorporates some enhancements. The sample detection feature has been improved and the MSS chamber contains an additional junction in the front to allow for direct aspiration of standby solution.
Reagent Supply	The Omni S will provide enhanced customer convenience by utilizing two reagent packs (7 incorporated pouches) plus two bottles instead of the fourteen bottles currently used on the Omni Modular system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 17 2003

Ms. Jennifer Tribbett
Regulatory Affairs Principal
Roche Diagnostics Corporation
9115 Hague Road
P.O. Box 50457
Indianapolis, IN 46250-0457

Re: k032311
Trade/Device Name: Omni S. Analyzer
Regulation Number: 21 CFR 862.1120
Regulation Name: Blood gases ($P_{co}2$, P_o2) and blood pH test system
Regulatory Class: Class II
Product Code: CEM; JFP; JGS; CGZ; CHL;KHP; CGA; CDS;GKR; GGZ; GKF; GHS; KHG
Dated: July 25, 2003
Received: July 28, 2003

Dear Ms. Tribbett:

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 (301) 594-3084. 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/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known):
Device Name: Omni S Analyzer

Indications for Use:

The Roche Diagnostics Omni S Analyzer is a fully automated critical care analyzer intended to be used for the measurement of pH, PO2, PCO2, sodium, potassium, ionized calcium, chloride, hematocrit, glucose, lactate, urea/BUN, total hemoglobin, oxygen saturation, oxyhemoglobin, deoxyhemoglobin, carboxyhemoglobin and methemoglobin in samples of whole blood, serum, plasma and aqueous solutions as appropriate.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K032311

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)