

## 510(k) Summary

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**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.

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**1) Submitter name, address, contact** Roche Diagnostics Corporation  
9115 Hague Rd.  
Indianapolis, IN 46250  
Contact Person: Jennifer Tribbett  
Date Prepared: July 25, 2003

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**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.

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

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**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.

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**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, PO<sub>2</sub>, PCO<sub>2</sub>, 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.

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## 510(k) Summary, Continued

### 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<br>(K990092)   | OMNI C Analyzer<br>(K013373)   |
|---------------------|--|--|--|
| <b>Intended Use</b> | Omni S Analyzer is intended to be used for the measurement of pH, PO <sub>2</sub> , PCO <sub>2</sub> , sodium, potassium, ionized calcium, chloride, hematocrit, glucose, lactate, urea/BUN, total hemoglobin, <b>oxygen saturation</b> , 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, PCO <sub>2</sub> , PO <sub>2</sub> , 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, PO <sub>2</sub> , PCO <sub>2</sub> , sodium, potassium, ionized calcium, chloride, hematocrit, total hemoglobin, and <b>oxygen saturation</b> 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                                   | <p>pH, PO<sub>2</sub>, PCO<sub>2</sub>, sodium, potassium, ionized calcium, chloride, hematocrit, glucose, lactate, urea/BUN, total hemoglobin, oxygen saturation, oxyhemoglobin, deoxyhemoglobin, carboxyhemoglobin and methemoglobin</p> <p>Same as the combination of Omni Modular and Omni C parameters.</p> <p><b>Omni Modular:</b> pH, PCO<sub>2</sub>, PO<sub>2</sub>, total hemoglobin, deoxyhemoglobin, oxyhemoglobin, carboxyhemoglobin, methemoglobin, sulfhemoglobin sodium, potassium, chloride, ionized calcium, hematocrit, glucose, lactate and urea nitrogen</p> <p><b>Omni C:</b> pH, PO<sub>2</sub>, PCO<sub>2</sub>, sodium, potassium, ionized calcium, chloride, hematocrit, total hemoglobin, and oxygen saturation</p> |
| Sample Types  | <p>Same as Omni Modular and Omni C:<br/>Whole blood, serum, plasma and aqueous (QC material and dialysis) solutions</p>  |
| Blood Gases (pO <sub>2</sub> , pCO <sub>2</sub> , 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 SO <sub>2</sub>                               | The Omni S has incorporated the same tHb (total hemoglobin ) and SO <sub>2</sub> (oxygen saturation) sensor as utilized in the Omni C analyzer.  |
| MSS (glucose, lactate, urea/BUN) chamber              | <p>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.</p> <p>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.</p>  |
| 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<sub>co2</sub>, P<sub>o2</sub>) 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.

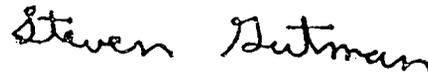
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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).

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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,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive style.

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):

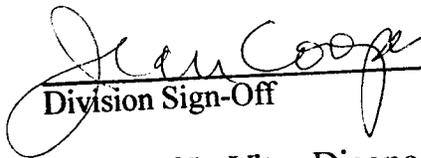
Device Name: Omni S Analyzer

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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
Division Sign-Off

Office of In Vitro Diagnostic Device  
Evaluation and Safety

510(k) K 032311

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)